Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0000 - INITIAL COMMENTS

Title INITIAL COMMENTS

Type Memo Tag

CFR

Regulation Definition	Interpretive Guideline

FED - C0330 - PERIODIC EVALUATION & QA REVIEW

Title PERIODIC EVALUATION & QA REVIEW

Type Condition

CFR 485.641

Regulation Definition	Interpretive Guideline
Periodic Evaluation and Quality Assurance Review	While conducting the survey, a surveyor may identify a patient care practice or other CAH practice with which the surveyor is unfamiliar. Health care and CAH practice are continually changing due to new laws, regulations and standards of practice. In order for the surveyor to determine compliance with the CAH CoP, the surveyor should interview appropriate CAH staff to gather additional information, such as: o Tell me about this practice. o Is the practice a requirement or standard of practice? o What is your source for this requirement, activity or standard of practice? o Show me your source material for this practice. If the CAH produces a law, regulation, or standard of practice from a nationally recognized organization, evaluate whether the CAH's policies and procedures reflect the law, regulation, or standard of practice. Then, evaluate whether the CAH's actual practice reflects their policies and procedures, as well as the law, regulation or standard of practice.

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FED - C0331 - PERIODIC EVALUATION

Title PERIODIC EVALUATION

Type Standard

CFR 485.641(a)(1)

Regulation Definition	Interpretive Guideline
The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of--	Survey Procedures o How is information obtained to be included in the periodic evaluation? o How does the CAH conduct the periodic evaluation? o Who is responsible for conducting the periodic evaluation?

FED - C0332 - PERIODIC EVALUATION

Title PERIODIC EVALUATION

Type Standard

CFR 485.641(a)(1)(i)

Regulation Definition	Interpretive Guideline
[The evaluation is done at least once a year and includes review of--] the utilization of CAH services, including at least the number of patients served and the volume of services.	Survey Procedures How does the CAH ensure that the yearly program evaluation includes a review of all CAH services, the number of patients served and the volume of services provided?

FED - C0333 - PERIODIC EVALUATION

Title PERIODIC EVALUATION

Type Standard

CFR 485.641(a)(1)(ii)

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Regulation Definition	Interpretive Guideline
[The evaluation is done at least once a year and includes review of--] a representative sample of both active and closed clinical records.	"A representative sample of both active and closed clinical records" means not less than 10 percent of both active and closed patient records and both inpatient and outpatient records. Survey Procedures o Who is responsible for the review of both active and closed clinical records? o How are records selected and reviewed in the periodic evaluation? o How does the evaluation process ensure that the sample of records is representative of services furnished? o What criteria are utilized in the review of both active and closed records?

FED - C0334 - PERIODIC EVALUATION

Title PERIODIC EVALUATION

Type Standard

CFR 485.641(a)(1)(iii)

Regulation Definition	Interpretive Guideline
[The evaluation is done at least once a year and includes review of--] the CAH's health care policies.	Survey Procedures What evidence demonstrates that the health care policies of the CAH are evaluated, reviewed and/or revised as part of the annual program evaluation?

FED - C0335 - PERIODIC EVALUATION

Title PERIODIC EVALUATION

Type Standard

CFR 485.641(a)(2)

Regulation Definition	Interpretive Guideline
The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.	Survey Procedures o How does the CAH use the results of the yearly program evaluation? o Were policies, procedures and /or facility practices added, deleted or revised as a result of the yearly program

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evaluation if needed?

FED - C0336 - QUALITY ASSURANCE

Title QUALITY ASSURANCE

Type Standard

CFR 485.641(b)

Regulation Definition	Interpretive Guideline
The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that --	"An effective quality assurance program" means a QA program that includes: o Ongoing monitoring and data collection; o Problem prevention, identification and data analysis; o Identification of corrective actions; o Implementation of corrective actions; o Evaluation of corrective actions; and o Measures to improve quality on a continuous basis. Survey Procedures Review a copy of the CAH QA plan and other documentation regarding QA activities, (e.g., meeting notes from QA committees, reports produced by the QA director and/or QA committees, if designated, and follow-up communication relative to corrective actions) to become familiar with the scope, methodology and organization of the CAH QA program.

FED - C0337 - QUALITY ASSURANCE

Title QUALITY ASSURANCE

Type Standard

CFR 485.641(b)(1)

Regulation Definition	Interpretive Guideline
The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment	Survey Procedures o Who is responsible to evaluate CAH patient care services? o How are patient care services evaluated?

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outcomes. The program requires that-

all patient care services and other services affecting patient health and safety are evaluated.

o What other services are evaluated?
o How does the CAH ensure quality assurance data is provided to the medical staff and governing body?

FED - C0338 - QUALITY ASSURANCE

Title QUALITY ASSURANCE

Type Standard

CFR 485.641(b)(2)

Regulation Definition

[The program requires that--] nosocomial infections and medication therapy are evaluated;

Interpretive Guideline

Survey Procedures
o What methodology does the CAH use to evaluate nosocomial infections and medications therapy?
o Review committee meeting minutes for current issues or projects, etc.

FED - C0339 - QUALITY ASSURANCE

Title QUALITY ASSURANCE

Type Standard

CFR 485.641(b)(3)

Regulation Definition

[The program requires that--] the quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;

Interpretive Guideline

Survey Procedures
o How does the CAH ensure that a doctor of medicine or osteopathy evaluates the quality of care provided by mid-level practitioners in the CAH?
o How is clinical performance of mid-level practitioners evaluated?
o What evidence demonstrates that there is an ongoing evaluation of care provided by mid-level practitioners (e.g., reports, periodic written evaluation, QA meeting notes)?
o How does the reviewing MD/DO inform the CAH if he/she determines that there are problems relative to the diagnosis and treatment provided by mid-level practitioners?
o What follow-up actions are called for in the QA plan?

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FED - C0340 - QUALITY ASSURANCE

Title QUALITY ASSURANCE

Type Standard

CFR 485.641(b)(4)

Regulation Definition

[The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that--]

(4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by--

(i) One hospital that is a member of the network, when applicable;

(ii) One QIO or equivalent entity;

(i) One other appropriate and qualified entity identified in the State rural health care plan;

(ii) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site hospital, the distant-site hospital; or

(v) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, one of the entities listed in paragraphs (b)(4)(i) through (iii)of this section; and

Interpretive Guideline

All CAHs must, as a part of their quality assurance program, have an arrangement with an outside entity to review the appropriateness of the diagnosis and treatment provided by each MD/DO providing services to the CAH ' s patients. This includes MDs and DOs providing telemedicine services to the CAH ' s patients from a distant-site hospital or distant-site telemedicine entity. (See §485.616(c) for more information about requirements for telemedicine services.)

Some CAHs may prefer to conduct their own internal review in addition to the outside review; this is neither prohibited nor required under the regulation. The regulation does not specify the frequency of the outside review, since a quality assurance program is ongoing in nature. The CAH and the outside entity must reach a mutual agreement on the extent and frequency of the outside review.

Entities eligible to provide this outside review include, for MDs and DOs who provide services on-site at the CAH, a hospital that is a member of the same rural health network as the CAH; a Medicare Quality Improvement Organization, or its equivalent; or another appropriate and qualified entity identified in the State's Rural Health Plan to perform this function.

In the case of MDs or DOs who provide telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site hospital, the distant-site hospital is the outside entity responsible for reviewing the quality of care provided by these physicians.

In the case of MDs or DOs who provide telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, the outside entity responsible for reviewing the quality of care provided by these physicians include a hospital that is a member of the same rural health network as the CAH; a Medicare Quality Improvement Organization, or its equivalent; another appropriate and qualified entity identified in the State's Rural Health Plan to perform this function; or a distant-site hospital with which the CAH has an agreement for provision of telemedicine services.

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Survey Procedures §485.641 (b)(4)
o Is there evidence that the CAH has an agreement for outside review of the quality of care provided on-site (i.e., not including telemedicine services) by the CAH's MDs and DOs with at least one of the following: a hospital that is a member of the same rural health network as the CAH; a Medicare Quality Improvement Organization, or its equivalent; or another appropriate and qualified entity identified in the State ' s Rural Health Plan?

o If the CAH has one or more agreements for the provision of telemedicine services to CAH patients by a distant-site hospital(s), does each such agreement include a provision for the distant-site hospital to conduct the required outside review of the quality of telemedicine services provided by the MDs and DOs covered by the agreement?

o If the CAH has one or more agreements for the provision of telemedicine services to CAH patients by a distant-site telemedicine entity, does the CAH have an agreement for outside review of the quality of telemedicine services provided by the MDs and DOs covered under the agreement? Is the outside review agreement with at least one of the following: a hospital that is a member of the same rural health network as the CAH; a Medicare Quality Improvement Organization, or its equivalent; another appropriate and qualified entity identified in the State's Rural Health Plan; or a distant-site hospital with which the CAH has an agreement for telemedicine services?

o Can the CAH provide examples of any reviews of the quality and appropriateness of diagnosis and treatment of the CAHs MDs and DOs conducted by an eligible outside entity in the prior 12 - 24 months?

FED - C0341 - QUALITY ASSURANCE

Title QUALITY ASSURANCE

Type Standard

CFR 485.641(b)(5)(i)

Regulation Definition

[The program requires that--] the CAH staff considers the findings of the evaluations, including any findings or recommendations of the QIO, and takes corrective action if necessary.

Interpretive Guideline

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FED - C0342 - QUALITY ASSURANCE

Title QUALITY ASSURANCE

Type Standard

CFR 485.641(b)(5)(ii)

Regulation Definition	Interpretive Guideline
[The program requires that--] the CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program.	Survey Procedures o How does the CAH ensure that proper remedial actions are taken to correct deficiencies identified in the quality assurance program? o Who is responsible for implementing remedial actions to correct deficiencies identified by the quality assurance program?

FED - C0343 - QUALITY ASSURANCE

Title QUALITY ASSURANCE

Type Standard

CFR 485.641(b)(5)(iii)

Regulation Definition	Interpretive Guideline
[The program requires that--] the CAH documents the outcome of all remedial action.	Survey Procedures How does the CAH document the outcome of any remedial action?

FED - C0500 - PSYCH & REHAB DISTINCT PART UNITS -- PSYCH

Title PSYCH & REHAB DISTINCT PART UNITS -- PSYCH

Type Condition

CFR 485.647(a)(1)

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Regulation Definition

Conditions.

(1) If a CAH provides inpatient psychiatric services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of §412.25(a)(2) through (f) of Part 412 of this chapter for hospital units excluded from the prospective payment systems, and the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Interpretive Guideline

FED - C0501 - ELIGIBILITY REQUIREMENTS

Title ELIGIBILITY REQUIREMENTS

Type Standard

CFR 485.647(b)

Regulation Definition

(b)(1) To be eligible to receive Medicare payments for psychiatric or rehabilitation services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit.

(2) The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in §485.620(a).

(3) The average annual 96-hour length of stay requirement specified under §485.620(b) does not apply to the 10 beds in the distinct part units specified in paragraph (b)(1) of this section, and admissions and days of inpatient care in the distinct part units are not taken into account in determining the CAH's compliance with the limits on the number of beds and length of stay in §485.620.

Interpretive Guideline

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FED - C0504 - ADMISSION CRITERIA

Title ADMISSION CRITERIA

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ... §412.25(a)(2) through (f) of Part 412 ...]

Basis for exclusion (§412.25(a)(2)):

" In order to be excluded from the prospective payment systems ... a psychiatric ... unit must meet the following requirements:

(2) Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients."

Interpretive Guideline

FED - C0505 - SEPARATE MEDICAL RECORDS

Title SEPARATE MEDICAL RECORDS

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

" In order to be excluded from the prospective payment

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systems ...a psychiatric ...unit must meet the following requirements:]

(3) Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available."

FED - C0506 - POLICIES

Title POLICIES

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(4) Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the hospital."

Interpretive Guideline

FED - C0507 - STATE LICENSURE

Title STATE LICENSURE

Type Standard

CFR 485.647(a)(1)

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Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(5) Meet all applicable State licensure laws."

Interpretive Guideline

FED - C0508 - UTILIZATION REVIEW

Title UTILIZATION REVIEW

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(6) Have utilization review standards applicable for the type of care offered in the unit."

Interpretive Guideline

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FED - C0509 - SEPARATE BEDS

Title SEPARATE BEDS

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Basis for exclusion (§412.25(a)): "In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.] (7) Have beds physically separate from (that is, not commingled with) the hospital's other beds."	

FED - C0510 - FISCAL INTERMEDIARY

Title FISCAL INTERMEDIARY

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Basis for exclusion (§412.25(a)): "In order to be excluded from the prospective payment	Compliance with this requirement is determined by the FI.

systems ...a psychiatric ...unit must meet the following requirements.]

(8) Be serviced by the same fiscal intermediary as the hospital."

FED - C0511 - SEPARATE COST CENTER

Title SEPARATE COST CENTER

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Basis for exclusion (§412.25(a)): "In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.] (9) Be treated as a separate cost center for cost finding and apportionment purposes."	Compliance with this requirement is determined by the FI.

FED - C0512 - ACCOUNTING SYSTEM

Title ACCOUNTING SYSTEM

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply	Compliance with this requirement is determined by the FI.

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with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(10) Use an accounting system that properly allocates costs."

FED - C0513 - MAINTAIN ALLOCATION DATA

Title MAINTAIN ALLOCATION DATA

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(11) Maintain adequate statistical data to support the basis of allocation."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

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FED - C0514 - FISCAL PERIOD

Title FISCAL PERIOD

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Basis for exclusion (§412.25(a)): "In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.] (12) Report its cost in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital."	Compliance with this requirement is determined by the FI.

FED - C0515 - FULLY EQUIPPED AND STAFFED

Title FULLY EQUIPPED AND STAFFED

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Basis for exclusion (§412.25(a)):	

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"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(13) As of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient psychiatric or rehabilitation care regardless of whether there are any inpatients in the unit on that date."

FED - C0516 - INCREASE IN SIZE

Title INCREASE IN SIZE

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the size of excluded units (§412.25(b)).]

"For purposes of exclusions from the prospective payment systems under this section, changes in the number of beds and square footage considered to be part of each excluded unit are allowed as specified in paragraphs (b)(1) through (b)(3) of this section.

(1) Increase in size. Except as described in paragraph (b)(3) of this section, the number of beds and square footage of an excluded unit may be increased only at the start of a cost reporting period."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

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FED - C0517 - DECREASE IN SIZE

Title DECREASE IN SIZE

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the size of excluded units (§412.25(b)):

"For purposes of exclusions from the prospective payment systems under this section, changes in the number of beds and square footage considered to be part of each excluded unit are allowed as specified in paragraphs (b)(1) through (b)(3) of this section.]

(2) Decrease in size. Except as described in paragraph (b)(3) of this section, the number of beds and square footage of an excluded unit may be decreased at any time during a cost reporting period if the hospital notifies its fiscal intermediary and the CMS Regional Office in writing of the planned decrease at least 30 days before the date of the decrease, and maintains the information needed to accurately determine costs that are attributable to the excluded unit. Any decrease in the number of beds or square footage considered to be part of an excluded unit made during a cost reporting period must remain in effect for the rest of that cost reporting period."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

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FED - C0518 - RELOCATION OF A UNIT

Title RELOCATION OF A UNIT

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the size of excluded units (§412.25(b)):

"For purposes of exclusions from the prospective payment systems under this section, changes in the number of beds and square footage considered to be part of each excluded unit are allowed as specified in paragraphs (b)(1) through (b)(3) of this section.]

(3) Exception to changes in square footage and bed size. The number of beds in an excluded unit may be decreased, and the square footage considered to be part of the unit may be either increased or decreased, at any time, if these changes are made necessary by relocation of a unit-

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

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FED - C0519 - CHANGES IN STATUS OF UNITS

Title CHANGES IN STATUS OF UNITS

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...] Changes in the status of hospital units (§412.25(c)): ["For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section.] (1) The status of a hospital unit may be changed from not excluded to excluded only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the prospective payment systems before the start of a hospital's next cost reporting period. "	Compliance with this requirement is determined by the FI.

FED - C0520 - 30-DAY NOTICE

Title 30-DAY NOTICE

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply	Compliance with this requirement is determined by the FI.

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with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the status of hospital units (§412.25(c)):]

"For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section.]

(2) The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period."

FED - C0521 - NUMBER OF EXCLUDED UNITS

Title NUMBER OF EXCLUDED UNITS

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Number of excluded units (§412.25(d)):

"Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

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FED - C0522 - SATELLITES-DEFINITION

Title SATELLITES-DEFINITION

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...] Satellite facilities (§412.25(e)): "(1) For purposes of paragraphs (e)(2) through (e)(4) of this section, a satellite facility is a part of a hospital unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital."	Compliance with this requirement is determined by the FI.

FED - C0523 - SATELLITES-NUMBER OF BEDS

Title SATELLITES-NUMBER OF BEDS

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Satellite facilities (§412.25(e)):] "(2) Except as provided in paragraphs (e)(3) and (e)(5) of this section, effective for cost reporting periods beginning on or	Compliance with this requirement is determined by the FI.

after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period.

(i) In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's number of State-licensed and Medicare-certified beds on the last day of the unit's last cost reporting period beginning before October 1, 1997."

FED - C0524 - SATELLITES-ADMISSION CRITERIA

Title SATELLITES-ADMISSION CRITERIA

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(2)):

"(ii) The satellite facility independently complies with-

(A) For a rehabilitation unit, the requirements under §412.23(b)(2); or

(B) For a psychiatric unit, the requirements under §412.27(a)."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

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FED - C0525 - SATELLITES-INDEPENDENT STAFF

Title SATELLITES-INDEPENDENT STAFF

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Satellite facilities (§412.25(e)(2)).] "(iii) The satellite facility meets all of the following requirements: (A) Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located."	Compliance with this requirement is determined by the FI.

FED - C0526 - SATELLITES-SEPARATE RECORDS

Title SATELLITES-SEPARATE RECORDS

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...	

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Satellite facilities (§412.25(e)(2)):

"(iii) The satellite facility meets all of the following requirements:]

(B) It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available."

FED - C0527 - SATELLITES-SEPARATE BEDS

Title SATELLITES-SEPARATE BEDS

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)).

" (iii) The satellite facility meets all of the following requirements:]

(C) It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located."

Interpretive Guideline

FED - C0528 - SATELLITES-FISCAL INTERMEDIARY

Title SATELLITES-FISCAL INTERMEDIARY

Type Standard

CFR 485.647(a)(1)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Satellite facilities (§412.25(e)(2)): "(iii) The satellite facility meets all of the following requirements:] (D) It is serviced by the same fiscal intermediary as the hospital unit of which it is a part."	Compliance with this requirement is determined by the FI.

FED - C0529 - SATELLITES-COST CENTER

Title SATELLITES-COST CENTER

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Satellite facilities (§412.25(e)(2)): "(iii) The satellite facility meets all of the following requirements:] (E) It is treated as a separate cost center of the hospital unit of which it is a part."	Compliance with this requirement is determined by the FI.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0530 - SATELLITES-MAINTAIN DATA

Title SATELLITES-MAINTAIN DATA

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Satellite facilities (§412.25(e)(2)): "(iii) The satellite facility meets all of the following requirements:] (F) For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation."	Compliance with this requirement is determined by the FI.

FED - C0531 - SATELLITES-FISCAL PERIOD

Title SATELLITES-FISCAL PERIOD

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Satellite facilities (§412.25(e)(2)): "(iii) The satellite facility meets all of the following	Compliance with this requirement is determined by the FI.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

requirements:]

(G) It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part."

FED - C0532 - SATELLITE FACILITIES

Title SATELLITE FACILITIES

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(3)):

"Except as specified in paragraph (e)(4) of this section, the provisions of paragraph (e)(2) of this section do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage considered to be part of the unit, in effect on September 30, 1999."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

FED - C0533 - SATELLITES-RELOCATION

Title SATELLITES-RELOCATION

Type Standard

CFR 485.647(a)(1)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(4)):

" In applying the provisions of paragraph (e)(3) of this section, any unit structured as a satellite facility on September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility considered to be part of the satellite facility at any time, if these changes are made by the relocation of a facility-

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

FED - C0534 - SATELLITES-DECREASE NUMBER OF BEDS

Title SATELLITES-DECREASE NUMBER OF BEDS

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(5)&(6)):

"(5) For cost reporting periods beginning on or after October

Interpretive Guideline

Compliance with this requirement is determined by the FI.

1, 2006, in applying the provisions of paragraph (e)(3) of this section-

(i) Any unit structured as a satellite facility on September 30, 1999, may increase the square footage of the unit only at the beginning of a cost reporting period or decrease the square footage or number of beds considered to be part of the satellite facility subject to the provisions of paragraph (b)(2) of this section, without affecting the provisions of paragraph (e)(3) of this section; and

(ii) If the unit structured as a satellite facility decreases its number of beds below the number of beds considered to be part of the satellite facility on September 30, 1999, subject to the provisions of paragraph (b)(2) of this section, it may subsequently increase the number of beds at the beginning or a cost reporting period as long as the resulting total number of beds considered to be part of the satellite facility does not exceed the number of beds at the satellite facility on September 30, 1999.

(6) The provisions of paragraph (e)(2)(i) of this section do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of this part, effective for cost reporting periods beginning on or after October 1, 2003."

FED - C0535 - CHANGES IN CLASSIFICATION

Title CHANGES IN CLASSIFICATION

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply

Interpretive Guideline

Compliance with this requirement is determined by the FI.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

with ...§412.25(a)(2) through (f) of Part 412 ...]

Changes in classification (§412.25(f)):

"For purposes of exclusions from the prospective payment system under this section, the classification of a hospital unit is effective for the unit's entire cost reporting period. Any changes in the classification of a hospital unit is made only at the start of a cost reporting period."

FED - C0547 - ADMISSIONS

Title ADMISSIONS

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"In order to be excluded from the prospective payment system as specified in §412.1(a)(1), and paid under the prospective payment system as specified in §412.1(a)(2), a psychiatric unit must meet the following requirements:

(a) Admit only patients whose admission to the unit is required for active treatment, of an intensity that can be provided appropriately only in an inpatient hospital setting, of a psychiatric principal diagnosis that is listed in the Fourth Edition, Text Revision of the American Psychiatric Association's Diagnostic and Statistical Manual, or in Chapter

Interpretive Guideline

Five ("Mental Disorders") of the International Classification of Diseases, Ninth Revision, Clinical Modification."

FED - C0548 - QUALIFIED PERSONNEL

Title QUALIFIED PERSONNEL

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"In order to be excluded from the prospective payment system ... a psychiatric unit must meet the following requirements:]

(b) Furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, and therapeutic activities."

Interpretive Guideline

FED - C0549 - MEDICAL RECORDS

Title MEDICAL RECORDS

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of

Interpretive Guideline

this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"In order to be excluded from the prospective payment system ... a psychiatric unit must meet the following requirements:]

(c) Maintain medical records that permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the unit, and that meet the following requirements:

(1) Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit."

FED - C0550 - INPATIENT LEGAL STATUS

Title INPATIENT LEGAL STATUS

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):]

"(c)(1) Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record,

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.

(i) Identification data must include the inpatient's legal status."

FED - C0551 - ADMITTING DIAGNOSIS

Title ADMITTING DIAGNOSIS

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(1) Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.]

(ii) A provisional or admitting diagnosis must be made on every inpatient at the time of admission, and must include the diagnoses of every inpatient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses."

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0552 - REASONS FOR ADMISSION

Title REASONS FOR ADMISSION

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.] Excluded psychiatric units: Additional requirements (§412.27): "(c)(1) Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.] (iii) The reasons for admission must be clearly documented as stated by the inpatient or others significantly involved, or both."	

FED - C0553 - SOCIAL SERVICE RECORDS

Title SOCIAL SERVICE RECORDS

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply	

with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(1) Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.]

(iv) The social service records, including reports of interviews with inpatients, family members, and others must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history."

FED - C0554 - NEUROLOGICAL EXAMINATION

Title NEUROLOGICAL EXAMINATION

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(1) Development of assessment/diagnostic data. Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the

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unit.]

(v) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination."

FED - C0555 - PSYCHIATRIC EVALUATION

Title PSYCHIATRIC EVALUATION

Type Standard

CFR 485.647(a)(1)

Regulation Definition **Interpretive Guideline**

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c) (2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-

(i) Be completed within 60 hours of admission."

FED - C0556 - MEDICAL HISTORY

Title MEDICAL HISTORY

Type Standard

CFR 485.647(a)(1)

Regulation Definition **Interpretive Guideline**

[...the services furnished by the distinct part unit must comply

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with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-]

(ii) Include a medical history."

FED - C0557 - MENTAL STATUS

Title MENTAL STATUS

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-]

(iii) Contain a record of mental status."

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0558 - ONSET OF ILLNESS

Title ONSET OF ILLNESS

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-]

(iv) Note the onset of illness and the circumstances leading to admission."

Interpretive Guideline

FED - C0559 - ATTITUDES AND BEHAVIOR

Title ATTITUDES AND BEHAVIOR

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

(§412.27):

"(c)(2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-]

(v) describe attitudes and behavior."

FED - C0560 - INTELLECTUAL FUNCTIONING

Title INTELLECTUAL FUNCTIONING

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-]

(vi) Estimate intellectual functioning, memory functioning, and orientation."

Interpretive Guideline

FED - C0561 - INPATIENT'S ASSETS

Title INPATIENT'S ASSETS

Type Standard

CFR 485.647(a)(1)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(2) Psychiatric evaluation. Each inpatient must receive a psychiatric evaluation that must-]

(vii) Include an inventory of the inpatient's assets in descriptive, not interpretative fashion."

Interpretive Guideline

FED - C0562 - TREATMENT PLAN-DIAGNOSIS

Title TREATMENT PLAN-DIAGNOSIS

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(3) Treatment plan.

(i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include a substantiated diagnosis."

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0563 - TREATMENT PLAN-GOALS

Title TREATMENT PLAN-GOALS

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(3) Treatment plan.

(i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include ...] short-term and long-term goals."

Interpretive Guideline

FED - C0564 - TREATMENT PLAN-MODALITIES

Title TREATMENT PLAN-MODALITIES

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(3) Treatment plan

(i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include ...] the specific treatment modalities utilized."

FED - C0565 - TREATMENT PLAN-TEAM

Title TREATMENT PLAN-TEAM

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(3) Treatment plan.

(i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include ...] the responsibilities of each member of the treatment team."

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0566 - TREATMENT PLAN-DOCUMENTATION

Title TREATMENT PLAN-DOCUMENTATION

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(3) Treatment plan

(i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include ...] adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out."

Interpretive Guideline

FED - C0567 - TREATMENT PLAN-THERAPY

Title TREATMENT PLAN-THERAPY

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(3) Treatment plan]

(ii) The treatment received by the inpatient must be documented in such a way as to assure that all active therapeutic efforts are included."

FED - C0568 - PROGRESS NOTES-MD/DO

Title PROGRESS NOTES-MD/DO

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(4) Recording progress. Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the inpatient."

Interpretive Guideline

FED - C0569 - PROGRESS NOTES-NURSE

Title PROGRESS NOTES-NURSE

Type Standard

CFR 485.647(a)(1)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(4) Recording progress. Progress notes must be recorded by ...] a nurse."

Interpretive Guideline

FED - C0570 - PROGRESS NOTES-SOCIAL WORKER

Title PROGRESS NOTES-SOCIAL WORKER

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(4) Recording progress. Progress notes must be recorded by ...] a social worker."

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0571 - PROGRESS NOTES-OTHERS

Title PROGRESS NOTES-OTHERS

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(4) Recording progress. Progress notes must be recorded by ...] others significantly involved in active treatment modalities, when appropriate."

Interpretive Guideline

FED - C0572 - PROGRESS NOTES-FREQUENCY

Title PROGRESS NOTES-FREQUENCY

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

"(c)(4) Recording progress.] ...The frequency of progress notes is determined by the condition of the inpatient but must be recorded at least weekly for the first two months and at least once a month thereafter."

FED - C0573 - PROGRESS NOTES-REVISIONS

Title PROGRESS NOTES-REVISIONS

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(4) Recording progress.] ...progress notes must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the inpatient's progress in accordance with the original or revised treatment plan."

Interpretive Guideline

FED - C0574 - DISCHARGE SUMMARY

Title DISCHARGE SUMMARY

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(5) Discharge planning and discharge summary. The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the inpatient's hospitalization in the unit ..."

FED - C0575 - DISCHARGE PLANNING-FOLLOW-UP

Title DISCHARGE PLANNING-FOLLOW-UP

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(5) Discharge planning and discharge summary. The record of each patient who has been discharged must have ...] recommendations from appropriate services concerning follow-up or aftercare ..."

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0576 - CONDITION ON DISCHARGE

Title CONDITION ON DISCHARGE

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"(c)(5) Discharge planning and discharge summary. The record of each patient who has been discharged must have ...] a brief summary of the patient's condition on discharge."

Interpretive Guideline

FED - C0577 - ADEQUATE NUMBER OF STAFF

Title ADEQUATE NUMBER OF STAFF

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

"...A psychiatric unit must ...

(d)Meet special staff requirements in that the unit must have adequate numbers of qualified professional and supportive staff to evaluate inpatients, formulate written, individualized, comprehensive treatment plans, provide active treatment measures and engage in discharge planning ..."

FED - C0578 - ADEQUATE TYPES OF PERSONNEL

Title ADEQUATE TYPES OF PERSONNEL

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...]

(d)(1) Personnel. The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to-

(i) evaluate inpatients;

(ii) formulate written, individualized, comprehensive treatment plans;

(iii) provide active treatment measures; and

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

(iv) engage in discharge planning."

FED - C0579 - DIRECTOR

Title DIRECTOR

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units. Excluded psychiatric units: Additional requirements (§412.27): "...A psychiatric unit must ...] (d)(2) Director of inpatient psychiatric services: Medical staff. Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program."	

FED - C0580 - MEDICAL DOCTORS

Title MEDICAL DOCTORS

Type Standard

CFR 485.647(a)(1)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of	

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(2) Director of inpatient psychiatric services: Medical staff.]

...The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services."

FED - C0581 - CLINICAL DIRECTOR

Title CLINICAL DIRECTOR

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(2) Director of inpatient psychiatric services: Medical staff.]

(i) The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by

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the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry."

FED - C0582 - QUALITY OF SERVICES

Title QUALITY OF SERVICES

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(2) Director of inpatient psychiatric services: Medical staff.]

(ii) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff."

Interpretive Guideline

FED - C0583 - NURSING DIRECTOR

Title NURSING DIRECTOR

Type Standard

CFR 485.647(a)(1)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...]

(d)(3) Nursing services. The unit must have a qualified director of psychiatric nursing services ..."

Interpretive Guideline

FED - C0584 - NUMBERS OF NURSING STAFF

Title NUMBERS OF NURSING STAFF

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(3) Nursing services.]

...In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care

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necessary under each inpatient's active treatment program and to maintain progress notes on each inpatient."

FED - C0585 - DON QUALIFICATIONS

Title DON QUALIFICATIONS

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(3) Nursing services.]

(i) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent, from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill."

Interpretive Guideline

FED - C0586 - DON COMPETENCE

Title DON COMPETENCE

Type Standard

CFR 485.647(a)(1)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.
Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(3) Nursing services.]

...The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished."

Interpretive Guideline

FED - C0587 - RN REQUIREMENT

Title RN REQUIREMENT

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(3) Nursing services.]

Interpretive Guideline

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(ii) The staffing pattern must ensure the availability of a registered nurse 24 hours each day..."

FED - C0588 - STAFF FOR NURSING CARE

Title STAFF FOR NURSING CARE

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(3) Nursing services ....]

(ii) ...There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each inpatient's active treatment program."

Interpretive Guideline

FED - C0589 - PSYCHOLOGICAL SERVICES

Title PSYCHOLOGICAL SERVICES

Type Standard

CFR 485.647(a)(1)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...]

(d)(4) Psychological services. The unit must provide or have available psychological services to meet the needs of the inpatients ...."

Interpretive Guideline

FED - C0590 - PSYCHOLOGICAL SERVICES

Title PSYCHOLOGICAL SERVICES

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(4) Psychological services.]

...The services must be furnished in accordance with acceptable standards of practice, service objectives, and

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

established policies and procedures."

FED - C0591 - SOCIAL SERVICES DIRECTOR

Title SOCIAL SERVICES DIRECTOR

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...]

(d)(5) Social services. There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished ..."

Interpretive Guideline

FED - C0592 - SOCIAL SERVICES

Title SOCIAL SERVICES

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

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Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(5) Social services.]

...The social services must be furnished in accordance with accepted standards of practice and established policies and procedures ..."

FED - C0593 - SOCIAL SERVICE RESPONSIBILITIES

Title SOCIAL SERVICE RESPONSIBILITIES

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(5) Social services.]

...Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital."

Interpretive Guideline

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FED - C0594 - THERAPEUTIC ACTIVITIES

Title THERAPEUTIC ACTIVITIES

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...]

(d)(6) Therapeutic activities. The unit must provide a therapeutic activities program."

Interpretive Guideline

FED - C0595 - ACTIVITIES PROGRAM

Title ACTIVITIES PROGRAM

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

"...A psychiatric unit must ...

(d)(6) Therapeutic activities. The unit must provide a therapeutic activities program.]

(i) The [program must be appropriate to the needs and interests of inpatients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning."

FED - C0596 - ACTIVITIES STAFF

Title ACTIVITIES STAFF

Type Standard

CFR 485.647(a)(1)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.27 of Part 412 of this chapter for excluded psychiatric units.]

Excluded psychiatric units: Additional requirements (§412.27):

"...A psychiatric unit must ...

(d)(6) Therapeutic activities. The unit must provide a therapeutic activities program.]

(ii) The number of qualified therapeutic activities therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each inpatient's active treatment program."

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0700 - PSYCH & REHAB DISTINCT PART UNITS -- REHAB

Title PSYCH & REHAB DISTINCT PART UNITS -- REHAB

Type Condition

CFR 485.647(a)(2)

Regulation Definition

If a CAH provides inpatient rehabilitation services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of §412.25(a)(2) through (f) of Part 412 of this chapter for hospital units excluded from the prospective payment systems, and the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Interpretive Guideline

FED - C0701 - ELIGIBILITY REQUIREMENTS

Title ELIGIBILITY REQUIREMENTS

Type Standard

CFR 485.647(b)

Regulation Definition

(1) To be eligible to receive Medicare payments for psychiatric or rehabilitation services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit.

(2) The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in §485.620(a).

(3) The average annual 96-hour length of stay requirement

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

specified under §485.620(b) does not apply to the 10 beds in the distinct part units specified in paragraph (b)(1) of this section, and admissions and days of inpatient care in the distinct part units are not taken into account in determining the CAH's compliance with the limits on the number of beds and length of stay in §485.620.

FED - C0704 - ADMISSION CRITERIA

Title ADMISSION CRITERIA

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Basis for exclusion (§412.25(a)(2)):

"In order to be excluded from the prospective payment systems ... a rehabilitation unit must meet the following requirements:

(2) Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients."

Interpretive Guideline

FED - C0705 - SEPARATE MEDICAL RECORDS

Title SEPARATE MEDICAL RECORDS

Type Standard

CFR 485.647(a)(2)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ... a rehabilitation unit must meet the following requirements:]

(3) Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available."

Interpretive Guideline

FED - C0706 - POLICIES

Title POLICIES

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(4) Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the hospital."

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0707 - STATE LICENSURE

Title STATE LICENSURE

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(5) Meet all applicable State licensure laws."

Interpretive Guideline

FED - C0708 - UTILIZATION REVIEW

Title UTILIZATION REVIEW

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following

Interpretive Guideline

requirements.]

(6) Have utilization review standards applicable for the type of care offered in the unit."

FED - C0709 - SEPARATE BEDS

Title SEPARATE BEDS

Type Standard

CFR 485.647(a)(2)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Basis for exclusion (§412.25(a)): "In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.] (7) Have beds physically separate from (that is, not commingled with) the hospital's other beds."	

FED - C0710 - FISCAL INTERMEDIARY

Title FISCAL INTERMEDIARY

Type Standard

CFR 485.647(a)(2)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...	Compliance with this requirement is determined by the FI.

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Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(8) Be serviced by the same fiscal intermediary as the hospital."

FED - C0711 - SEPARATE COST CENTER

Title SEPARATE COST CENTER

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.]

(9) Be treated as a separate cost center for cost finding and apportionment purposes."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0712 - ACCOUNTING SYSTEM

Title ACCOUNTING SYSTEM

Type Standard

CFR 485.647(a)(2)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Basis for exclusion (§412.25(a)): "In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.] (10) Use an accounting system that properly allocates costs."	Compliance with this requirement is determined by the FI.

FED - C0713 - MAINTAIN ALLOCATION DATA

Title MAINTAIN ALLOCATION DATA

Type Standard

CFR 485.647(a)(2)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Basis for exclusion (§412.25(a)): "In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following	Compliance with this requirement is determined by the FI.

requirements.]

(11) Maintain adequate statistical data to support the basis of allocation."

FED - C0714 - FISCAL PERIOD

Title FISCAL PERIOD

Type Standard

CFR 485.647(a)(2)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Basis for exclusion (§412.25(a)): "In order to be excluded from the prospective payment systems ...a rehabilitation unit must meet the following requirements.] (12) Report its cost in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital."	Compliance with this requirement is determined by the FI.

FED - C0715 - FULLY EQUIPPED AND STAFFED

Title FULLY EQUIPPED AND STAFFED

Type Standard

CFR 485.647(a)(2)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply	

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with ...§412.25(a)(2) through (f) of Part 412 ...

Basis for exclusion (§412.25(a)):

"In order to be excluded from the prospective payment systems ...a psychiatric ...unit must meet the following requirements.]

(13) As of the first day of the first cost reporting period for which all other exclusion requirements are met, be fully equipped and staffed and capable of providing hospital inpatient rehabilitation care, regardless of whether there are any inpatients in the unit on that date."

FED - C0716 - INCREASE IN SIZE

Title INCREASE IN SIZE

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the size of excluded units (§412.25(b)).]

"For purposes of exclusions from the prospective payment systems under this section, changes in the number of beds and square footage considered to be part of each excluded unit are allowed as specified in paragraphs (b)(1) through (b)(3) of this section.

(1) Increase in size. Except as described in paragraph (b)(3) of this section, the number of beds and square footage of an excluded unit may be increased only at the start of a cost

Interpretive Guideline

Compliance with this requirement is determined by the FI.

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reporting period."

FED - C0717 - DECREASE IN SIZE

Title DECREASE IN SIZE

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the size of excluded units (§412.25(b)):

"For purposes of exclusions from the prospective payment systems under this section, changes in the number of beds and square footage considered to be part of each excluded unit are allowed as specified in paragraphs (b)(1) through (b)(3) of this section.]

"(2) Decrease in size. Except as described in paragraph (b)(3) of this section, the number of beds and square footage of an excluded unit may be decreased at any time during a cost reporting period if the hospital notifies its fiscal intermediary and the CMS Regional Office in writing of the planned decrease at least 30 days before the date of the decrease, and maintains the information needed to accurately determine costs that are attributable to the excluded unit. Any decrease in the number of beds or square footage considered to be part of an excluded unit made during a cost reporting period must remain in effect for the rest of that cost reporting period."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

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FED - C0718 - EXCEPTION TO CHANGES IN SIZE

Title EXCEPTION TO CHANGES IN SIZE

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the size of excluded units (§412.25(b)(3)):

"For purposes of exclusions from the prospective payment systems under this section, changes in the number of beds and square footage considered to be part of each excluded unit are allowed as specified in paragraphs (b)(1) through (b)(3) of this section.]

(3) Exception to changes in square footage and bed size. The number of beds in an excluded unit may be decreased, and the square footage considered to be part of the unit may be either increased or decreased, at any time, if these changes are made necessary by relocation of a unit-

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

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FED - C0719 - CHANGES IN STATUS OF HOSPITAL UNITS

Title CHANGES IN STATUS OF HOSPITAL UNITS

Type Standard

CFR 485.647(a)(2)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Changes in the status of hospital units (§412.25(c)): "For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section.] (1) The status of a hospital unit may be changed from not excluded to excluded only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the prospective payment systems before the start of a hospital's next cost reporting period. "	Compliance with this requirement is determined by the FI.

FED - C0720 - 30-DAY NOTICE

Title 30-DAY NOTICE

Type Standard

CFR 485.647(a)(2)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply	[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

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with ...§412.25(a)(2) through (f) of Part 412 ...

Changes in the status of hospital units (§412.25(c)):

"For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section.]

(2) The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if he hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period."

Changes in the status of hospital units (§412.25(c)):

" For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of this section.]

(2) The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if he hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period. "

FED - C0721 - NUMBER OF EXCLUDED UNITS

Title NUMBER OF EXCLUDED UNITS

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Number of excluded units (§412.25(d)):

"Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

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FED - C0722 - SATELLITES-DEFINITION

Title SATELLITES-DEFINITION

Type Standard

CFR 485.647(a)(2)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...] Satellite facilities (§412.25(e)): "(1) For purposes of paragraphs (e)(2) through (e)(4) of this section, a satellite facility is a part of a hospital unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital."	Compliance with this requirement is determined by the FI.

FED - C0723 - SATELLITES-NUMBER OF BEDS

Title SATELLITES-NUMBER OF BEDS

Type Standard

CFR 485.647(a)(2)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Satellite facilities (§412.25(e)).] "(2) Except as provided in paragraphs (e)(3) and (e)(5) of this section, effective for cost reporting periods beginning on or	Compliance with this requirement is determined by the FI.

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after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period.

(i) In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's on the last day of the unit's last cost reporting period beginning before October 1, 1997."

FED - C0724 - SATELLITES-ADMISSION CRITERIA

Title SATELLITES-ADMISSION CRITERIA

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)).]

"(ii) The satellite facility independently complies with-

(A) For a rehabilitation unit, the requirements under §412.23(b)(2); or

(B) For a psychiatric unit, the requirements under §412.27(a)."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

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FED - C0725 - SATELLITES-INDEPENDENT STAFF

Title SATELLITES-INDEPENDENT STAFF

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Satellite facilities (§412.25(e)(2)).]

"(iii) The satellite facility meets all of the following requirements:

(A) Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located."

Interpretive Guideline

FED - C0726 - SATELLITES-SEPARATE RECORDS

Title SATELLITES-SEPARATE RECORDS

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...

Interpretive Guideline

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Satellite facilities (§412.25(e)(2)):

"(iii) The satellite facility meets all of the following requirements:]

(B) It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available."

FED - C0727 - SATELLITES-SEPARATE BEDS

Title SATELLITES-SEPARATE BEDS

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...
Satellite facilities (§412.25(e)(2)):

"(iii) The satellite facility meets all of the following requirements:]

(C) It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located."

Interpretive Guideline

FED - C0728 - SATELLITES-FISCAL INTERMEDIARY

Title SATELLITES-FISCAL INTERMEDIARY

Type Standard

CFR 485.647(a)(2)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Satellite facilities (§412.25(e)(2)): "(iii) The satellite facility meets all of the following requirements:] (D) It is serviced by the same fiscal intermediary as the hospital unit of which it is a part."	Compliance with this requirement is determined by the FI.

FED - C0729 - SATELLITES-COST CENTER

Title SATELLITES-COST CENTER

Type Standard

CFR 485.647(a)(2)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Satellite facilities (§412.25(e)(2)): "(iii) The satellite facility meets all of the following requirements:] (E) It is treated as a separate cost center of the hospital unit of which it is a part."	Compliance with this requirement is determined by the FI.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0730 - SATELLITES-MAINTAIN DATA

Title SATELLITES-MAINTAIN DATA

Type Standard

CFR 485.647(a)(2)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Satellite facilities (§412.25(e)(2)): "(iii) The satellite facility meets all of the following requirements:] (F) For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation."	Compliance with this requirement is determined by the FI.

FED - C0731 - SATELLITES-FISCAL PERIOD

Title SATELLITES-FISCAL PERIOD

Type Standard

CFR 485.647(a)(2)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ... Satellite facilities (§412.25(e)(2)): "(iii) The satellite facility meets all of the following requirements:]	Compliance with this requirement is determined by the FI.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

(G) It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part."

FED - C0732 - SATELLITE FACILITIES

Title SATELLITE FACILITIES

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...]

Satellite facilities (§412.25(e)(3)):

"Except as specified in paragraph (e)(4) of this section, the provisions of paragraph (e)(2) of this section do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage considered to be part of the unit, in effect on September 30, 1999."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

FED - C0733 - SATELLITES-RELOCATION

Title SATELLITES-RELOCATION

Type Standard

CFR 485.647(a)(2)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...] Satellite facilities (§412.25(e)(4)): "In applying the provisions of paragraph (e)(3) of this section, any unit structured as a satellite facility on September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility considered to be part of the satellite facility at any time, if these changes are made by the relocation of a facility- (i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or (ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes."	Compliance with this requirement is determined by the FI.

FED - C0734 - SATELLITE FACILITIES

Title SATELLITE FACILITIES

Type Standard

CFR 485.647(a)(2)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ...§412.25(a)(2) through (f) of Part 412 ...] Satellite facilities (§412.25(e)(5)&(6)): "(5) For cost reporting periods beginning on or after October	Compliance with this requirement is determined by the FI.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

1, 2006, in applying the provisions of paragraph (e)(3) of this section-

(i) Any unit structured as a satellite facility on September 30, 1999, may increase the square footage of the unit only at the beginning of a cost reporting period or decrease the square footage or number of beds considered to be part of the satellite facility subject to the provisions of paragraph (b)(2) of this section, without affecting the provisions of paragraph (e)(3) of this section; and

(ii) If the unit structured as a satellite facility decreases its number of beds below the number of beds considered to be part of the satellite facility on September 30, 1999, subject to the provisions of paragraph (b)(2) of this section, it may subsequently increase the number of beds at the beginning or a cost reporting period as long as the resulting total number of beds considered to be part of the satellite facility does not exceed the number of beds at the satellite facility on September 30, 1999.

(6) The provisions of paragraph (e)(2)(i) of this section do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of this part, effective for cost reporting periods beginning on or after October 1, 2003."

FED - C0735 - CHANGES IN CLASSIFICATION

Title CHANGES IN CLASSIFICATION

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

with ...§412.25(a)(2) through (f) of Part 412 ...
Changes in classification (§412.25(f)):

"For purposes of exclusions from the prospective payment system under this section, the classification of a hospital unit is effective for the unit's entire cost reporting period. Any changes in the classification of a hospital unit is made only at the start of a cost reporting period."

FED - C0747 - NEW VS CONVERTED UNITS

Title NEW VS CONVERTED UNITS

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.]

Excluded rehabilitation units: Additional requirements (§412.29):

"In order to be excluded from the prospective payment systems described in §412.1(a)(1) and to be paid under the prospective payment system specified in §412.1(a)(2), a rehabilitation unit must meet the following requirements:

(a) Have met either the requirements for-

(1) New units under §412.30(a); or

(2) Converted units under §412.30(c)."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0748 - PREADMISSION SCREENING

Title PREADMISSION SCREENING

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29).]

"...A rehabilitation unit must ...

(b) Have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient program or assessment."

Interpretive Guideline

FED - C0749 - REHABILITATION NURSING

Title REHABILITATION NURSING

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...]

(c) Ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel, rehabilitation nursing."

FED - C0750 - PHYSICAL & OCCUPATIONAL THERAPY

Title PHYSICAL & OCCUPATIONAL THERAPY

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...

(c) Ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel ...]

...physical therapy and occupational therapy."

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0751 - OTHER SERVICES

Title OTHER SERVICES

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...

(c) Ensure that the patients receive close medical supervision and furnish, through the use of qualified personnel ...]

... plus, as needed speech therapy, social services or psychological services, and orthotic and prosthetic services."

Interpretive Guideline

FED - C0752 - PLAN OF TREATMENT

Title PLAN OF TREATMENT

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...]

(d) :Have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient."

FED - C0753 - MULTIDISCIPLINARY TEAM

Title MULTIDISCIPLINARY TEAM

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...]

(e) " Use a coordinated multidisciplinary team approach in the rehabilitation of each inpatient, as documented by periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment."

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0754 - TEAM CONFERENCES

Title TEAM CONFERENCES

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...]

(e) Use ...team conferences [that] are held at least every two weeks to determine the appropriateness of treatment."

Interpretive Guideline

FED - C0755 - DIRECTOR

Title DIRECTOR

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...]

(f) Have a director of rehabilitation who-

(1) Provides services to the unit and to its inpatients for at least 20 hours per week."

FED - C0756 - DIRECTOR MD/DO

Title DIRECTOR MD/DO

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...

(f) Have a director of rehabilitation who-

(2) Is a doctor of medicine or osteopathy."

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0757 - DIRECTOR-LICENSED

Title DIRECTOR-LICENSED

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...

(f) Have a director of rehabilitation who-

(3) Is licensed under State law to practice medicine or surgery."

Interpretive Guideline

FED - C0758 - DIRECTOR-TRAINING/EXPERIENCE

Title DIRECTOR-TRAINING/EXPERIENCE

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

units.

Excluded rehabilitation units: Additional requirements (§412.29):

"...A rehabilitation unit must ...

(f) Have a director of rehabilitation who-

(4) Has had, after completing a one-year hospital internship, at least two years of training or experience in the medical management of inpatients requiring rehabilitation services."

FED - C0770 - DECREASE IN BEDS

Title DECREASE IN BEDS

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.]

Exclusion of new rehabilitation units and expansion of units already excluded (§412.30):

"(a) Bed capacity in units. A decrease in bed capacity must remain in effect for at least a full 12-month cost reporting period before an equal or lesser number of beds can be added to the hospital's licensure and certification and considered "new" under paragraph (b) of this section..."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0771 - DELICENSED/DECERTIFIED BEDS

Title DELICENSED/DECERTIFIED BEDS

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ...the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Exclusion of new rehabilitation units and expansion of units already excluded (§412.30).]

"(a) Bed capacity in units ...When a hospital seeks to establish a new unit under the criteria under paragraph (b) of this section, or to enlarge an existing unit under the criteria under paragraph (d) of this section, the regional office will review its records on the facility to determine whether any beds have been delicensed and decertified during the 12-month cost reporting period before the period for which the hospital seeks to add the beds. To the extent bed capacity was removed from the hospital's licensure and certification during that period, that amount of bed capacity may not be considered "new" under paragraph (b) of this section."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

FED - C0772 - NEW UNITS

Title NEW UNITS

Type Standard

CFR 485.647(a)(2)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units. Exclusion of new rehabilitation units and expansion of units already excluded (§412.30).] "(b) New units. (1) A hospital unit is considered a new unit if the hospital- (i) has not previously sought exclusion for any rehabilitation unit, and (ii) has obtained approval, under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds in the unit."	Compliance with this requirement is determined by the FI.

FED - C0773 - WRITTEN CERTIFICATION

Title WRITTEN CERTIFICATION

Type Standard

CFR 485.647(a)(2)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units. Exclusion of new rehabilitation units and expansion of units already excluded (§412.30).]	Compliance with this requirement is determined by the FI.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

"(2) A hospital that seeks exclusion of a new rehabilitation unit may provide a written certification that the inpatient population the hospital intends the unit to serve meets the requirements of §412.23(b)(2) instead of showing that the unit has treated such a population during the hospital's most recent cost reporting period."

FED - C0774 - WRITTEN CERTIFICATION

Title WRITTEN CERTIFICATION

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Exclusion of new rehabilitation units and expansion of units already excluded (§412.30).]

"(3) The written certification described in paragraph (b)(2) of this section is effective for the first full cost reporting period during which the unit is used to provide hospital inpatient care."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

FED - C0775 - WRITTEN CERTIFICATION

Title WRITTEN CERTIFICATION

Type Standard

CFR 485.647(a)(2)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units. Exclusion of new rehabilitation units and expansion of units already excluded (§412.30).] "(4) If a hospital that has not previously participated in the Medicare program seeks exclusion of a rehabilitation unit, it may designate certain beds as a new rehabilitation unit for the first full 12-month cost reporting period that occurs after it becomes a Medicare-participating hospital. The written certification described in paragraph (b)(2) of this section also is effective for any cost reporting period of not less than 1 month and not more than 11 months occurring between the date the hospital began participating in Medicare and the start of the hospital's regular 12-month cost reporting period."	Compliance with this requirement is determined by the FI.

FED - C0776 - CHANGE OF OWNERSHIP

Title CHANGE OF OWNERSHIP

Type Standard

CFR 485.647(a)(2)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units. Exclusion of new rehabilitation units and expansion of units already excluded (§412.30).]	Compliance with this requirement is determined by the FI.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

"(5) A hospital that has undergone a change of ownership or leasing as defined in §489.18 of this chapter is not considered to have participated previously in the Medicare program."

FED - C0777 - CONVERTED UNITS

Title CONVERTED UNITS

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Exclusion of new rehabilitation units and expansion of units already excluded (§412.30).]

"(c) Converted units. A hospital unit is considered a converted unit if it does not qualify as a new unit under paragraph (a) of this section. A converted unit must have treated, for the hospital's most recent, consecutive, and appropriate 12-month cost reporting period (as defined by CMS or the fiscal intermediary), an inpatient population meeting the requirements of §412.23(b)(2)."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

FED - C0778 - EXPANSION OF UNITS

Title EXPANSION OF UNITS

Type Standard

CFR 485.647(a)(2)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units. Exclusion of new rehabilitation units and expansion of units already excluded (§412.30).] "(d) Expansion of excluded rehabilitation units. -(1) New bed capacity. The beds that a hospital seeks to add to its excluded rehabilitation unit are considered new beds only if- (i) the hospital's State-licensed and Medicare-certified bed capacity increases at the start of the cost reporting period for which the hospital seeks to increase the size of its excluded rehabilitation unit, or at any time after the start of the preceding cost reporting period; and (ii) the hospital has obtained approval, under State licensure and Medicare certification, for an increase in its hospital bed capacity that is greater than 50 percent of the number of beds it seeks to add to the unit."	Compliance with this requirement is determined by the FI.

FED - C0779 - CONVERSION OF BEDS

Title CONVERSION OF BEDS

Type Standard

CFR 485.647(a)(2)

Regulation Definition	Interpretive Guideline
[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation	Compliance with this requirement is determined by the FI.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

units.
Exclusion of new rehabilitation units and expansion of units already excluded (§412.30).]

"(2) Conversion of existing bed capacity.

(i) Bed capacity is considered to be existing bed capacity if it does not meet the definition of new bed capacity under paragraph (d)(1) of this section."

FED - C0780 - INCREASE IN SIZE

Title INCREASE IN SIZE

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Exclusion of new rehabilitation units and expansion of units already excluded (§412.30).]

"(ii) A hospital may increase the size of its excluded rehabilitation unit through the conversion of existing bed capacity only if it shows that, for all of the hospital's most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the fiscal intermediary), the beds have been used to treat an inpatient population meeting the requirements of §412.23(b)(2)."

Interpretive Guideline

Compliance with this requirement is determined by the FI.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0781 - RETROACTIVE ADJUSTMENTS

Title RETROACTIVE ADJUSTMENTS

Type Standard

CFR 485.647(a)(2)

Regulation Definition

[...the services furnished by the distinct part unit must comply with ... the additional requirements of §412.29 and §412.30 of Part 412 of this chapter related specifically to rehabilitation units.

Exclusion of new rehabilitation units and expansion of units already excluded (§412.30):]

" (e) Retroactive adjustments for certain units. For cost reporting periods beginning on or after October 1, 1991, if a hospital has a new rehabilitation unit excluded from the prospective payment systems for a cost reporting period under paragraph (a) of this section or expands an existing rehabilitation unit under paragraph (c) of this section, but the inpatient population actually treated in the new unit or the beds added to the existing unit during that cost reporting period does not meet the requirements in §412.23(b)(2), CMS adjusts payments to the hospital retroactively in accordance with the provisions in §412.130 of this part. "

Interpretive Guideline

Compliance with this requirement is determined by the FI.

FED - C0800 - BASIS AND SCOPE

Title BASIS AND SCOPE

Type Standard

CFR 485.601

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition

(a) Statutory basis. This subpart is based on section 1820 of the Act which sets forth the conditions for designating certain hospitals as CAHs.

(b) Scope. This subpart sets forth the conditions that a hospital must meet to be designated as a CAH.

Interpretive Guideline

FED - C0802 - RURAL HEALTH NETWORK

Title RURAL HEALTH NETWORK

Type Standard

CFR 485.603

Regulation Definition

§485.603 Rural health network
A rural health network is an organization that meets the following specifications
(a) It includes-
(1) At least one hospital that the State has designated or plans to designate as a CAH; and
(2) At least one hospital that furnishes acute care services.
(b) The members of the organization have entered into agreements regarding-
(1) Patient referral and transfer;
(2) The development and use of communications systems, including, where feasible, telemetry systems and systems for electronic sharing of patient data; and
(3) The provision of emergency and nonemergency transportation among members.
(c) Each CAH has an agreement with respect to credentialing and quality assurance with at least-
(1) One hospital that is a member of the network when applicable;

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

(2) One QIO or equivalent entity; or
(3) One other appropriate and qualified entity identified in the State rural health care plan.

FED - C0804 - PERSONNEL QUALIFICATION

Title PERSONNEL QUALIFICATION

Type Standard

CFR 485.604

Regulation Definition

Staff that furnish services in a CAH must meet the applicable requirements of this section.

(a) Clinical nurse specialist. A clinical nurse specialist must be a person who-

(1) Is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed in accordance with State nurse licensing laws and regulations; and

(2) Holds a master's or doctoral level degree in a defined clinical area of nursing from an accredited educational institution.

(b) Nurse practitioner. A nurse practitioner must be a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualification of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates.

Interpretive Guideline

(2) Has successfully completed a 1 academic year program that-

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program.

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (a)(2) of this section, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

(c) Physician assistant. A physician assistant must be a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians.

(2) Has satisfactorily completed a program for preparing physician assistants that-

(i) Was at least one academic year in length;

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (c)(2) of this section and has been assisting primary care physicians for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

FED - C0808 - DESIGNATION AND CERTIFICATION OF CAHS

Title DESIGNATION AND CERTIFICATION OF CAHS

Type Standard

CFR 485.606

Regulation Definition

(a) Criteria for State Designation.

(1) A State that has established a Medicare rural hospital flexibility program described in section 1820(c) of the Act may designate one or more facilities as CAHs if each facility meets the CAH conditions of participation in this subpart F.

(2) The State must not deny any hospital that is otherwise eligible for designation as a CAH under this paragraph (a) solely because the hospital has entered into an agreement under which the hospital may provide posthospital SNF care as described in §482.58 of this chapter.

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

(b) Criteria for CMS certification. CMS certifies a facility as a CAH if-

(1) The facility is designated as a CAH by the State in which it is located and has been surveyed by the State survey agency or by CMS and found to meet all conditions of participation in this part and all other applicable requirements for participation in part 489 of this chapter.

(2) The facility is a medical assistance facility operating in Montana or a rural primary care hospital designated by CMS before August 5, 1997, and is otherwise eligible to be designated as a CAH by the State under the rules in this subpart.

FED - C0810 - COMPLIANCE WITH FED, ST, AND LOCAL LAWS

Title COMPLIANCE WITH FED, ST, AND LOCAL LAWS

Type Condition

CFR 485.608

Regulation Definition

The CAH and its staff are in compliance with applicable Federal, State and local laws and regulations.

Interpretive Guideline

Failure of the CAH to meet a Federal, State or local law may only be cited when the Federal, State or local authority having jurisdiction has made both a determination of noncompliance and has taken a final adverse action as a result.

Refer or report suspected violations to the appropriate Federal, State, or local agency.

FED - C0812 - COMPLIANCE FED, ST, AND LOCAL LAWS AND REGS

Title COMPLIANCE FED, ST, AND LOCAL LAWS AND REGS

Type Standard

CFR 485.608(a)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition

The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.

Interpretive Guideline

Interpretive Guidelines §485.608(a)

Each CAH must be in compliance with applicable Federal laws and regulations related to the health and safety of patients. This includes other Medicare regulations and Federal laws and regulations not specifically addressed in the CoPs. State Survey Agencies are expected to assess the CAH's compliance with the following Medicare provider agreement regulation provisions when surveying for compliance with §485.608(a):

Advance Directives

An advance directive is defined at 42 CFR 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." In accordance with the provisions of 42 CFR 489.102(a), the advance directives regulations apply to CAHs. The CAH patient (inpatient or outpatient) has the right to formulate advance directives, and to have CAH staff implement and comply with the individual's 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.

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 specified in §485.635(f), 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 CAH must, when presented with the document, provide the designated individual the information required to make informed decisions about the patient's care. The CAH 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 CAH 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 CAH may provide the advance directive information required under §489.100 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)) §489.102(b)(1) requires that notice of the CAH's advance directive policy be provided at the time an individual is admitted as an inpatient. However, the CAH should also consider providing the advance directive notice at the time of registration, 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 must include a clear and precise statement of limitation if the CAH 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 CAH 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 CAH'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;

- Assure 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;

- 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 CAH 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 CAH, 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. CAHs 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. 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 CAH's professional staff as they develop a plan of care and treatment for the patient.

Required CAH Disclosures to Patients:

Physician Ownership

- 42 CFR 489.3 defines a "physician-owned hospital" as any participating hospital, including a CAH, in which a physician or immediate family member of a physician (as defined in §411.351) has an ownership or investment interest in the CAH, 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 CAH meets the Medicare definition of "physician-owned," but they must ask whether the CAH is physician-owned.

- However, the notice requirement does not apply to any physician-owned CAH that does not have at least one

referring physician (as defined at §411.351 of this chapter) who has an ownership or investment interest in the CAH or who has an immediate family member who has an ownership or investment interest in the CAH. In such cases, the CAH 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 CAH. The CAH must maintain this attestation in its records.

- 42 CFR 489.20(u)(1) requires that all physician-owned CAHs provide written notice to their patients at the beginning of each patient's CAH inpatient stay or outpatient visit stating that the CAH is physician-owned, in order to assist the patient in making an informed decision about his or her care.

- 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 CAH 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 CAH.

- The notice must disclose, in a manner reasonably designed to be understood by all patients, that the CAH 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 CAH must provide it at the time of the request.

- 42 CFR 489.20(u)(2) provides that physician-owned CAHs must require each physician owner who is a member of the hospital's medical staff to agree, as a condition of obtaining/retaining CAH medical staff membership or admitting privileges, to disclose in writing to all patients they refer to the CAH their ownership or investment interest or that of any immediate family member in the CAH. The CAH 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 CAH may exempt from this disclosure requirement any physician owner who does not refer any patients to the CAH.

- 42 CFR 489.12 permits CMS to refuse to enter into a provider agreement with a physician-owned CAH applicant that does not have procedures in place to notify patients of physician ownership in the hospital, as required under §483.20(u).

- 42 CFR 489.53(c) permits CMS to terminate the provider agreement of a physician-owned CAH if the CAH 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 CAH 24 hours per day, seven days per week the CAH must provide written notice to all inpatients at the beginning of a planned or unplanned inpatient stay, and to outpatients for certain types of outpatient visits. The purpose of the requirement is to assist the patient in making an informed decision about his/her care. CAHs that have an MD/DO (including residents who are MDs or DOs) on-site 24/7 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 applicable outpatient visit.

- 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 CAH 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 CAH.

- Individual notices are not required in the CAH'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 dedicated emergency department. The posted notice must state that the CAH 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 CAH will meet the medical needs of any patient with an emergency medical condition, as defined in 42 CFR 489.24(b) [the EMTALA definition], at a time when there is no doctor of medicine or doctor of osteopathy present in the CAH. If an emergency department patient is determined to require admission, then the individual notice provisions of 42 CFR 489.20(w) would apply to that patient.

- Before admitting an inpatient or providing outpatient services requiring notice, the CAH 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 during all hours 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 CAH must provide notice and obtain acknowledgement as soon as possible after the patient's stay or visit begins.

- For a CAH that participates in Medicare with multiple campuses providing inpatient services (e.g., a main provider campus and a separate remote location for a psychiatric or rehabilitation distinct part unit (DPU)) under one CMS Certification Number) a separate determination is made for each campus/location with inpatient services as to whether the disclosure notice is required. For example, if a CAH has a main campus with 25 inpatient beds and a remote location with 10 psychiatric DPU beds and 10 rehabilitation DPU beds, and a physician is present 24/7 on the main campus, but not at the DPU remote location, the CAH is required to provide the disclosure notice at the DPU location. No notice is required for patients coming to the main provider campus. In this same example, if the CAH also has a provider-based, off-campus ambulatory surgery department, no notice is required at that off-campus surgery site, since the CAH'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 CAH if the CAH fails to comply with the requirements at §489.20(w) when it does not have an MD or DO on-site 24/ 7.

Other Federal Requirements

Other Federal requirements also apply to patient health and safety in the CAH. For example, Federal laws and regulations govern both the disposal of medical waste and occupational health. However, surveyors are not expected to be knowledgeable about the requirements of other Federal agencies and therefore do not assess compliance with non-CMS regulations. A surveyor who suspects a CAH may not be in compliance with other Federal requirements may refer the matter to the appropriate Federal agency. If CMS is notified or becomes aware of another Federal agency's final enforcement action, action will be taken only if the final enforcement action remains in effect.

Survey Procedures §485.608(a)

Assessing Compliance with Advance Directives Requirements

- Review the CAH'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 CAH staff comply with the advance directive (in accordance with State law)? Does it include a clear, precise, and valid statement of limitation if the CAH cannot implement an advance directive on the basis of conscience?

- Review the records of a sample of patients for evidence of CAH compliance with advance directive notice requirements. Does every inpatient or applicable outpatient record contain documentation that notice of the CAH'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 CAH have in place to allow patients to formulate an advance directive or to update their current advance directive? Is there evidence that the CAH is promoting and protecting each patient's right to formulate an advance directive?

- Determine to what extent the CAH 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 CAH 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 CAH provides education for the patient population regarding one's rights under State law to formulate advance directives.

Assessing Required Disclosures

Physician Ownership

- If the CAH 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 was has an ownership/investment interest in the CAH. (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 CAH would not be cited.)

- If the CAH is physician-owned but not exempt from the physician ownership disclosure requirements:

- Verify that appropriate policies and procedures are in place to assure that written notices are provided to all patients at the beginning of an inpatient or outpatient stay.

- Review the notice the CAH issues to each patient to verify that it discloses, in a manner reasonably designed to be understood by all patients, that the CAH 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 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 CAH 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 CAH'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 CAH agree to provide written disclosure of their own or any immediate family member's ownership or investment interest to all patients at time of the referral to the CAH.

MD/DO 24/7 On-site Presence

- Determine through interviews, observation, and medical record review whether an MD/DO is present in the CAH 24 hours per day, 7 days per week. For each required location where an MD/DO is not present:

- Verify that appropriate policies and procedures are in place to assure that written notices that a MD/DO is not present at all times are provided at the beginning of a planned or unplanned inpatient stay or outpatient visit to all inpatients and to all outpatients receiving observation services, surgery or another procedure requiring anesthesia.

- Verify that there is a signed acknowledgement by the patient of such disclosure, obtained by the CAH 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 CAH.

- Verify that the CAH's emergency department has signage with the appropriate disclosure information.

- Review the notice the CAH issues to verify that it indicates how the CAH will meet the medical needs of any patient who develops an emergency medical condition at a time when no physician is present at that CAH, including any remote location.

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Other Federal Requirements

Surveyors do not assess compliance with Medicare payment provisions or non-Medicare requirements. However, a surveyor may refer suspected noncompliance with Federal laws and regulations to the appropriate agency having jurisdiction (e.g., hazardous chemical and waste issues to EPA, blood-borne pathogens and TB control to OSHA, etc.).

FED - C0814 - COMPLIANCE STATE AND LOCAL LAWS AND REGS

Title COMPLIANCE STATE AND LOCAL LAWS AND REGS

Type Standard

CFR 485.608(b)

Regulation Definition

All patient care services are furnished in accordance with applicable State and local laws and regulations.

Interpretive Guideline

Interpretive Guidelines §485.608(b)

There are wide variations in the States' practice acts relative to the extent to which MD/DOs may delegate responsibilities to nurse practitioners, clinical nurse specialists, and physician assistants. Some states have updated their practice acts to include definitions and specific references to permitted/prohibited activities, supervision/guidance required by a MD/DO, and local situations in which nurse practitioners, clinical nurse specialists, and physician assistants may function.

Survey Procedures §485.608(b)

Prior to going on the survey, determine what professional specialists provide patient care services at the CAH and review State practice act requirements.

FED - C0816 - LICENSURE OF CAH

Title LICENSURE OF CAH

Type Standard

CFR 485.608(c)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
The CAH is licensed in accordance with applicable Federal, State and local laws and regulations.	Survey Procedures §485.608(c) Prior to the survey, determine whether the CAH is subject to licensure requirements and verify that the licensing agency has approved the CAH as meeting the standards for licensure as set forth by the agency of the State or locality responsible for licensing CAHs.

FED - C0818 - LICENSURE, CERT., OR REG OF PERSONNEL

Title LICENSURE, CERT., OR REG OF PERSONNEL

Type Standard

CFR 485.608(d)

Regulation Definition	Interpretive Guideline
Staff of the CAH are licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations.	Interpretive Guidelines §485.608(d) All staff required by the State to be licensed must possess a current license. The CAH must ensure that these personnel are in compliance with the State's licensure laws. The laws requiring licensure vary from state to state. Examples of healthcare professionals that a state may require to be licensed could include: nurses, MD/DOs, physician assistants, dieticians, x-ray technologists, dentists, physical therapists, occupational therapists, respiratory technicians and facility administrators. All CAH staff must meet all applicable standards required by State or local law for CAH personnel. This would include at a minimum: - Certification requirements; - Minimum qualifications; and - Training/education requirements. Survey Procedures §485.608(d) - Verify for those personnel required to be licensed by the State, that the CAH has established, and follows,

procedures for determining that personnel providing patient care services are properly licensed.

- Check a sample of personnel files to verify that licensure information is up to date. Verify that appropriate categories of staff and personnel are licensed in accordance with State requirements. Verify state licensure compliance of the direct care personnel, as well as administrators and supervisory personnel, and any contracted personnel.

- Verify that there are procedures in place to guarantee licensure of employees working at the CAH under contract or agreement.

- Review CAH policies regarding certification, licensure, and registration of personnel. Are the CAH policies compliant with State and local laws? Are the personnel in compliance with CAH policy?

FED - C0822 - STATUS AND LOCATION

Title STATUS AND LOCATION

Type Condition

CFR 485.610

Regulation Definition

Interpretive Guideline

Interpretive Guidelines §485.610

The CAH must meet the location requirements of §485.610(b) and §485.610(c) at the time of the initial survey. Compliance with these location requirements must be reconfirmed at the time of every subsequent recertification (including the recertification of a deemed status CAH whose accreditation has been renewed). If the CAH moves, its eligibility for continued CAH status must be reassessed in accordance with §485.610(b) and (c). If a CAH that has been certified on the basis of having been designated by the State as a necessary provider moves, its eligibility for continued CAH status must be reassessed in accordance with §485.610(b) and §485.610(d).

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FED - C0824 - STATUS

Title STATUS

Type Standard

CFR 485.610(a)

Regulation Definition

The facility is--

(1) A currently participating hospital that meets all conditions of participation set forth in this subpart;

(2) A recently closed facility, provided that the facility--

(i) Was a hospital that ceased operations on or after the date that is 10 years before November 29, 1999; and

(ii) Meets the criteria for designation under this subpart as of the effective date of its designation; or

(3) A health clinic or a health center (as defined by the State) that--

(i) Is licensed by the State as a health clinic or a health center;

(ii) Was a hospital that was downsized to a health clinic or a health center; and

(iii) As of the effective date of its designation, meets the criteria for designation set forth in this subpart.

Interpretive Guideline

Interpretive Guidelines §485.610(a)

Confirm that a CAH meets the basic status requirement prior to scheduling the survey. The appropriate RO will reverify the status requirement prior to approving a CAH for Medicare certification.

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FED - C0826 - LOCATION IN A RURAL AREA OR TREATMENT AS RURA

Title LOCATION IN A RURAL AREA OR TREATMENT AS RURA

Type Standard

CFR 485.610(b)

Regulation Definition

The CAH meets the requirements of either paragraph (b)(1) or (b)(2) of this section or the requirements of paragraph (b)(3), (b)(4), or (b)(5) of this section.

(1) The CAH meets the following requirements:

(i) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under §412.64(b), excluding paragraph (b)(3) of this chapter;

(ii) The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under §412.230(e) of this chapter and is not among a group of hospitals have been redesignated to an adjacent urban area under §412.232 of this chapter.

(2) The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with §412.103 of this chapter.

(3) Effective for October 1, 2004 through September 30, 2006, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2004, was not part of a Metropolitan

Interpretive Guideline

Interpretive Guidelines §485.610(b)

Among other requirements, pursuant to 42 CFR 485.610(b), all CAH applicants and existing CAHs, including necessary provider CAHs, must either be:

- located in a rural area; or
- treated as rural in accordance with 42 CFR 412.103

in order to be eligible for CAH designation and certification. (The temporary provisions at 42 CFR 485.610(b)(3) and (4) have expired and no longer apply.)

Only the CMS Regional Office makes the determination whether a CAH applicant or existing CAH meets the rural location requirement, following the instructions below. However, State Survey Agencies (SA) may wish to make informal assessments prior to conducting a survey, following the guidance provided in Section 2256 A of the SOM. If the SA's informal assessment suggests the CAH applicant or existing CAH is not rural, it should consult with the RO before conducting a survey.

Survey Procedures §485.610(b)

Conduct an informal assessment of the CAH's rural status, following the procedures in Section 2256 A of the SOM, and if it appears the CAH no longer has rural status, confer with the CMS RO prior to scheduling the initial or recertification survey.

Statistical Area as defined by the Office of Management and Budget, but as of FY 2005 was included as part of such Metropolitan Statistical Area as a result of the most recent census data and implementation of the new Metropolitan Statistical Area definitions announced by the Office of Management and Budget on June 3, 2003.

(4) Effective for October 1, 2009 through September 30, 2011, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2009, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2010, was included as part of such Metropolitan Statistical Area as a result of the most recent census data and implementation of the new Metropolitan Statistical Area definitions announced by the Office of Management and Budget on November 20, 2008.

(5) Effective on or after October 1, 2014, for a period of 2 years beginning with the effective date of the most recent Office of Management and Budget (OMB) standards for delineating statistical areas adopted by CMS, the CAH no longer meets the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, prior to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, was located in a rural area as defined by OMB, but under the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, is located in an urban area.

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FED - C0830 - LOCATION RELATIVE TO OTHER FACILITIES OF NEC

Title LOCATION RELATIVE TO OTHER FACILITIES OF NEC

Type Standard

CFR 485.610(c)

Regulation Definition

The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider on or before December 31, 2005, will maintain its necessary provider designation after January 1, 2006.

Interpretive Guideline

Interpretive Guidelines §485.610(c)

A CAH that has not been designated by a State as a necessary provider prior to December 31, 2005 must be located more than a 35-mile drive (or in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from any other CAH or hospital. An exception is made for Indian Health Service (IHS) or Tribal CAHs and hospitals that are located less than the 35 or 15 miles from another hospital or CAH. Given that IHS and Tribal CAHs and hospitals serve distinctly different populations, IHS CAHs and hospitals are excluded from consideration when determining the proximity of non-IHS hospitals seeking CAH certification to other CAHs or hospitals. For the same reason, when an IHS or Tribal hospital applies for certification to participate in Medicare as a CAH, CMS will consider only its proximity to other IHS and Tribal CAHs and hospitals in determining whether it meets the location requirement under section 485.610(c).

If a CAH is located on an island and the location meets the following characteristics, the CAH is considered to be in compliance with the distance requirements relative to other hospitals and CAHs under §485.610(c):

- The island is entirely surrounded by water;
- The CAH is the only hospital or CAH on the island; and
- The island is not accessible by any roads.

CAHs located on islands that meet the criteria above are still required to comply with the rural location requirement under §485.610(b).

A CAH that can document that it was designated by a State as a necessary provider CAH prior to January 1, 2006, does not have to meet the location relative to other facilities standard at §485.610(c). As of January 1, 2006, States do not have the authority to designate any new necessary provider CAHs. Necessary provider CAHs that were designated prior to that date are grandfathered by statute, subject to certain conditions if they relocate (see the discussion related to §485.610(d)). ROs and SAs should have the documentation related to a CAH's original

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designation as a necessary provider in the file on each CAH. If they do not, they should ask the CAH to supply copies of the original necessary provider designation documents.

For applicants seeking a new CAH provider agreement, or for CAHs that seek to relocate and do not have a grandfathered necessary provider designation, ROs will review the application and make the determination whether it satisfies the CAH location relative to other facilities standard at §485.610(c), using the guidance found in Chapter 2, §2256A of the State Operations Manual. At the conclusion of its review, the RO will notify the SA of its determination. Existing CAHs that are not grandfathered necessary provider CAHs must be periodically evaluated to determine whether there are any more recently certified Medicare-participating hospitals that are not more than a 35-mile drive, or 15-mile drive, as applicable, from the CAH. In the event that an existing CAH that is not a grandfathered necessary provider no longer meets the minimum distance requirement, it is provided the opportunity to avoid termination of its provider agreement by converting to a certified Medicare hospital after demonstrating compliance with the hospital CoPs.

FED - C0832 - RELOCATION OF CAH W/ NECESSARY PROVIDER DESIG

Title RELOCATION OF CAH W/ NECESSARY PROVIDER DESIG

Type Standard

CFR 485.610(d)

Regulation Definition

A CAH that has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocates its facility after January 1, 2006, can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the relocated facility meets the requirements as specified in paragraph (d)(1) of this section.

(1) If a necessary provider CAH relocates its facility and begins providing services in a new location, the CAH can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the CAH in its new location--

Interpretive Guideline

Interpretive Guidelines §485.610(d)

Renovation or expansion of a CAH's existing building or addition of building(s) on the existing main campus of the CAH is not considered a relocation. However, as discussed in the adoption of this regulation (70 FR 47472), all newly-constructed, necessary provider CAH facilities, including entirely new replacement facilities constructed on the same site as the existing CAH main campus, are considered relocated facilities. The determination of whether or not CAHs with a necessary provider designation have met the requirements at §485.610(d) will be made by the RO, generally prior to an SA or accreditation survey. The RO will utilize the evaluation criteria set forth in the SOM, Chapter 2, §2256F to make this determination. At the conclusion of its review, the RO will notify the SA of its results.

(i) Serves at least 75 percent of the same service area that it served prior to its relocation;

(ii) Provides at least 75 percent of the same services that it provided prior to the relocation; and

(iii) Is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees) that were on staff at the original location.

(2) If a CAH that has been designated as a necessary provider by the State begins providing services at another location after January 1, 2006, and does not meet the requirements in paragraph (d)(1) of this section, the action will be considered a cessation of business as described in §489.52(b)(3).

FED - C0834 - OFF-CAMPUS AND CO-LOCATION REQ FOR CAHS

Title OFF-CAMPUS AND CO-LOCATION REQ FOR CAHS

Type Standard

CFR 485.610(e)(1)
485.610(e)(3)

Regulation Definition

Standard: Off-campus and co-location requirements for CAHs. A CAH may continue to meet the location requirement of paragraph(c) of this section based only if the CAH meets the following:

(1) If a CAH with a necessary provider designation is co-located (that is, it shares a campus, as defined in §413.65(a)(2) of this chapter, with another hospital or CAH), the necessary provider CAH can continue to meet the location requirement of paragraph (c) of this section only if the co-location arrangement was in effect before January 1, 2008, and the type and scope of services offered by the facility

Interpretive Guideline

Interpretive Guidelines §485.610(e)(1) & (3)

A CAH may not be co-located with another hospital or CAH, because this would violate the minimum distance requirement found at §485.610(c). However, some CAHs that were designated as necessary providers prior to January 1, 2006, and therefore exempted from this distance requirement, also chose to co-locate with another hospital. Co-location occurs when a necessary provider CAH shares the same campus and/or building in which the CAH is currently located with another hospital or necessary provider CAH. For example, a necessary provider CAH shares the same campus with an unrelated psychiatric or rehabilitation hospital.

Effective January 1, 2008, grandfathered necessary provider CAHs may no longer enter into co-location arrangements with another CAH or hospital (72 FR 66878). However, necessary provider CAHs that had co-location arrangements in effect prior to January 1, 2008, are permitted to continue these arrangements as long as the type and scope of

co-located with the necessary provider CAH do not change. A change of ownership of any of the facilities with a co-location arrangement that was in effect before January 1, 2008, will not be considered to be a new co-location arrangement.

(3) If either a CAH or a CAH that has been designated as a necessary provider by the State does not meet the requirements in paragraph (e)(1) of this section, by co-locating with another hospital or CAH on or after January 1, 2008, [or creates or acquires an off-campus provider-based location or off-campus distinct part unit on or after January 1, 2008, that does not meet the requirements in paragraph (e)(2) of this section,] the CAH's provider agreement will be subject to termination in accordance with the provisions of §489.53(a)(3) of this subchapter, unless the CAH terminates the off-campus arrangement or the co-location arrangement, or both.

services offered by the facility co-located with the CAHs do not change. An example of a change in type of services would be when a hospital that provides only rehabilitation services chooses to provide general hospital acute care services. An example of a change in scope of services would be when a grandfathered necessary provider CAH is currently co-located with a 20 bed psychiatric hospital and the psychiatric hospital now decides to increase the number of beds to 30.

The determination of whether or not CAHs with a grandfathered necessary provider designation have met the requirements at §485.610(e)(1) is made by the RO. If the SA or accreditation organization (AO) becomes aware of a co-location arrangement, the SA or AO must notify the RO. The RO will utilize the co-location guidance in §2256G of the SOM to determine if such CAHs satisfy the co-location requirements at §485.610(e)(1). The RO will notify the CAH as well as the SA (and the AO, if applicable) of its determination.

A CAH found out of compliance with the requirements is subject to termination of its Medicare provider agreement under §489.53(a)(3). In such cases the CAH is placed on a 90-day termination track, as outlined in §3012 of the SOM. If the CAH corrects the situation, by terminating the co-location arrangement that led to the non-compliance during this 90 day period, then the provider agreement is not terminated.

A facility facing termination of its CAH designation as a result of non-compliance with §485.610(e)(1) could also continue to participate in Medicare by converting to a hospital, assuming that the facility satisfies all requirements for participation as a hospital in the Medicare program under the provisions at 42 CFR Part 482. Under this scenario, the CAH would apply to convert back to a hospital, with the effective date coinciding with the date of termination of CAH status. A new CMS Certification Number (CCN) would be assigned accordingly.

FED - C0836 - OFF-CAMPUS AND CO-LOCATION REQ FOR CAHS

Title OFF-CAMPUS AND CO-LOCATION REQ FOR CAHS

Type Standard

CFR 485.610(e)(2)
485.610(e)(3)

Regulation Definition

[§485.610(e) Standard: Off-campus and Co-Location Requirements for CAHs. A CAH may continue to meet the location requirement of paragraph(c) of this section based only if the CAH meets the following:]

Interpretive Guideline

Interpretive Guidelines §485.610(e)(2) & (3)

Section 42 CFR 485.610(e)(2) requires that if a CAH operates an off-campus provider-based facility as defined in §413.65(a)(2) (except for a rural health clinic (RHC)) or off-campus rehabilitation or psychiatric distinct part unit as defined at §485.647, that was created or acquired on or after January 1, 2008, then the off-campus facility must meet

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(2) If a CAH or a necessary provider CAH operates an off-campus provider-based location, excluding an RHC as defined in §405.2401(b) of this chapter, but including a department or remote location, as defined in §413.65(a)(2) of this chapter, or an off-campus distinct part psychiatric or rehabilitation unit, as defined in §485.647, that was created or acquired by the CAH on or after January 1, 2008, the CAH can continue to meet the location requirement of paragraph (c) of this section only if the off-campus provider-based location or off-campus distinct part unit is located more than a 35 mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15 mile drive) from a hospital or another CAH.

(3) If either a CAH or a CAH that has been designated as a necessary provider by the State [does not meet the requirements in paragraph (e)(1) of this section, by co-locating with another hospital or CAH on or after January 1, 2008, or] creates or acquires an off-campus provider-based location or off-campus distinct part unit on or after January 1, 2008, that does not meet the requirements in paragraph (e)(2) of this section, the CAH's provider agreement will be subject to termination in accordance with the provisions of §489.53(a)(3) of this subchapter, unless the CAH terminates the off-campus arrangement or the co-location arrangement, or both.

the requirement at 42 CFR 485.610(c) to be more than a 35 mile drive (or 15 miles in the case of mountainous terrain or an area with only secondary roads) from any other CAH or hospital. Off-campus CAH facilities that were in existence prior to January 1, 2008, are not subject to this requirement.

If a non-IHS or non-Tribal CAH operates an off-campus provider-based facility, its proximity to an IHS or Tribal CAH or hospital is not considered when assessing compliance with the requirements of this section. Similarly, if an IHS or Tribal CAH operates an off-campus provider-based facility, its proximity to a non-IHS or non-Tribal CAH or hospital is not considered when assessing compliance.

The drive to another hospital or CAH is to be calculated from the provider-based facility's location to the main campus of the other hospital or CAH.
The distance to another hospital or CAH requirement does not apply to the following types of facilities/services, because such facilities or services are not eligible for provider-based status in accordance with §413.65(a)(1)(ii):

- Ambulatory surgical centers (ASCs);

- Comprehensive outpatient rehabilitation facilities (CORFs);

- Home Health Agencies (HHAs);

- Skilled nursing facilities (SNFs);

- Hospices;

- Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services, facilities that furnish only clinical diagnostic laboratory tests, or facilities that furnish only some combination of these services;

- ESRD facilities;

- Departments of providers that perform functions necessary for the successful operation of the CAH, but for which separate CAH payment may not be claimed under Medicare or Medicaid, e.g., laundry, or medical records department; and

- Ambulances.

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In the case of Federally Qualified Health Centers (FQHCs), although CMS rules permit them to be provider-based departments of a hospital or CAH, it is unlikely that there are new FQHCs that meet the provider-based criteria, since the Health Resources and Services Administration (HRSA) requirements for separate FQHC governance make it unlikely an FQHC could meet provider-based governance requirements. However, there are grandfathered FQHCs that were in operation prior to April 7, 2000 which are permitted to retain their provider-based status.

Those CAHs seeking a provider-based determination for newly created or acquired provider-based departments, remote locations and/or psychiatric or rehabilitation units located off-campus must submit an attestation to the Regional Office (RO), as specified in §2254H of the SOM, who makes the determination of whether it satisfies the CAH provider-based criteria at §485.610(e)(2), and the provider-based rules at §413.65. At the conclusion of its review, the RO will notify the CAH and the SA (and accreditation organization (AO), if applicable) of its determination.

If the SA or AO becomes aware of a provider-based off-campus facility that appears not to comply with the provider-based location requirements, the SA or AO must notify the RO. The RO will utilize the guidance in §2254H of the SOM to determine if the CAH satisfies the provider-based location requirements at §485.610(e)(2). The RO will notify the CAH as well as the SA (and the AO, if applicable) of its determination.

A CAH found out of compliance with the off-campus location requirements at §485.610(e)(2) is subject to termination of its Medicare provider agreement. In such cases the CAH is placed on a 90-day termination track, as outlined in §3012 of the SOM. If the CAH corrects the situation, by terminating the off-campus provider-based arrangement that led to the non-compliance during this 90 day period, then the provider agreement is not terminated.

A facility facing termination of its CAH status as a result of non-compliance with §485.610(e)(2) could also continue to participate in Medicare by converting to a hospital, assuming that the facility satisfies all requirements for participation as a hospital in the Medicare program under the provisions at 42 CFR Part 482. Under this scenario, the CAH would apply to convert back to a hospital, with the effective date coinciding with the date of termination of CAH status. A new CCN number would be assigned accordingly.

FED - C0840 - COMPLIANCE WITH CAH REQ AT THE TIME OF APPLIC

Title COMPLIANCE WITH CAH REQ AT THE TIME OF APPLIC

Type Condition

CFR 485.612

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition

Except for recently closed facilities as described in §485.610(a)(2), or health clinics or health centers as described in §485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.

Interpretive Guideline

Interpretive Guidelines §485.612

This COP only applies to initial surveys. All facilities that apply to become a CAH are surveyed using the CAH CoP to determine compliance, whether they are:

- A currently operating CAH; or

- A re-opened CAH; or

- A CAH that down-sized to become a clinic.

If a facility has never been a Medicare participating hospital and wishes to be a CAH, the facility is a new provider to Medicare and must first meet the certification as a hospital and then put in a change of status request to be a CAH. In these cases, the facility must be surveyed twice. They must be initially surveyed using the hospital CoP and, when the change request is received, they must be surveyed again using the CAH CoP. In addition, these facilities are to be treated as new providers to Medicare necessitating completion of an application package as a new Medicare provider.

FED - C0860 - AGREEMENTS

Title AGREEMENTS

Type Condition

CFR 485.616

Regulation Definition

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0862 - AGREEMENT WITH NETWORK HOSPITAL

Title AGREEMENT WITH NETWORK HOSPITAL

Type Standard

CFR 485.616(a)

Regulation Definition

In the case of a CAH that is a member of a rural health network as defined in §485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for:

Interpretive Guideline

Interpretive Guidelines §485.616(a)

Section 485.603 defines a rural health network as an organization that includes at least one hospital that the State has designated or plans to designate as a CAH, and at least one hospital that furnishes acute care (hospital) services.

Survey Procedures §485.616(a)

" If the CAH is a member of a rural health network having a communications system, ask to see the agreement.

" How does the CAH participate with other hospitals and facilities in the network communications system?

o Is a communications log kept at the facility?

o Ask staff if there have been difficulties in contacting network members. If so, ask how the CAH deals with communication delays.

" How does the network's communications system compare with any available communications equipment in the CAH?

" When the network communications system is not in operation, how does the CAH communicate and share patient data with other network members?

" Review any policies and procedures related to the operation of any communications system.

" How is the CAH staff educated on the use of any communication system utilized in the facility?

" Review any written agreements with the local EMS service.

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FED - C0864 - PATIENT REFERRAL AND TRANSFER

Title PATIENT REFERRAL AND TRANSFER

Type Standard

CFR 485.616(a)(1)

Regulation Definition	Interpretive Guideline
§485.616(a)(1) Patient referral and transfer;	

FED - C0866 - DEVELOPMENT AND USE OF COMMUNICATION SYSTEM

Title DEVELOPMENT AND USE OF COMMUNICATION SYSTEM

Type Standard

CFR 485.616(a)(2)

Regulation Definition	Interpretive Guideline
§485.616(a)(2) The development and use of communications systems of the network, including the network's system for the electronic sharing of patient data, and telemetry and medical records, if the network has in operation such a system; and	

FED - C0868 - PROVISION OF EMERGENCY AND NON-EMERGENCY TRAN

Title PROVISION OF EMERGENCY AND NON-EMERGENCY TRAN

Type Standard

CFR 485.616(a)(3)

Regulation Definition	Interpretive Guideline
The provision of emergency and non-emergency transportation between the facility and the hospital.	

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FED - C0870 - AGREEMENTS FOR CREDENTIALING AND QLTY ASSURAN

Title AGREEMENTS FOR CREDENTIALING AND QLTY ASSURAN

Type Standard

CFR 485.616(b)

Regulation Definition	Interpretive Guideline
Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least-- (1) One hospital that is a member of the network; (2) One QIO or equivalent entity; or (3) One other appropriate and qualified entity identified in the State rural health care plan.	Interpretive Guidelines §485.616(b) Other qualified entities could include another CAH or any licensed firms, businesses, or agencies that provide credentialing and QA services. The location for these other qualified entities is not limited to local entities. Agreements for QA need to include medical record review as part of the determination of the quality and medical necessity of medical care at the CAH. Survey Procedures §485.616(b) - Review any agreements related to credentialing or quality assurance to determine the level of assistance to be provided and the responsibilities of the CAH. - Review policies and procedures to determine how information is to be obtained, utilized, and how confidentiality of information will be maintained.

FED - C0872 - AGREEMENT FOR CRED. AND PRIV FOR TELEMEDICINE

Title AGREEMENT FOR CRED. AND PRIV FOR TELEMEDICINE

Type Standard

CFR 485.616(c)(1)
485.616(c)(1)(2)

Regulation Definition	Interpretive Guideline
Agreements for credentialing and privileging of telemedicine physicians and practitioners.	Interpretive Guidelines §485.616(c) §485.616(c)(1)&(2)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

(1) The governing body of the CAH must ensure that, when telemedicine services are furnished to the CAH's patients through an agreement with a distant-site hospital, the agreement is written and specifies that it is the responsibility of the governing body of the distant-site hospital to meet the following requirements with regard to its physicians or practitioners providing telemedicine services:

(i) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.

(ii) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.

(iii) Assure that the medical staff has bylaws.

(iv) Approve medical staff bylaws and other medical staff rules and regulations.

(v) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.

(vi) Ensure the criteria for selection are individual character, competence, training, experience, and judgment.

(vii) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship or membership in a specialty body or society.

(2) When telemedicine services are furnished to the CAH's patients through an agreement with a distant site

"Telemedicine," as the term is used in this regulation, means the provision of clinical services to patients by physicians and practitioners from a distance via electronic communications. The distant-site telemedicine physician or practitioner provides clinical services to the CAH patient either simultaneously, as is often the case with teleICU services, for example, or non-simultaneously, as may be the case with many teleradiology services. "Simultaneously" means that the clinical services (for example, assessment of the patient with a clinical plan for treatment, including any medical orders needed) are provided to the patient in "real time" by the telemedicine physician or practitioner, similar to the actions of an on-site practitioner when called in by a patient's attending physician to see the patient. "Non-simultaneously" means that, while the telemedicine physician or practitioner still provides clinical services to the patient, such services may involve after-the-fact interpretation of diagnostic tests in order to provide an assessment of the patient's condition and do not necessarily require the telemedicine practitioner to directly assess the patient in "real time." This would be similar to the services provided by an on-site radiologist who interprets a patient's x-ray or CT scan and then communicates his or her assessment to the patient's attending physician who then bases his or her diagnosis and treatment plan on these findings. . (See 76 FR 25552, May 5, 2011)

A CAH may make arrangements with a distant-site Medicare-participating hospital for the provision of telemedicine services to the CAH's patients by physicians or practitioners granted privileges by the distant-site hospital.

If a CAH enters into an agreement for telemedicine services with a distant-site hospital, the agreement must be in writing. Furthermore, the written agreement must specify that it is the responsibility of the distant-site hospital to conduct its credentialing and privileging process for those of its physicians and practitioners providing telemedicine services such that the distant-site hospital:

" Determines, in accordance with State law, which categories of practitioners are eligible candidates for privileges or membership on the distant-site hospital's medical staff.

" Appoints members and grants medical staff privileges after considering the recommendations of the existing members of the distant-site hospital's medical staff.

" Assures that the distant-site hospital's medical staff has bylaws.

" Approves the distant-site hospital's medical staff bylaws and other medical staff rules and regulations.

" Ensures that the medical staff is accountable to the distant-site hospital's governing body for the quality of care provided to patients.

hospital, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions made by the governing body of the distant-site hospital regarding individual distant-site physicians or practitioners. The CAH's governing body or responsible individual must ensure, through its written agreement with the distant-site hospital, that the following provisions are met:

(i) The distant-site hospital providing telemedicine services is a Medicare-participating hospital.

(ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician's or practitioner's privileges;

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the CAH is located; and

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the CAH whose patients are receiving the telemedicine services, the CAH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital such information for use in the periodic appraisal of the individual distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the CAH's patients and all complaints the CAH has received about the distant-site physician or practitioner.

" Ensures the criteria for granting medical staff membership/privileges to an individual are the individual's character, competence, training, experience, and judgment.

" Ensures that under no circumstances is the accordance of distant-site hospital medical staff membership or privileges dependent solely upon certification, fellowship or membership in a specialty body or society.

Since the distant-site hospital must also participate in Medicare, it has an independent obligation to comply with these same requirements for all of its medical staff under §§482.12(a)(1) through (a) (7). Nevertheless, the written telemedicine services agreement between the CAH and the distant-site hospital must explicitly include a provision addressing the distant-site hospital's obligation to comply with these provisions.

The CAH's governing body (or the individual responsible for the CAH if it has no governing body) has the option, when considering granting privileges to telemedicine physicians and practitioners, to rely upon the credentialing and privileging decisions of the distant-site hospital for these physicians and practitioners. In order to exercise this alternative credentialing and privileging option, the CAH's governing body must ensure that its written agreement with the distant-site hospital addresses all of the following:

" That the distant-site hospital participates in the Medicare program. If the distant-site hospital's participation in Medicare is terminated, either voluntarily or involuntarily, at any time during the agreement, then as of the effective date of the termination, the CAH may no longer receive telemedicine services under the agreement;

" That the distant-site hospital provides a list to the CAH of all its physicians and practitioners covered by the agreement, including their privileges at the distant-site hospital. The list may not include any physician or practitioner who does not hold privileges at the distant-site hospital. The list must be current, so the agreement must address how the distant-site hospital will keep the list current;

" That each physician or practitioner who provides telemedicine services to the CAH's patients under the agreement holds a license issued or recognized by the State where the CAH is located. States may have varying requirements as to whether they will recognize an out-of-state license for purposes of practicing within their State, and they may also vary as to whether they establish different standards for telemedicine services. The licensure requirements governing in the State where the CAH whose patients are receiving the telemedicine services is located must be satisfied, whatever they may be; and

" That the CAH has evidence that it reviews the telemedicine services provided to its patients and provides feedback based on this review to the distant-site hospital for the latter's use in its periodic appraisal of each physician

and practitioner providing telemedicine services under the agreement. At a minimum, the CAH must review and send information to the distant-site hospital on all adverse events that result from a physician or practitioner's provision of telemedicine services and on all complaints the CAH has received about a telemedicine physician or practitioner.

If the CAH's governing body or responsible individual does not rely on the privileging decisions of the distant-site hospital, then it must for each physician or practitioner providing telemedicine services under an agreement follow the CAH's standard process for review of credentials and granting of privileges to physicians and practitioners.

Survey Procedures §485.616(c)(1)&(2)

" Ask the CAH's leadership whether it uses telemedicine services. If yes,

" Ask to see a copy of the written agreement(s) with the distant-site hospital(s). Does each agreement include the required elements concerning credentialing and privileging of the telemedicine physicians and practitioners by the distant-site hospital?

" Does the CAH have documentation indicating that it granted privileges to each telemedicine physician and practitioner?

" Does the documentation indicate that the CAH's governing body or responsible individual made the privileging decision based on the privileging decisions of the distant-site hospital? If yes:

" Does the agreement address the required elements concerning the distant-site hospital's Medicare participation, appropriate licensure of telemedicine physicians and practitioners, current list of telemedicine physicians and practitioners with privileges, and review by the CAH of the telemedicine physicians' and practitioners' services?

" Ask to see the list provided by the distant-site hospital of the telemedicine physicians and practitioners, including their privileges and pertinent licensure information.

" Ask for evidence that the CAH conducts the required review of the telemedicine services provided by the telemedicine physicians and practitioners, including any associated adverse events and complaints, and that it provides the required feedback to the distant-site hospital.

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FED - C0874 - GOVERNING BODY AND TELEMEDICINE SERVICES

Title GOVERNING BODY AND TELEMEDICINE SERVICES

Type Standard

CFR 485.616(c)(3)
485.616(c)(4)

Regulation Definition

§485.616(c)(3) The governing body of the CAH must ensure that when telemedicine services are furnished to the CAH's patients through an agreement with a distant-site telemedicine entity, the agreement is written and specifies that the distant-site telemedicine entity is a contractor of services to the CAH and as such, in accordance with §485.635(c)(4)(ii), furnishes the contracted services in a manner that enables the CAH to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in this section with regard to its physicians and practitioners providing telemedicine services.

§485.616(c)(4) When telemedicine services are furnished to the CAH's patients through an agreement with a distant-site telemedicine entity, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions made by the governing body of the distant-site telemedicine entity regarding individual distant-site physicians or practitioners. The CAH's governing body or responsible individual must ensure, through its written agreement with the distant-site telemedicine entity, that the following provisions are met:

(i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at (c)(1)(i) through (c)(1)(vii).

Interpretive Guideline

Interpretive Guidelines §485.616(c)(3)&(4)

For the purposes of this rule, a distant-site telemedicine entity is defined as an entity that -- (1) provides telemedicine services; (2) is not a Medicare-participating hospital; and (3) provides contracted services in a manner that enables a CAH using its services to meet all applicable CoPs, particularly those requirements related to the credentialing and privileging of physicians and practitioners providing telemedicine services to the patients of a CAH. A distant-site telemedicine entity would include a distant-site hospital that does not participate in the Medicare program that is providing telemedicine services to a Medicare-participating CAH. (See 76 FR 25553, May 5, 2011)

A CAH may have an agreement with a distant-site telemedicine entity for the provision of telemedicine services to the CAH's patients by physicians or practitioners granted privileges by the distant-site telemedicine entity.

If a CAH enters into an agreement for telemedicine services with a distant-site telemedicine entity, the agreement must be in writing. Furthermore, the written agreement must specify that under the agreement the distant-site telemedicine entity is a contractor providing services to the CAH, and that, in accordance with the requirements of §485.635(c)(4)(ii), the distant-site telemedicine entity furnishes its telemedicine services in a manner that enables the CAH to comply with all applicable CAH Conditions of Participation (CoPs), including, but not limited to, the specific requirements governing telemedicine services. Under §485.635(c)(4)(ii,) the CAH's governing body or responsible individual is obligated to ensure that all contractors of services furnish those services in a manner that enables the CAH to comply with all applicable CoPs.

The CAH's governing body (or the individual responsible for the CAH if it has no governing body) has the option, when considering granting privileges to telemedicine physicians and practitioners, to rely upon the credentialing and privileging decisions of the distant-site telemedicine entity for these physicians and practitioners. In order to exercise this alternative credentialing and privileging option, the CAH's governing body must ensure through its written agreement with the distant-site telemedicine entity that all of the following requirements are included in the agreement and that the contractor fulfills these requirements:

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(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides a current list to the CAH of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the CAH whose patients are receiving the telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the CAH whose patients are receiving the telemedicine services, the CAH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site telemedicine entity such information for use in periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the CAH's patients and all complaints the CAH has received about the distant-site physician or practitioner.

- The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meets the standards at §485.616(c)(1)(i) through (c)(1)(vii). In other words, the distant-site telemedicine entity must at a minimum:

- Determine, in accordance with State law, which categories of practitioners are eligible candidates for medical staff privileges or membership at the telemedicine entity;

- Appoint members and grant medical staff privileges after considering the recommendations of the existing members of its medical staff;

- Assure that its medical staff has bylaws;

- pprove its medical staff's bylaws and other medical staff rules and regulations;

- Ensure that the medical staff is accountable to the distant-site telemedicine entity's governing body for the quality of care provided to patients;

- Ensure the criteria for granting distant-site telemedicine medical staff membership/privileges to an individual are the individual's character, competence, training, experience, and judgment; and

- Ensure that under no circumstances is the accordance of medical staff membership or privileges dependent solely upon certification, fellowship or membership in a specialty body or society.

- The distant-site telemedicine entity provides to the CAH a list of all its physicians and practitioners covered by the agreement, including their privileges at the distant-site telemedicine entity. The list may not include any physician or practitioner who does not hold privileges at the distant-site telemedicine entity. The list must be current, so the agreement must address how the distant-site telemedicine entity will keep the list current;

- Each physician or practitioner who provides telemedicine services to the CAH's patients under the agreement holds a license issued or recognized by the State where the CAH is located. States may have varying requirements as to whether they will recognize an out-of-state license for purposes of practicing within their State, and they may also vary as to whether they establish different standards for telemedicine services. The licensure requirements governing in the State where the hospital whose patients are receiving the telemedicine services is located must be satisfied, whatever they may be; and

- The CAH reviews the performance of the physicians and practitioners providing telemedicine services to its patients and provides a written review to the distant-site telemedicine entity for the latter's use in its periodic appraisal of each physician and practitioner providing telemedicine services under the agreement. At a minimum, the CAH must review and send information to the distant-site telemedicine entity on all adverse events that result from a physician's or practitioner's provision of telemedicine services and on all complaints the CAH has received about a telemedicine physician or practitioner.

If the CAH's governing body or responsible individual does not rely on the privileging decisions of the distant-site telemedicine entity, then it must for each practitioner providing telemedicine services under an agreement follow the CAH's standard process for review of credentials and granting of privileges to physicians and practitioners.

Survey Procedures §485.616(c)(3)&(4)

- Ask the CAH's leadership whether it uses telemedicine services. If yes,

- Ask to see a copy of the written agreement(s) with the distant-site telemedicine entity(ies). Does each agreement explicitly state that the distant-site telemedicine entity will provide telemedicine services in a manner that enables the CAH to comply with all applicable CoPs?

- Does the CAH have documentation indicating that it granted privileges to each telemedicine physician and practitioner?

- Does the documentation indicate that the CAH's governing body or responsible individual made the privileging decision based on the privileging decisions of the distant-site telemedicine entity? If yes:

- Does the written agreement with the distant-site telemedicine entity address the required elements concerning the distant-site telemedicine entity's utilization of a medical staff credentialing and privileging process that meets the requirements of the hospital CoPs, licensure of telemedicine physicians and practitioners, current list of telemedicine physicians and practitioners with privileges at the distant-site telemedicine entity, and written review by the CAH of the telemedicine physicians' and practitioners' services?

- Is there a list provided by the distant-site telemedicine entity of the telemedicine physicians and practitioners covered by the agreement, including their privileges and pertinent licensure information?

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- Is there evidence that the CAH reviews the services provided by the telemedicine physicians and practitioners, including any adverse events and complaints, and provides written feedback to the distant-site telemedicine entity?

- Ask the CAH how it verifies that the telemedicine entity fulfills the terms of the agreement with respect to its credentialing and privileging process and otherwise assures that services are provided in a manner that enables the CAH to meet all applicable CAH requirements? (Surveyors do not attempt to independently verify whether or not the distant-site telemedicine entity's credentialing and privileging process fulfills the regulatory requirements. Surveyors focus only on what actions the CAH takes to ensure that the distant-site telemedicine entity complies with the terms of the agreement.)

FED - C0880 - EMERGENCY SERVICES

Title EMERGENCY SERVICES

Type Standard

CFR 485.618

Regulation Definition

The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.

Interpretive Guideline

Interpretive Guidelines §485.618

All emergency services must be provided as a direct service in the CAH. The ED cannot be a provider-based off-site location. Emergency needs of patients must be met in accordance with acceptable standards of practice.

Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations, and guidelines governing all services provided in the CAH'S emergency department, as well as any standards and recommendations promoted by or established by nationally recognized professional organizations such as the American Medical Association, American Association for Respiratory Care, American Society of Emergency Medicine, American College of Surgeons, American Nursing Association, etc.

The CAH'S emergency services must be under the direction of a qualified member of the CAH'S medical staff. The CAH'S medical staff establishes criteria for the qualifications for the director of the CAH'S emergency services in accordance with State law and acceptable standards of practice.

The CAH'S medical staff must establish policies and procedures governing the medical care provided in the emergency services or emergency department. Emergency services or emergency department policies must be current and revised as necessary based on the ongoing monitoring conducted by the medical staff and the emergency service

or department QA activities. The CAH'S emergency services must be integrated into the CAH-wide QA program.

The medical staff must establish criteria, in accordance with State law, regulations, and guidelines, delineating the qualifications a medical staff member must possess in order to be granted privileges for the provision of emergency care services. Qualifications include necessary education, experience and specialized training, consistent with State law and acceptable standards of practice.

The CAH must staff the emergency department with the appropriate numbers and types of professionals and other staff who possess the skills, education, certifications, specialized training and experience in emergency care to meet the written emergency procedures and needs anticipated by the facility. There must be sufficient medical and nursing personnel to respond to the emergency medical needs and care of the patient population being served.

The CAH must determine the categories and numbers of MD/DOs, specialists, RNs, EMTs, and emergency department support staff the CAH needed to meet its anticipated emergency needs. The medical staff must establish criteria, in accordance with State law and regulations and acceptable standards of practice delineating the qualifications required for each category of emergency services staff (e.g., emergency physicians, specialist MD/DO, RNs, EMTs, mid-level practitioners, etc.).

The CAH must conduct ongoing assessments of its emergency needs in order to anticipate the policies, procedures, staffing, training, and other resources that may be needed to address likely demands.

Emergency care necessary to meet the needs of its inpatients and outpatients would include the provision of respiratory services as needed by the CAH'S emergency patients. When respiratory services are provided those services must be provided in accordance with acceptable standards of practice. The scope of diagnostic and/or therapeutic respiratory services offered by the CAH should be defined in writing, and approved by the medical staff.

The CAH must provide the appropriate equipment and qualified personnel necessary to furnish all services offered in a safe manner in accordance with acceptable standards of practice.

There should be written policies for the delivery of any services provided. The policies and procedures must be developed and approved by the medical staff and include the participation of any mid-level practitioners working in the ED. The written policies should address the following services, as appropriate:

- Each type of service provided by the CAH;

- The qualifications, including job title, licensure requirements, education, training and experience of personnel authorized to perform each type of respiratory care service and whether they may perform it without supervision;

- Equipment assembly and operation;

- Safety practices, including infection control measures;

- Handling, storage, and dispensing of therapeutic gases;

- Cardiopulmonary resuscitation;

- Procedures to follow in the advent of adverse reactions to treatments or interventions;

- Pulmonary function testing;

- Therapeutic percussion and vibration;

- Bronchopulmonary drainage;

- Mechanical ventilatory and oxygenation support;

- Aerosol, humidification, and therapeutic gas administration;

- Administration of medications; and

- Procedures for obtaining and analyzing blood samples (arterial blood gases).

Survey Procedures §485.618

- Verify that emergency services are organized under the direction of a qualified member of the medical staff.

- Verify that procedures and policies for emergency medical services (including triage of patients and any respiratory services provided) are established, evaluated, and updated on an ongoing basis.

- Verify that there are sufficient medical and nursing personnel qualified in the needs anticipated by the facility and

that there are specific assigned duties for emergency care

- Review any policies and procedures for emergency services in the CAH. What evidence indicates that the CAH is capable of providing necessary emergency care for its inpatients and outpatients?

- Review a sample of patient records for patients treated in the emergency services department to see if the CAH followed its own policies and procedures.

- Verify that emergency services are provided in accordance with acceptable standards of practice.

- Interview staff to determine that they are knowledgeable, within their own level of participation in emergency care including:

o Parenteral administration of electrolytes, fluids, blood and blood components;

o Care and management of injuries to extremities and central nervous system;

o Prevention of contamination and cross infection; and

o Provision of emergency respiratory services.

- Determine if the CAH provides any degree of respiratory care services and that the type and amount of respiratory care provided meets the needs of the patients and is delivered in accordance with acceptable standards of practice.

- Review the CAH policies and procedures to verify that the scope of the diagnostic and/or therapeutic respiratory care services provided is defined in writing and approved by the medical staff.

- Review staffing schedules to determine that the number and type of staff available is appropriate to the volume and types of treatments furnished.

- If blood gases or other laboratory tests are performed as part of the delivery of respiratory services, verify that there is a current CLIA certificate.

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FED - C0882 - AVAILABILITY

Title AVAILABILITY

Type Standard

CFR 485.618(a)

Regulation Definition	Interpretive Guideline
Emergency services are available on a 24-hours a day basis.	Interpretive Guidelines §485.618(a) The CAH "makes available 24-hour emergency services." This does not mean that the CAH must remain open 24 hours a day when it does not have inpatients (including swing-bed patients). A CAH that does not have inpatients may close with no staff present, provided that it has an effective system in place to meet the requirement. The system must ensure that a practitioner with training and experience in emergency care is on call and immediately available by telephone or radio, and available on site within 30 minutes, (or 1 hour in certain frontier areas), 24 hours a day. In addition to these items, the CAH must maintain the types, quality and numbers of supplies, drugs and biologicals, blood and blood products, and equipment required by state and local law and in accordance with accepted standards of practice. Survey Procedures §485.618(a) Ascertain by record review of patients admitted through the emergency department, interviews with staff, patients, and families, and/or observations that ED services were made available to patients presenting on a 24-hour a day basis. How does the CAH ensure that emergency services are made available on a 24-hour a day basis?

FED - C0884 - EQUIPMENT, SUPPLIES, AND MEDICATION

Title EQUIPMENT, SUPPLIES, AND MEDICATION

Type Standard

CFR 485.618(b)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition

Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following:

Interpretive Guideline

Interpretive Guidance §485.618(b)

In addition to these items, the CAH must maintain the types, quality and numbers of supplies, drugs and biologicals, blood and blood products, and equipment required by State and local law and in accordance with accepted standards of practice.

Survey Procedures §485.618(b)

- How does the CAH ensure that the required equipment, supplies and medications are always readily available in the CAH?

- Interview staff and tour the ER to ascertain compliance and ability to provide emergency services.

FED - C0886 - DRUG AND BIOLOGICALS

Title DRUG AND BIOLOGICALS

Type Standard

CFR 485.618(b)(1)

Regulation Definition

Drugs and biologicals commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.

Interpretive Guideline

Survey Procedures §485.618(b)(1)

- How does the CAH ensure that staff knows where drugs and biologicals are kept?

- How is the inventory maintained?

- Who is responsible for monitoring drugs and biologicals?

- How are drugs and biologicals replaced?

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0888 - EMERGENCY AND SUPPLIES

Title EMERGENCY AND SUPPLIES

Type Standard

CFR 485.618(b)(2)

Regulation Definition

Equipment and supplies commonly used in life-saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.

Interpretive Guideline

Survey Procedures §485.618(b)(2)

- How does the CAH ensure that required equipment and supplies are readily available to staff?
- How does the CAH ensure that staff knows where emergency equipment and supplies are kept?
- How is the supply inventory maintained?
- Who is responsible for monitoring supplies?
- How are supplies replaced?
- When was the last time emergency supplies were used?
- Is there an equipment maintenance schedule (e.g., for the defibrillator)?
- Ask staff if equipment has ever failed to work when needed.
- Examine sterilized equipment (e.g., tracheostomy sets) for expiration dates when applicable.
- Examine the oxygen supply system to determine functional capabilities.
- Check the force of the vacuum (suction) equipment to see that it is in operating condition.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0890 - BLOOD AND BLOOD PRODUCTS

Title BLOOD AND BLOOD PRODUCTS

Type Standard

CFR 485.618(c)(1)

Regulation Definition

The facility provides, either directly or under arrangements, the following--

(1) Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis.

Interpretive Guideline

Interpretive Guidelines §485.618(c)(1)

This requirement can be met at a CAH by providing blood or blood products on an emergency basis at the CAH, either directly or through arrangement, if that is what the patient's condition requires. There is no requirement in the regulation for a CAH to store blood on site, although it may choose to do so. In some cases, it may be more practical to transport a patient to the source of the blood supply than to bring blood to the patient at the CAH. A facility that has the capability of providing blood services on site would be in compliance even if, in virtually all cases, the patients were actually taken to the blood rather than vice versa.

A CAH that performs CLIA tests on blood on-site must have a CLIA certificate and is subject to survey under CLIA. A CAH that is only storing blood for transfusion and refers all related testing out to another laboratory, is not performing testing as defined by CLIA. However, under this regulation, the CAH must ensure that blood is appropriately stored to prevent deterioration, including documenting refrigerator temperatures. The provision of blood services between the CAH and the testing laboratory should be reflected in the written agreement or arrangement between the two. Also, if the CAH is collecting blood, it must register with the Food and Drug Administration.

"Availability" in this context, means that the blood and blood products must be accessible to CAH staff in time to effectively treat emergency patients at the CAH. In order to comply with this requirement, a CAH must demonstrate that it has the capability (i.e., an effective system is in place regardless of whether, in actual practice, it has been utilized) of making blood products available to its emergency patients 24 hours a day.

If a CAH performs type and compatibility testing it must have the necessary equipment, (i.e., serofuge and heat block), as well as typing and cross matching reagents, some of which have a 30-day expiration date. Another way for a CAH to meet this requirement would be to properly store 4 units of O negative packed red blood cells (the universal donor type) for availability at all times for emergencies only. CAHs that choose to store O negative packed red blood cells for emergency release of uncross matched blood will require a release form to be signed by a doctor, prior to

transfusion, acknowledging that the blood has not been cross matched for the patient. Facilities that elect to store units of O negative packed red blood cells should be able to demonstrate that they have an arrangement (e.g., with the Red Cross or other similar product provider) for the provision of fresh units of O negative packed red blood cells.

FED - C0892 - BLOOD STORAGE

Title BLOOD STORAGE

Type Standard

CFR 485.618(c)(2)

Regulation Definition

Blood storage facilities that meet the requirements of 42 CFR part 493, subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.

Interpretive Guideline

Survey Procedures §485.618(c)(2)

- If blood banking services are provided on site, what evidence shows that the blood facility is under the control and supervision of a pathologist or other qualified MD/DO?

- For blood banking services provided under arrangement, what evidence shows that the CAH medical staff and the person responsible for CAH operations have approved the arrangement?

FED - C0894 - PERSONNEL

Title PERSONNEL

Type Standard

CFR 485.618(d)(1)
485.618(d)(2)
485.618(d)(3)
485.618(d)(4)

Regulation Definition

(1) Except as specified in paragraph (d)(3) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner or a clinical nurse specialist with training or experience in emergency care on call and immediately available by telephone or radio contact, and available on site within the following timeframes:

Interpretive Guideline

Interpretive Guidance § 485.618(d)

When State laws are more stringent and require more stringent staffing or expanded operational hours, the CAH must staff its emergency department in accordance with state laws. For example, if State law requires the CAH emergency department be open and be staffed with a MD/DO 24/7 then the CAH must comply.

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(i) Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described in paragraph (d)(1)(ii) of this section; or

(ii) Within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:

(A) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act.

(B) The State has determined under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH.

(C) The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.

(2) A registered nurse with training and experience in emergency care can be utilized to conduct specific medical screening examinations only if-

(i) The registered nurse is on site and immediately available at the CAH when a patient requests medical care; and

(ii) The nature of the patient's request for medical care is within the scope of practice of a registered nurse and

Survey Procedures §485.618(d)

- Review on-call schedules to determine how the CAH ensures that a qualified staff member is on call 24 hours a day and available on site at the CAH within 30 minutes, or 60 minutes in certain frontier areas.

- Interview staff to determine how the CAH staff knows who is on call.

- What documentation demonstrates that a MD/DO, nurse practitioner, physician assistant, clinical nurse specialist or registered nurse (as allowed under (d)(3)) with emergency training or experience has been on call and available on site at the CAH within 30 or 60 minutes, as appropriate?

consistent with applicable State laws and the CAH's bylaws or rules and regulations.

(3) A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if--

(i) The CAH has no greater than 10 beds;

(ii) The CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(1)(ii)(A) of this section;

(iii) The State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation on the issue of using RNs on a temporary basis as part of their State rural health care plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified in paragraph (d)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(1) of this section;

(iv) Once a Governor submits a letter, as specified in paragraph (d)(3)(iii) of this section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in this paragraph (d).

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(4) The request, as specified in paragraph (d)(3)(iii) of this section, and the withdrawal of the request, may be submitted to us at any time, and are effective upon submission.

FED - C0898 - COORDINATION WITH EMERGENCY RESPONSE SYSTEMS

Title COORDINATION WITH EMERGENCY RESPONSE SYSTEMS

Type Standard

CFR 485.618(e)

Regulation Definition

The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.

Interpretive Guideline

Interpretive Guidelines §485.618(e)

The CAH, not the local ambulance service, is responsible for ensuring that an effective procedure is in place to meet this requirement.

Survey Procedures §485.618(e)

- Verify that the CAH has policies and procedures in place to ensure an MD/DO is available by telephone or radio, on a 24-hour a day basis to receive emergency calls and provide medical direction in emergency situations?

- What evidence demonstrates that the procedures are followed and evaluated for effectiveness?

- Interview staff to see how an MD/DO is contacted when emergency instructions are needed.

FED - C0900 - NUMBER OF BEDS AND LENGTH OF STAY

Title NUMBER OF BEDS AND LENGTH OF STAY

Type Condition

CFR 485.620

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition

§485.620 Condition of Participation: Number of Beds and Length of Stay

Interpretive Guideline

FED - C0902 - NUMBER OF BEDS

Title NUMBER OF BEDS

Type Standard

CFR 485.620(a)

Regulation Definition

Except as permitted for CAHs having distinct part units under §485.647, the CAH maintains no more than 25 inpatient beds. Inpatient beds may be used for either inpatient or swing-bed services.

Interpretive Guideline

Interpretive Guidelines §485.620(a)

Section 1820(c)(2)(B)(iii) of the Social Security Act limits a CAH to a maximum of 25 inpatient beds that can be used for inpatient acute care or swing bed services. The statute also requires CAHs to provide inpatient acute care limited, on an annual average basis, to 96 hours per patient (see interpretive guidelines for §485.620(b)).

Section 1820(c)(2)(E) of the Act also permits a CAH to operate a 10-bed psychiatric distinct part unit (DPU) and a 10-bed rehabilitation DPU, without counting these beds toward the 25-bed inpatient limit.

The limit applies to the number of inpatient beds; not to the number of inpatients on any given day. CAHs that were larger hospitals prior to converting to CAH status may not maintain more than 25 inpatient beds, plus a maximum of 10 psychiatric DPU inpatient beds, and 10 rehabilitation DPU inpatient beds. Any bed used for inpatient services at any time must be counted when assessing compliance with the 25 inpatient bed limit. Beds used for outpatient services, such as observation services, sleep studies, emergency services, etc. do not count towards the CAH's 25-bed limit only if they are never used for inpatient services.

Beds Used for Observation Services

Beds used solely for patients receiving observation services are not included in the 25-bed maximum, nor in the calculation of the average annual acute care patient length of stay. This makes it essential for surveyors to determine that CAHs with observation beds are using them appropriately, and not as a means to circumvent the CAH size and length-of-stay limits.

Inappropriate use of observation services also subjects Medicare beneficiaries to an increased beneficiary coinsurance liability that could have been avoided, had the beneficiary been properly admitted as an inpatient. This is the case because, as CAHs are not paid under the hospital Outpatient Prospective Payment System (OPPS), the beneficiary in an observation status will be liable for a coinsurance charge equal to 20 percent of the CAH's customary charges for the services. Further, as CAHs are also not subject to the preadmission payment window, a Medicare beneficiary would be liable for the coinsurance charges for the observation status services even when subsequently admitted. Depending on the terms of their health insurance coverage, other CAH patients may also face similar increased and avoidable costs when inappropriately placed in an observation status.

Observation care is a well-defined set of specific, clinically appropriate services that include ongoing short-term treatment, assessment, and reassessment, that are provided before a decision can be made regarding whether a patient will require further treatment as an inpatient, or may be safely discharged. Observation status is commonly assigned to patients with unexpectedly prolonged recovery after outpatient surgery, and to patients who present to the emergency department and who then require a significant period of treatment or monitoring before a clinical decision is made concerning their next placement. The CAH should ensure that once there is sufficient information to render this clinical decision, the patient should be expeditiously admitted, appropriately transferred, or discharged.

A patient may be in an observation status even though the CAH furnishes the patient overnight accommodation, food, and nursing care.

Observation services are NOT appropriate:

As a substitute for an inpatient admission;

For continuous monitoring;

- For medically stable patients who need diagnostic testing or outpatient procedures (e.g., blood transfusion, chemotherapy, dialysis) that are routinely provided in an outpatient setting;

- For patients awaiting nursing home placement;

- To be used as a convenience to the patient, his or her family, the CAH, or the CAH's staff;

- For routine prep or recovery prior to or following diagnostic or surgical services; or

- As a routine "stop" between the emergency department and an inpatient admission.

Observation services BEGIN and END with an order by a physician or other qualified licensed practitioner of the CAH.

- The order for observation services must be written prior to initiation of the service, as documented by a dated and timed order in the patient's medical record. The order may not be backdated. Orders should be clear for the level of care intended, such as "admit to inpatient" or "place in observation." (NOTE: It is not uncommon for hospitals and practitioners to refer to "admitting" a patient for observation. Technically, only inpatients are "admitted," while patients receiving observation services are in an outpatient status. However, usage of the term "admit" in an order placing a patient in observation status does not violate any CAH CoP and is not cited.)

- Observation services end when the physician or other qualified licensed practitioner orders an inpatient admission, a transfer to another health care facility, or discharge. The inpatient stay begins on the date and time of the new order.
- Standing orders for observation services are not acceptable, since it is not necessary to employ observation services for every patient in a given category, e.g., every emergency department patient, in order to reach a clinical decision about the appropriate next step in the patient's care.

Medicare generally will not pay for observation services lasting more than 48 hours. However, some States may have more stringent limits in their licensure or other regulatory requirements on the length of observation services, e.g., 24 hours. In such cases the State's more stringent limit on the length of an observation stay applies to Medicare beneficiaries as well, but is not enforced through the Federal survey process, unless the State has taken a final enforcement action.

The CAHs must provide appropriate documentation upon surveyor request to show that an observation bed is not an inpatient bed. The CAH must be able to document that it has specific clinical criteria for placing a patient in and discharging from, the observation service, and that these criteria are clearly distinguishable from those used for inpatient admission and discharge. CMS expects a CAH to employ the same type of clinical criteria for observation versus inpatient status for all patients, regardless of their payer status. For example, if a CAH were routinely placing only Medicare beneficiaries in its dedicated observation unit, then this could suggest that non-clinical criteria were being used in the decision to admit versus place in observation status. This would not only call the observation bed status into question, but could also violate the CAH's provider agreement requirement that prohibits differential treatment of Medicare beneficiaries. (See 42 CFR 489.53(a)(2)).

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If a CAH maintains beds that are dedicated to observation services, the CAH must be able to provide evidence, such as the clinical criteria for admission to that unit and how patients in the unit meet those criteria, to demonstrate that its observation beds are not being used for inpatient services. CMS expects there to be a reasonable relationship between the size of the CAH's inpatient and observation operations. For example, a 10-bed observation unit in a 25-bed CAH might be disproportionately large, and the surveyor must determine whether the observation unit is actually functioning as an inpatient overflow unit. A CAH observation unit that routinely operates at a high occupancy rate could also be an indicator of the need to probe further.

Other Types of Beds

Other bed types that do not count toward the 25 inpatient bed limit include, but are not limited to:
Examination or procedure tables;

- Stretchers;

- Operating room tables;
-
Beds in a surgical recovery room used exclusively for surgical patients during recovery from anesthesia;

- Beds in an obstetric delivery room used exclusively for OB patients in labor or recovery after delivery of newborn infants;

- Newborn bassinets and isolettes used for well-baby boarders (NOTE: If the baby is being held for treatment at the CAH, his or her bassinet or isolette does count towards the CAHs 25-bed limit);

- Stretchers in emergency departments; and

- Inpatient beds in Medicare-certified distinct part rehabilitation or psychiatric units.

Beds Used for Hospice Services

A CAH can dedicate beds to a hospice under arrangement, but the beds must count as part of the maximum bed count. The computation contributing to the 96 hour annual average length of stay does not apply to hospice patients. The hospice patient can be admitted to the CAH for any care involved in their hospice treatment plan or for respite care.

Medicare does not reimburse the CAH for the hospice CAH benefit. Medicare reimburses the hospice. The CAH must negotiate payment for services from the hospice through an agreement.

Survey Procedures §485.620(a)

- Count the number of inpatient beds the CAH maintains, excluding any DPU beds.

- Ask the CAH how frequently it uses observation services, and for its policies and procedures governing use of observation services.

- Verify that patients are never pre-registered for observation services; there should be no scheduled observation stays.

- Check to see if the CAH has specific clinical criteria for placement in and discharge from observation status, and that these clinical criteria are clearly distinguishable from those used for inpatient admission and discharge.

- If there is a separate unit of observation beds, ask the CAH for evidence of how its criteria for placement in the observation unit differ from admission criteria for an inpatient bed. Count the number of beds in the observation unit and compare them to the number of inpatient beds. The higher the proportion of observation beds, the greater is the CAH's burden to prove these are not being used as inpatient beds. Ask for the occupancy rates for the observation unit; the higher the occupancy rate, particularly if there are more than a couple of beds, the greater is the CAH's burden to prove these are not being used as inpatient beds.

- Review the medical records for patients who are in observation status at the time of survey. Verify that the medical record includes an order to place the patient in observation status, including the clinical reason for observation, e.g., as "Place patient in observation to rule out possible myocardial infarction (MI)."

- Select a sample of closed medical records for patients who were in an observation status. Verify that the medical record includes an order to place the patient in observation status, as well as a later order to admit, discharge, or transfer the patient.

- Verify through medical record review that observation services are not ordered as a standing order following outpatient surgery or prior to admission from the emergency department.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0904 - LENGTH OF STAY

Title LENGTH OF STAY

Type Standard

CFR 485.620(b)

Regulation Definition

The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.

Interpretive Guideline

Interpretive Guidelines §485.620(b)

The Fiscal Intermediary (FI) will determine compliance with this CoP. The FI will calculate the CAH'S length of stay based on patient census data. If a CAH exceeds the length of stay limit, the FI will send a report to the CMS-RO as well as a copy of the report to the SA. The CAH will be required to develop and implement a plan of correction (POC) acceptable to the CMS Regional Office or provide adequate information to demonstrate compliance.

FED - C0910 - PHYSICAL PLANT AND ENVIRONMENT

Title PHYSICAL PLANT AND ENVIRONMENT

Type Condition

CFR 485.623

Regulation Definition

§485.623 Condition of Participation: Physical Plant and Environment

Interpretive Guideline

Interpretive Guidelines §485.623

This CoP applies to all locations of the CAH, all campuses, all satellites, all provider-based activities, and all inpatient and outpatient locations.

The CAH'S departments or services responsible for the CAH'S building and equipment maintenance (both facility equipment and patient care equipment) must be incorporated into the CAH'S QA program and be in compliance with the QA requirements.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0912 - CONSTRUCTION

Title CONSTRUCTION

Type Standard

CFR 485.623(a)

Regulation Definition

The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of services.

Interpretive Guideline

Interpretive Guidelines §485.623(a)

The CAH's physical facilities must be constructed, designed and maintained such that patients are always accessible and the safety of patients is assured. The CAH's construction must be in accordance with applicable Federal, State and local law, as determined by the authorities having jurisdiction to enforce such law.

The CAH's physical plant must provide sufficient space to support those services the CAH provides on-site. There must also be adequate space to support all additional services the CAH offers.

Survey Procedures §485.623(a)

- Verify through observation that the physical facilities are large enough for the scope of services the CAH is required to provide on-site, as well as any additional services it offers on-site or at a provider-based, off-site location. The adequacy of the space depends on both the nature of the services provided and the number of patients to whom the CAH typically provides those services.

- Verify through observation that the CAH's building(s) is/are maintained in a manner to ensure the safety and well being of patients (e.g., condition of ceilings, walls, and floors, presence of patient hazards, etc.).

- Verify through observation that the design of the CAH assures that staff can reach patients readily.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C0914 - MAINTENANCE

Title MAINTENANCE

Type Standard

CFR 485.623(b)
485.623(b)(1)

Regulation Definition

The CAH has housekeeping and preventive maintenance programs to ensure that--

(1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;

Interpretive Guideline

Interpretive Guidelines §485.623(b)(1)

In order to ensure all essential mechanical, electrical and patient-care equipment is maintained in safe operating condition, the CAH must identify the essential equipment required to meet its patients' needs for both day-to-day operations and in a likely emergency/disaster situation, such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, internal disasters, etc. In addition, the CAH must make adequate provisions to ensure the availability and reliability of equipment needed for its operations and services. Equipment includes both facility equipment, which supports the physical environment of the CAH (e.g., elevators, generators, air handlers, medical gas systems, air compressors and vacuum systems, electrical systems, etc.) and medical equipment, which are devices intended to be used for diagnostic, therapeutic or monitoring care provided to a patient by the CAH (e.g., IV infusion equipment, ventilators, laboratory equipment, surgical devices, etc.).

All equipment must be inspected and tested for performance and safety before initial use and after major repairs or upgrades. Equipment to be used for the first time should be inspected and tested for performance and safety in accordance with manufacturer recommendations, unless a sufficient amount of maintenance history has been acquired, either based on its contractor's records or available publicly from nationally recognized sources, to determine whether the alteration of initial inspection and testing activities and frequencies would be safe.

All equipment must be inspected, tested, and maintained to ensure their safety, availability and reliability. Equipment maintenance activities may be conducted using CAH personnel, contracted services, or through a combination of CAH personnel and contracted services. Individual(s) responsible for overseeing the development, implementation, and management of equipment maintenance programs and activities must be qualified. The CAH maintains records of CAH personnel qualifications and is able to demonstrate how it assures all personnel, including contracted personnel, are qualified.

All equipment maintenance policies, procedures and programs, as well as specific equipment maintenance inventories, activities and schedules fall under the purview of the CAH's clinical maintenance personnel, safety

department personnel or other personnel who have been assigned responsibility for equipment maintenance by CAH leadership.

CAHs comply with this regulation when they follow the manufacturer-recommended maintenance activities and schedule. CAHs may choose to perform maintenance more frequently than the manufacturer recommends, but must use the manufacturer-recommended maintenance activities in such cases. When equipment is maintained in accordance with the manufacturer's recommendations, the CAH must maintain documentation of those recommendations and the CAH's associated maintenance activity for the affected equipment.

Alternate Equipment Management (AEM) Program

A CAH may, under certain conditions, use equipment maintenance activities and frequencies that differ from those recommended by the manufacturer. CAHs that choose to employ alternate maintenance activities and/or schedules must develop, implement, and maintain a documented AEM program to minimize risks to patients and others in the CAH associated with the use of facility or medical equipment. The AEM program must be based on generally accepted standards of practice for facility or medical equipment maintenance. An example of guidelines for a medical equipment medical equipment maintenance program may be found in the American National Standards Institute/ Association for the Advancement of Medical Instrumentation document: ANSI/AAMI EQ 56:1999/ (R) 2013, Recommended Practice for a Medical Equipment Management Program. Likewise, an example of guidelines for physical plant equipment may be found in the American Society for Healthcare Engineering (ASHE) 2009 document: Maintenance Management for Health Care Facilities. There may be similar documents issued by other nationally recognized organizations which CAHs might choose to reference.

Decision to Place Equipment in an AEM Program

The determination of whether it is safe to perform facility or medical equipment maintenance without following the equipment manufacturer recommendations must be made by qualified personnel, regardless of whether they are CAH employees or contractors. CAHs must be able to verify that qualified personnel, employees or contractors, are making the decisions to place equipment in the AEM program, performing the risk-based assessments, establishing the alternate equipment maintenance requirements, managing the AEM program, and performing the maintenance in accordance with the AEM policies and procedures.

In the case of medical equipment, a clinical or biomedical technician or engineer would be considered qualified. Highly specialized or complex equipment may require specialized knowledge or training in order for personnel to be considered qualified to make a decision to place such equipment in an AEM program.

In the case of facility equipment, a Healthcare Facility Management professional (e.g., facility manager, director of facilities, vice president of facilities) would be considered qualified.

The CAH must maintain records of the qualifications of CAH personnel who make decisions on placing equipment in an AEM program, and must be able to demonstrate how they assure contracted personnel making such decisions are qualified.

In determining whether or not to include equipment in an AEM program, and which maintenance strategies to use in developing maintenance activities and frequencies for particular equipment, the CAH must take into account the typical health and safety risks associated with the equipment's use. Note that the risk may vary for the same type of equipment, depending on the patient care setting within the CAH where it is used.

A CAH is expected to identify any equipment in its AEM program which is critical equipment, i.e., biomedical or physical plant equipment for which there is a risk of serious injury or death to a patient or staff person should the equipment fail. Surveyors must focus their review of a CAH's AEM program on critical equipment in that program and the CAH's documentation of the factors and evidence it considered in developing an AEM strategy for that equipment.

Factors for a CAH to consider when evaluating the risks associated with a particular type of equipment include, but are not limited to:

" How the equipment is used and the likely consequences of equipment failure or malfunction: would failure or malfunction of the equipment CAH-wide or in a particular setting be likely to cause harm to a patient or a staff person?

" How serious is the harm likely to be? For example, a slightly miscalibrated scale in an adult internal medicine outpatient clinic might not present significant risk of harm. However, a miscalibrated scale in a neonatal intensive care unit could have very serious consequences for patient care.

" How widespread is the harm likely to be? For example, are many patients exposed to the equipment, resulting in harm due to failure impacting more patients or staff? If harm would be widespread, even if the harm to each affected individual is not serious, this would be a cause for concern.

" Information, if available, on the manufacturer's equipment maintenance recommendations, including the rationale

for the manufacturer's recommendations;

" Maintenance requirements of the equipment:

" Are they simple or complex?
" Are the manufacturer's instructions and procedures available in the CAH, and if so can the CAH explain how and why it is modifying the manufacturer's instructions?
" If the manufacturer's instructions are not available in the CAH, how does the CAH assess whether the AEM uses appropriate maintenance strategies?
" How readily can the CAH validate the effectiveness of AEM methods for particular equipment? For example, can the CAH explain how it ensures there is no reduction in the quality of the performance of biomedical equipment subjected to alternate maintenance methods?

" The timely availability of alternate devices or backup systems in the event of equipment failure or malfunction; and

" Incident history of identical or very similar equipment - is there documented evidence, based on the experience of the CAH (or its third party contractor), or on evidence publicly reported by credible sources outside the CAH, which:

" Provides the number, frequency and nature of previous failures and service requests?

" Indicates use of an AEM strategy does not result in degraded performance of the equipment?

Generally multiple factors must be considered, since different types of equipment present different combinations of severity of potential harm and likelihood of failure. The CAH is expected to be able to demonstrate to a surveyor the factors it considered in its risk assessment for equipment placed in its AEM program.

Equipment not Eligible for Placement in the AEM Program:

Some equipment may not be eligible for placement in the AEM program, for one or more of the following reasons:

" Other Federal law (for example, regulations promulgated by another Federal agency) or State law may require that facility or medical equipment maintenance, inspection and testing be performed strictly in accordance with the manufacturer's recommendations, or may establish other, more stringent maintenance requirements. In these

instances, the CAH must comply with these other Federal or State requirements, but State Surveyors conducting Federal surveys assess compliance only with the CAH Conditions of Participation (CoPs).

" Other CoPs require adherence to manufacturer's recommendations and/or set specific standards which preclude their inclusion in an AEM program. For example:

" The National Fire Protection Association Life Safety Code (LSC) requirements incorporated by reference at 42 CFR 485.623(d) have provisions that are pertinent to equipment maintenance, and compliance with these requirements are assessed on Federal surveys. Further, §485.623(d)(7)(v) requires CAHs to adhere to the manufacturer's maintenance guidelines for alcohol-based hand-rub dispensers. Compliance with these requirements is assessed on Federal surveys.

" Imaging/radiologic equipment, whether used for diagnostic or therapeutic purposes, must be maintained per manufacturer's recommendations.
" The equipment is a medical laser device. It should be noted that for medical lasers the U.S. Food and Drug Administration requires manufacturers to provide a schedule of maintenance and adequate instructions for service adjustments and service procedures to purchasers and, at cost, to any other parties requesting them.

" New equipment for which sufficient maintenance history, either based on the CAH's own or its contractor's records, or available publicly from nationally recognized sources, is not available to support a risk-based determination must not be immediately included in the AEM program. New equipment must be maintained in accordance with manufacturer recommendations until a sufficient amount of maintenance history has been acquired to determine whether the alteration of maintenance activities or frequencies would be safe. If a CAH later transitions the equipment to a risk-based maintenance regimen different than the manufacturers' recommendations, the CAH must maintain evidence that it has first evaluated the maintenance track record, risks, and tested the alternate regimen.

Alternative Maintenance Frequencies or Activities

Maintenance strategies are various methodologies used for determining the most efficient and effective maintenance activities and frequencies. Manufacturers' recommendations may be based on one or more such strategies. A CAH may also use one or more maintenance strategies for its AEM program in order to determine the appropriate maintenance, inspection, and testing activities and frequencies, based upon the nature of the equipment and the level of risk it presents to patient or staff health and safety. The risk to patient health and safety that is considered in developing alternative maintenance strategies must be explained and documented in the AEM program.

In developing AEM maintenance strategies, CAHs may rely upon information from a variety of sources, including, but not limited to: manufacturer recommendations and other materials, nationally recognized expert associations, and/or the CAH's (or its third party contractor's) own experience. Maintenance strategies may be applied to groups or to individual pieces of equipment.

The CAH is expected to adhere strictly to the AEM activities or strategies it has developed.

Background Information on Types of Maintenance Strategies

" Preventive Maintenance (Time-based Maintenance) - a maintenance strategy where maintenance activities are performed at scheduled time intervals to minimize equipment degradation and reduce instances where there is a loss of performance. Most preventive maintenance is "interval-based maintenance" performed at fixed time intervals (e.g., annual or semi-annual), but may also be "metered maintenance" performed according to metered usage of the equipment (e.g., hours of operation). In either case, the primary focus of preventive maintenance is reliability, not optimization of cost-effectiveness. Maintenance is performed systematically, regardless of whether or not it is needed at the time. Example: Replacing a battery every year, after a set number of uses or after running for a set number of hours, regardless.

" Predictive Maintenance (Condition-based Maintenance) - a maintenance strategy that involves periodic or continuous equipment condition monitoring to detect the onset of equipment degradation. This information is used to predict future maintenance requirements and to schedule maintenance at a time just before equipment experiences a loss of performance. Example: Replacing a battery one year after the manufacturer's recommended replacement interval, based on historical monitoring that has determined the battery capacity does not tend to fall below the required performance threshold before this extended time.

" Reactive Maintenance (Corrective, Breakdown or Run-to-Failure Maintenance) - a maintenance strategy based upon a "run it until it breaks" philosophy, where maintenance or replacement is performed only after equipment fails or experiences a problem. This strategy may be acceptable for equipment that is disposable or low cost, and presents little or no risk to health and safety if it fails. Example: Replacing a battery after equipment failure when the equipment has little negative health and safety consequences associated with a failure and there is a replacement readily available in supply.

" Reliability-Centered Maintenance - a maintenance strategy that not only considers equipment condition, but also considers other factors unique to individual pieces of equipment, such as equipment function, consequences of equipment failure, and the operational environment. Maintenance is performed to optimize reliability and cost

effectiveness. Example: Replacing a battery in an ambulance defibrillator more frequently than the same model used at a nursing station, since the one in the ambulance is used more frequently and is charged by an unstable power supply.

Maintenance Tools

Tools (e.g., hand tools, test equipment, software, etc.) necessary for performing equipment maintenance must be available and maintained to ensure that measurements are reliable. Tools used for maintenance are not required to be those specifically recommended by the manufacturer, but tools utilized must be capable of providing results equivalent to those required by the equipment manufacturer.

AEM Program Documentation

For each type of equipment subject to the AEM program, there must be documentation indicating:

" The pertinent types and level of risks to patient or staff health and safety;

" Alternate maintenance activities, and the maintenance strategy and any other rationale used to determine those activities; the differences from the manufacturer's recommended maintenance activities are made explicit, unless the CAH is unable to obtain the manufacturer's maintenance recommendations, due to the age of the equipment or the manufacturer's restricting the availability of its recommendations;

" Alternate maintenance frequencies to be used, if any, and the maintenance strategy and any other rationale used to determine those frequencies. For equipment identified as presenting a very low risk to patient or staff safety, it could be acceptable to not set a particular frequency but instead indicate a less specific approach, for example, an interval range, such as "every 12 - 24 months." It could also be acceptable to employ periodic "departmental sweeps" for such very low risk equipment, where equipment functioning is sampled and operators are polled about its functionality.

" The date when AEM program maintenance activities were performed and, if applicable, further actions required/taken; and

" Documentation of any equipment failures (not including failures due to operator error), including whether there was resulting harm to an individual. (Note: equipment failure that is due to operator error and which results in an adverse event or near miss must be documented in accordance with the QAPI CoP, as part of the CAH's required

tracking of patient safety-related incidents. However, there is no requirement to include operator failures in equipment maintenance documentation.)

When the CAH has multiple identical equipment items, the documentation may be generic to that type of equipment, except that documentation of maintenance activities performed must be specific to each item of equipment.

Evaluating Safety and Effectiveness of the AEM Program

The CAH must have policies and procedures which address the effectiveness of its AEM program. In evaluating the effectiveness of the AEM program, the CAH is expected to address factors including, but not limited to:

" How equipment is evaluated to ensure there is no degradation of performance, particularly for equipment where such degradation may not be readily apparent to staff using the equipment, e.g., miscalibration.

" How incidents of equipment malfunction are investigated, including:

" whether or not the malfunction could have been prevented, and what steps will be taken to prevent future malfunctions; and

" how a determination is made whether or not the malfunction resulted from the use of an AEM strategy;

" The process for the removal from service of equipment determined to be unsafe or no longer suitable for its intended application; and

" The use of performance data to determine if modifications in the AEM program procedures are required.

Equipment Inventory

All CAH facility and medical equipment essential to the operation of the CAH, regardless of whether it is leased or owned, and regardless of whether it is maintained according to manufacturer recommendations or is in an AEM program, is expected to be listed in an inventory which includes a record of maintenance activities. For low cost/low risk essential equipment, such as housekeeping cleaning equipment, it is acceptable for the inventory to indicate under one item the number of such pieces of equipment in the CAH, e.g., "15 vacuum cleaners for cleaning patient rooms and common areas."

If the CAH is using an AEM program, the equipment managed through that program must be readily separately identifiable as subject to AEM. Critical equipment, whether in an AEM program or not, must also be readily identified as such.

To facilitate effective management, a well-designed equipment inventory contains the following information for all equipment included. However, CAHs have the flexibility to demonstrate how alternative means they use are effective in enabling them to manage their equipment.

" A unique identification number;

" The equipment manufacturer;

" The equipment model number;

" The equipment serial number;

" A description of the equipment;

" The location of the equipment (for equipment generally kept in a fixed location);

" The identity of the department considered to "own" the equipment;

" Identification of the service provider;

" The acceptance date; and

" Any additional information the CAH believes may be useful for proper management of the equipment.

Survey Procedures §485.623(b)(1)

Interview personnel in charge of equipment maintenance:

" Determine if the CAH has identified equipment that is essential for both regular operations and in an emergency situation.

" Determine if the CAH has made adequate provisions to ensure the availability of those and equipment when needed.

Concerning facility and medical equipment:

" Interview equipment users when surveying the various units/departments of the CAH to determine if equipment failures are occurring and causing problems for patient health or safety.

" Determine if there is a complete inventory of equipment required to meet patient needs, regardless of ownership.

" Is critical equipment readily identified?
" If the CAH employs an AEM program, is equipment in this program readily identified?

" Determine if the CAH has documentation of the qualifications (e.g., training certificates, certifications, degrees, etc.) of CAH personnel responsible for the AEM program (if one is being used by the CAH) as well as for those performing maintenance.

" Determine if the CAH is able to demonstrate how it assures contractors use qualified personnel.

If the CAH is following the manufacturer-recommended equipment maintenance activities and frequencies:

In addition to reviewing maintenance records on equipment observed while inspecting various CAH locations for multiple compliance assessment purposes, select a sample of equipment from the CAH's equipment inventory to determine whether the CAH is following the manufacturer's recommendations. Critical equipment which poses a higher risk to patient safety if it were to fail, such as ventilators, defibrillators, robotic surgery devices, etc. should make up the sample majority.

For the sample selected, determine if:

" The CAH has available manufacturer's recommendations (e.g., manufacturer's operation and maintenance manual, standards, studies, guidance, recall information, service records, etc.);

" Maintenance is being performed in accordance with manufacturer's recommendations

If a CAH is using an AEM for some equipment:

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" Does the CAH's inventory include equipment which is not eligible for AEM, for example, any diagnostic imaging or therapeutic radiologic equipment?

" Determine if the CAH's development of alternate maintenance activities and frequencies for equipment in the AEM program as well as AEM activities are being performed by qualified personnel.

" Verify the CAH has documented maintenance activities and frequencies for all equipment included in the AEM program;

" Verify the CAH is evaluating the safety and effectiveness of the AEM program.

" If there is equipment on the inventory the CAH has identified as having such a very low level of risk that it has determined it can use a broad interval range or departmental "sweeps," ask the CAH for the evidence used to make this determination. Does it seem reasonable?

Select a sample of equipment in the AEM program. The majority of the sample must include critical equipment which poses a higher risk to patient safety if it were to fail, such as ventilators, defibrillators, robotic surgery devices, etc. For the sample selected:

" Ask the responsible personnel to explain how the decision was made to place the equipment in an AEM program. Does the methodology used consider risk factors and make use of available evidence?

" Ask the responsible personnel to describe the methodology for applying maintenance strategies and determining alternative maintenance activities or frequencies for the sampled equipment. Can they readily provide an explanation and point to sources of information they relied upon?

" Determine if maintenance is being performed in accordance with the maintenance activities and frequencies defined in the AEM program.

Verify the CAH is evaluating the safety and effectiveness of the AEM maintenance activities for this equipment and taking corrective actions when needed.

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FED - C0920 - ROUTINE STORAGE AND DISPOSAL OF TRASH

Title ROUTINE STORAGE AND DISPOSAL OF TRASH

Type Standard

CFR 485.623(b)(2)

Regulation Definition	Interpretive Guideline
(2) There is proper routine storage and prompt disposal of trash;	Interpretive Guidelines §485.623(b)(2) Guidance is pending and will be updated in future release.

FED - C0922 - DRUGS AND BIOLOGICALS ARE APPROPRIATELY STORE

Title DRUGS AND BIOLOGICALS ARE APPROPRIATELY STORE

Type Standard

CFR 485.623(b)(3)

Regulation Definition	Interpretive Guideline
(3) Drugs and biologicals are appropriately stored;	Survey Procedures §485.623(b)(3) What standards, guidelines, State and Federal law is the CAH following to ensure that drugs and biologicals are appropriately stored (e.g., properly locked) in all storage areas?

FED - C0924 - PREMISES ARE CLEAN AND ORDERLY

Title PREMISES ARE CLEAN AND ORDERLY

Type Standard

CFR 485.623(b)(4)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition	Interpretive Guideline
(4) The premises are clean and orderly; and	Interpretive Guidelines §485.623(b)(4) "Clean and orderly" means an uncluttered physical environment where patients and staff can function safely. Equipment and supplies are stored in proper spaces, not in corridors. Spills are not left unattended. There are no floor obstructions. The area is neat and well kept. There is no evidence of peeling paint, visible water leaks, or plumbing problems.

FED - C0926 - PROPER VENTILATION, LIGHTING, AND TEMPERATURE

Title PROPER VENTILATION, LIGHTING, AND TEMPERATURE

Type Standard

CFR 485.623(b)(5)

Regulation Definition	Interpretive Guideline
(5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.	Interpretive Guidelines §485.623(b)(5) Guidance is pending and will be updated in future release.

FED - C0930 - LIFE SAFETY FROM FIRE

Title LIFE SAFETY FROM FIRE

Type Standard

CFR 485.623(c)
485.623(c)(1)(i)

Regulation Definition	Interpretive Guideline
§485.623(c) Standard: Life Safety From Fire	Interpretive Guidelines §485.623(c)(1)(i)
(1) Except as otherwise provided in this section:	Guidance is pending and will be updated in future release.
(i) The CAH must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101	Survey Procedures §485.623(c)(1)(i)

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and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.)

(ii) Notwithstanding paragraph (d)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.

Survey procedures are pending and will be updated in future release.

FED - C0932 - CMS WAIVER OF LSC SPECIFIC PROVISIONS

Title CMS WAIVER OF LSC SPECIFIC PROVISIONS

Type Standard

CFR 485.623(c)(3)

Regulation Definition

§485.623(c)(3) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not adversely affect the health and safety of patients.

Interpretive Guideline

Interpretive Guidelines §485.623(c)(3)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(c)(3)

Survey procedures are pending and will be updated in future release.

FED - C0934 - REGULAR INSPECTION BY FIRE CONTROL AGENCIES

Title REGULAR INSPECTION BY FIRE CONTROL AGENCIES

Type Standard

CFR 485.623(c)(4)

Regulation Definition

The CAH maintains written evidence of regular inspection and approval by State or local fire control agencies.

Interpretive Guideline

Interpretive Guidelines §485.623(c)(4)

Guidance is pending and will be updated in future release.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Survey Procedures §485.623(c)(4)

Survey procedures are pending and will be updated in future release.

FED - C0936 - ALCOHOL-BASED HAND RUB DISPENSER

Title ALCOHOL-BASED HAND RUB DISPENSER

Type Standard

CFR 485.623(c)(5)

Regulation Definition	Interpretive Guideline
A CAH may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.	Interpretive Guidelines §485.623(c)(5) Guidance is pending and will be updated in future release. Survey Procedures §485.623(c)(5) Survey Procedures are pending and will be updated in future release.

FED - C0938 - SPRINKLER SYSTEM

Title SPRINKLER SYSTEM

Type Standard

CFR 485.623(c)(6)

Regulation Definition	Interpretive Guideline
(6) When a sprinkler system is shut down for more than 10 hours, the CAH must: (i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or (ii) Establish a fire watch until the system is back in service.	Interpretive Guidelines §485.623(c)(6) Guidance is pending and will be updated in future release. Survey Procedures §485.623(c)(6)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Survey Procedures are pending and will be updated in future release.

FED - C0940 - OUTSIDE WINDOW AND DOORS IN SLEEPING ROOMS

Title OUTSIDE WINDOW AND DOORS IN SLEEPING ROOMS

Type Standard

CFR 485.623(c)(7)

Regulation Definition	Interpretive Guideline
(7) Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement. (i) The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours. (ii) Special nursing care areas of new occupancies shall not exceed 60 inches.	Interpretive Guidelines §485.623(c)(7) Guidance is pending and will be updated in future release. Survey Procedures §485.623(c)(7) Survey Procedures are pending and will be updated in future release.

FED - C0942 - LIFE SAFETY PROVISION WAIVER

Title LIFE SAFETY PROVISION WAIVER

Type Standard

CFR 485.623(c)(2)

Regulation Definition	Interpretive Guideline
In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a CAH, but only if the waiver will not adversely affect the health and safety of the	Interpretive Guidelines §485.623(c)(2) Guidance is pending and will be updated in future release. Survey Procedures §485.623(c)(2)

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patients.

Survey Procedures are pending and will be updated in future release.

FED - C0944 - BUILDING SAFETY

Title BUILDING SAFETY

Type Standard

CFR 485.623(d)

Regulation Definition

Except as otherwise provided in this section, the CAH must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).
(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a CAH.
(2) If application of the Health Care Facilities Code required under paragraph (e) of this section would result in unreasonable hardship for the CAH, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

Interpretive Guideline

Interpretive Guidelines §485.623(d)

Guidance is pending and will be updated in future release.

Survey Procedures §485.623(d)

Survey Procedures are pending and will be updated in future release.

FED - C0950 - EMERGENCY PREPAREDNESS

Title EMERGENCY PREPAREDNESS

Type Condition

CFR 485.625

Regulation Definition

§485.625 Condition of Participation: Emergency Preparedness

The CAH must comply with all applicable Federal, State, and

Interpretive Guideline

Please refer to Appendix Z of the State Operations Manual to cite the specific Emergency Preparedness E-Tags, interpretive guidelines, and survey procedures.

local emergency preparedness requirements. The CAH must develop and maintain a comprehensive emergency preparedness program, utilizing an all-hazards approach. The emergency preparedness plan must include, but not be limited to, the following elements:

(a) Emergency plan. The CAH must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, persons at-risk; the type of services the CAH has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) Policies and procedures. The CAH must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures

must address the following:

(1) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to-

(i) Food, water, medical, and pharmaceutical supplies;

(ii) Alternate sources of energy to maintain:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions;

(B) Emergency lighting;

(C) Fire detection, extinguishing, and alarm systems; and

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered patients in the CAH's care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the CAH must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the CAH, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves patient

information, protects confidentiality of patient information, and secures and maintains the availability of records.

(6) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other CAHs or other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to CAH patients.

(8) The role of the CAH under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) Communication plan. The CAH must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other CAHs and hospitals.

(v) Volunteers.

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(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) CAH's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the CAH's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the CAH's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction or the Incident Command Center, or designee.

(d) Training and testing. The CAH must develop and maintain an emergency preparedness training and testing program that

is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) Training program. The CAH must do all of the following:

(i) Initial training in emergency preparedness policies and procedures, including prompt reporting and extinguishing of fires, protection, and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with firefighting and disaster authorities, to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least every 2 years.

(iii) Maintain documentation of the training.

(iii) Demonstrate staff knowledge of emergency procedures.

(v) If the emergency preparedness policies and procedures are significantly updated, the CAH must conduct training on the updated policies and procedures.

(2) Testing. The CAH must conduct exercises to test the emergency plan at least twice per year. The CAH must do the following:

(i) Participate in an annual full-scale exercise that is community-based; or

(A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or,

(B) If the CAH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CAH is exempt from engaging in its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an annual additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the CAH's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the CAH's emergency plan, as needed.

(e) Emergency and standby power systems. The CAH must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section.

(1) Emergency generator location. The generator must be located in accordance with the location requirements found in the Health Care Facilities Code (NFPA 99 and Tentative

Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6), Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.

(2) Emergency generator inspection and testing. The CAH must implement emergency power system inspection and testing requirements found in the Health Care Facilities Code, NFPA 110, and the Life Safety Code.

(3) Emergency generator fuel. CAHs that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

(f) Integrated healthcare systems. If a CAH is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the CAH may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must do all of the following:

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

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(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include-

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

(g) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain the material from the sources listed below. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park,

Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(i) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11, 2011.

(ii) Technical interim amendment (TIA) 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(xii) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

(2) [Reserved]

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FED - C0960 - ORGANIZATIONAL STRUCTURE

Title ORGANIZATIONAL STRUCTURE

Type Condition

CFR 485.627

Regulation Definition

Organizational Structure

Interpretive Guideline

FED - C0962 - GOVERNING BODY OR RESPONSIBLE INDIVIDUAL

Title GOVERNING BODY OR RESPONSIBLE INDIVIDUAL

Type Standard

CFR 485.627(a)

Regulation Definition

The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH'S total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.

Interpretive Guideline

Interpretive Guidelines §485.627(a)

The CAH must have only one governing body (or responsible individual) and this governing body (or responsible individual) is responsible for the conduct of the CAH as an institution. In the absence of an organized governing body, there must be written documentation that identifies the individual or individuals that are responsible for the conduct of the CAH operations.

The governing body (or responsible individual) must determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.

It is the responsibility of the governing body (or responsible individual) to appoint, with the advice of the medical staff, the individual practitioners to the medical staff. After considering medical staff recommendations, and in accordance with established CAH medical staff criteria and State and Federal laws and regulations, the governing body (or responsible individual) decides whether or not to appoint new medical staff members or to continue current members of the medical staff.

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The governing body (or responsible individual) must ensure that the medical staff has bylaws that comply with State and Federal law and the requirements of the CAH CoP.

The governing body (or responsible individual) decides whether or not to approve medical staff bylaws submitted by the medical staff. The medical staff bylaws and any revisions must be approved by the governing body (or responsible individual) before they are considered effective.

The governing body (or responsible individual) must ensure that the medical staff is accountable to the governing body (or responsible individual) for the quality of care provided to patients. The governing body (or responsible individual) is responsible for the conduct of the CAH and this conduct would include the quality of care provided to patients.

All CAH patients must be under the care of a member of the medical staff or under the care of a practitioner who is under the supervision of a member of the medical staff. All patient care is provided by or in accordance with the orders of a practitioner granted privileges to provide or order that care and is in accordance with State law.

Criteria for selection of both new medical staff members and selection of current medical staff members for continued membership must be based on:

" Individual character;

" Individual competence;

" Individual training;

" Individual experience; and

" Individual judgment

Survey Procedures §485.627(a)

" Verify that the CAH has an organized governing body or has written documentation that identifies the individual that is responsible for the conduct of the CAH operations.

" Review documentation and verify that the governing body (or responsible individual) has determined and stated

the categories of practitioners that are eligible candidates for appointment to the medical staff.

" Have the facility's operating policies been updated to fully reflect its responsibilities as a CAH (e.g., PA responsibilities, provision of required CAH direct services)?

" What evidence (e.g., minutes of board meetings) demonstrates that the governing body or the individual who assumes responsibility for CAH operation is involved in the day-to-day operation of the CAH and is fully responsible for its operations?

" Evaluate records of medical staff appointments to substantiate the governing body's (or responsible individual's) involvement in appointments of medical staff members.

" Confirm that the governing body (or responsible individual) appoints all members to the medical staff in accordance with established policies based on the individual practitioner's scope of clinical expertise and in accordance with Federal and State law.

" Verify that the medical staff operates under current bylaws that are in accordance with Federal and State laws and regulations.

" Verify that the medical staff operates under current bylaws, rules and policies that have been approved by the governing body (or responsible individual).

" Verify that any revisions or modifications in the medical staff bylaws, rules, and policies, have been approved by the medical staff and the governing body (or responsible individual). For example, look at the bylaws and check for date of last review and initials by the person(s) responsible.

" Verify that the governing body (or responsible individual) is periodically apprised of the medical staff evaluation of patient care services provided in the CAH, at every patient care location of the CAH.

" Verify that any individual providing patient care services is a member of the medical staff or is accountable to a member of the medial staff qualified to evaluate the quality of services provided, and in turn, is responsible to the governing body (or responsible individual) for the quality of services provided.

" Verify that there are written criteria for staff appointments to the medical staff.

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" Verify that selection of medical staff for membership, both new and renewal, is based upon an individual practitioner's compliance with the medical staff's membership criteria.

" Verify that at a minimum, criteria for selection to the medical staff are individual character, competence, training, experience, and judgment.

FED - C0964 - DISCLOSURE

Title DISCLOSURE

Type Standard

CFR 485.627(b)(1)

Regulation Definition	Interpretive Guideline
The person principally responsible for the operation of the CAH; and	Survey Procedures §485.627(b)(1) How does the CAH implement its policy or procedure for reporting changes in operating officials to the State agency?

FED - C0966 - RESPONSIBLE FOR MEDICAL DIRECTION

Title RESPONSIBLE FOR MEDICAL DIRECTION

Type Standard

CFR 485.627(b)(2)

Regulation Definition	Interpretive Guideline
	Survey Procedures §485.627(b)(2) How does the CAH implement its policy or procedure for reporting changes in medical director to the State agency?

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FED - C0970 - STAFFING AND STAFF RESPONSIBILITIES

Title STAFFING AND STAFF RESPONSIBILITIES

Type Condition

CFR 485.631

Regulation Definition	Interpretive Guideline
§485.631 Condition of Participation: Staffing and Staff Responsibilities	

FED - C0971 - STAFFING

Title STAFFING

Type Standard

CFR 485.631(a)(1)

Regulation Definition	Interpretive Guideline
(1) The CAH has a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.	Interpretive Guidelines §485.631(a)(1) A CAH may operate with a MD/DO on staff as well as with any combination of mid-level practitioners. Survey Procedures §485.631(a)(1) " Review listings or organizational charts showing the names of all staff MD/DOs, nurse practitioners, clinical nurse specialists and physician assistants on the CAH staff. " Review work schedules showing normal CAH hours of operation and coverage by members of the CAH staff.

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FED - C0972 - ANCILLARY PERSONNEL

Title ANCILLARY PERSONNEL

Type Standard

CFR 485.631(a)(2)

Regulation Definition	Interpretive Guideline
Any ancillary personnel are supervised by the professional staff.	Survey Procedures §485.631(a)(2) Use organizational charts and staff interviews to determine how the CAH ensures that the professional staff supervises all ancillary personnel.

FED - C0974 - SUFFICIENT STAFF

Title SUFFICIENT STAFF

Type Standard

CFR 485.631(a)(3)

Regulation Definition	Interpretive Guideline
The staff is sufficient to provide the services essential to the operation of the CAH.	Survey Procedures §485.631(a)(3) " How does the CAH ensure that staff coverage is sufficient to provide essential services at the facility (e.g., emergency services, direct services, and nursing services)? " Review staffing schedules and daily census records.

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FED - C0976 - STAFFING

Title STAFFING

Type Standard

CFR 485.631(a)(4)

Regulation Definition

A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates.

Interpretive Guideline

Interpretive Guidelines §485.631(a)(4)

Section 485.635(b)(1) requires CAHs to provide "those diagnostic and therapeutic services and supplies that are commonly furnished in "a physician's office" such as low intensity outpatient services. In order to demonstrate compliance, a CAH must demonstrate that a practitioner is physically present and prepared to treat patients at the CAH when patients present at the CAH outpatient clinic during announced hours of outpatient clinic operation. This requirement does not mean the CAH must have a practitioner physically present in the facility 24 hours per day, nor does it require their presence 24 hours per day when the CAH has inpatients, including swing-bed patients.

Survey Procedures §485.631(a)(4)

" If the CAH does not have regular announced hours of operation, ask the individual who is principally responsible for the operation of the CAH, when is the CAH is open to the public to provide outpatient services.

" What kinds of arrangements have been made by the CAH to ensure that a practitioner is available on site at all times the CAH operates to furnish patient care services?

FED - C0978 - STAFFING

Title STAFFING

Type Standard

CFR 485.631(a)(5)

Regulation Definition

A registered nurse, clinical nurse specialist, or licensed

Interpretive Guideline

Survey Procedures §485.631(a)(5)

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practical nurse is on duty whenever the CAH has one or more inpatients.

Review nursing staff schedules to ensure that a registered nurse, clinical nurse specialist or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

FED - C0980 - RESPONSIBILITIES OF MD AND DO

Title RESPONSIBILITIES OF MD AND DO

Type Standard

CFR 485.631(b)

Regulation Definition

Responsibilities of the Doctor of Medicine or Osteopathy

Interpretive Guideline

FED - C0981 - RESPONSIBILITIES OF MD AND DO

Title RESPONSIBILITIES OF MD AND DO

Type Standard

CFR 485.631(b)(1)(i)

Regulation Definition

The doctor of medicine or osteopathy--

(i) Provides medical direction for the CAH'S health care activities and consultation for, and medical supervision of, the health care staff;

Interpretive Guideline

Interpretive Guidelines §485.631(b)(1)(i)

A CAH must have a MD/DO on its staff. That individual must perform all of the medical oversight functions.

Survey Procedures §485.631(b)(1)(i)

What evidence demonstrates that an MD/DO provides medical direction for the CAH'S health care activities and is available for consultation and supervision of the CAH health care staff?

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FED - C0982 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

Type Standard

CFR 485.631(b)(1)(ii)

Regulation Definition

In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH'S written policies governing the services it furnishes.

Interpretive Guideline

Survey Procedures §485.631(b)(1)(ii)

" What evidence demonstrates that an MD/DO has participated in the development of policies governing CAH services?

" How does the CAH ensure that an MD/DO periodically reviews these policies?

FED - C0984 - PATIENT SERVICES

Title PATIENT SERVICES

Type Standard

CFR 485.631(b)(1)(iii)

Regulation Definition

In conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the CAH'S patient records, provides medical orders, and provides medical care services to the patients of the CAH; and

Interpretive Guideline

Survey Procedures §485.631(b)(1)(iii)

" How does the CAH ensure that an MD/DO periodically reviews CAH patient records in conjunction with staff mid-level practitioners and provides medical care to CAH patients?

" What evidence demonstrates that there is a periodic review of patient records by the CAH MD/DO(s)?

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FED - C0986 - PATIENT CARE SERVICES

Title PATIENT CARE SERVICES

Type Standard

CFR 485.631(b)(1)(iv)
485.631(b)(1)(v)

Regulation Definition

[The doctor of medicine or osteopathy-]

(iv) Periodically reviews and signs the records of all inpatients cared for by nurse practitioners, clinical nurse specialists, or physician assistants.

(v) Periodically reviews and signs a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants only to the extent required under State law where State law requires record reviews or co signatures, or both, by a collaborating physician.

Interpretive Guideline

Interpretive Guidelines §485.631(b)(1)(iv) & (v)

All inpatient records for patients whose treatment is/was managed by a nonphysician practitioner in the CAH, i.e., nurse practitioners, clinical nurse specialists, or physician assistants, must be reviewed periodically by a CAH MD/DO who must sign the records after the review has been completed. The MD/DO review is expected to cover all applicable inpatient records open at the time of the review, as well as all applicable inpatient records closed since the last review.

In the case of inpatients whose care is/was managed by an MD/DO, as evidenced by an admission order, progress notes, and/or medical orders, etc., but who also receive services from a non-physician practitioner, a subsequent MD/DO review of the inpatient record is not required.

In States where State law requires a collaborating physician to review medical records, co-sign medical records, or both for outpatients whose care is managed by a non-physician practitioner, i.e., a nurse practitioner, a clinical nurse specialist, a certified nurse midwife, or a physician assistant, a CAH MD/DO must review and sign a sample of outpatient records. The outpatient medical record sample reviewed must be representative of all non-physician practitioners providing care to patients of the CAH. The CAH determines by policy the size of the sample reviewed and signed; however, CMS recommends, but does not require, a sample size of 25% of the records of all outpatient encounters managed by a non-physician practitioner since the prior MD/DO review. If State law requires MD/DO review or signature of a larger percentage of the outpatient records, the CAH must comply with State law.

In States where no physician record review or physician co-signature is required for patients managed by a non-physician practitioner, an MD/DO is not required to review or sign outpatient records of such patients.

Neither the regulation nor the preamble to the final rule adopting this regulation (79 Fed. Reg. 27105, May 12, 2014) specify a particular timeframe to satisfy the requirement for "periodic" review, but the CAH must specify a maximum interval between inpatient record reviews in its policies and procedures. The CAH is expected to take into account

the volume and types of services it offers in developing its policy. For example, a CAH that has only four certified beds and one MD/DO on staff and which does not always have an inpatient in house would likely establish a different requirement for inpatient record review than a CAH with 25 certified beds, multiple MDs/DOs on staff and a high inpatient occupancy rate. Further, there is no regulatory requirement for the review of records to be performed on site and in person. Thus, if the CAH has electronic medical records that can be accessed and digitally signed remotely by the MD or DO, this method of review is acceptable. Therefore, CAHs with and without the capability for electronic record review and signature might also develop different policies for the maximum interval between reviews.

Survey Procedures §485.631(b)(1)(iv) & (v)

Select a sample of inpatient and outpatient records, including both open and closed records.

" For inpatient records of patients whose care is/was managed by a non-physician practitioner, verify that:

" An MD/DO has reviewed and signed all records that were open at the time of the review, and all inpatient records that were closed since the MD/DO's last review; and

" That reviews take place within the timeframe specified by the CAH's policy.

" If State law requires a physician to review or co-sign (or both) any outpatient records of patients whose care is/was managed by non-physician practitioner, determine whether an MD or DO has reviewed and/or co-signed a representative sample of these records within the timeframe specified in the CAH's policies.

" Ask the CAH how many outpatient encounters are managed by non-physician practitioners, what sample size its policy requires to have an MD/DO review, and what timeframe its policy specifies for reviews.

" Ask the CAH to explain how it ensures the sample is representative of the various non-physician practitioners as well as of the various types of outpatient services they provide.
" Ask the CAH to describe the method it uses to make sure that reviews are performed in a timely manner on a sample that complies with the CAH's policy.

" Review selected records from the CAH's outpatient sample to verify that there is evidence of an MD or DO review and/or signature.

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FED - C0988 - RESPONSIBILITIES OF MD OR DO

Title RESPONSIBILITIES OF MD OR DO

Type Standard

CFR 485.631(b)(2)

Regulation Definition

A doctor of medicine or osteopathy is present for sufficient periods of time to provide medical direction, consultation, and supervision for the services provided in the CAH, and is available through direct radio or telephone communication or electronic communication for consultation, assistance with medical emergencies, or patient referral.

Interpretive Guideline

Interpretive Guidelines §485.631(b)(2)

An MD/DO must be present in the CAH for sufficient periods of time to provide overall medical direction, consultation and supervision of the healthcare services the CAH furnishes. Being "present" in the CAH means being physically on-site in the CAH. The regulation does not specify a minimum amount of time an MD/DO must spend on-site that applies to all CAHs. Instead, CAHs have the flexibility to develop policies appropriate for their circumstances. With the development of technology such as telemedicine, a CAH may use a variety of ways and timeframes for MDs/DOs to provide the necessary medical direction and oversight. For CAHs that offer a range of more complex services, have more than one MD/DO on staff, and have busy emergency departments and/or extensive outpatient services, an on-site visit by an MD/DO only once every week or every two weeks, for example, would be grossly inadequate. On the other hand, a bi-weekly on-site visit could be unduly burdensome as well as unnecessary for a small CAH in a remote rural area that offers very limited services and has a low patient volume.

CAHs are expected to have adequate staffing to provide the services they have chosen to furnish, including staffing or supervision by MDs/DOs as applicable. CMS expects each CAH to evaluate its services and adjust its MD/DO on-site schedule accordingly, as an appropriate MD/DO schedule must reflect the volume and nature of services offered.

Note that §485.618(d) also establishes a maximum timeframe for an MD, DO, PA, NP, or clinical nurse specialist to be on-call and available to be on-site to provide emergency care, and that §489.20(r)(2) requires the CAH to maintain an on-call list of MDs/DOs who are available to be on-site as part of the CAH's Emergency Medical Treatment and Labor Act obligations. The CAH must consider all pertinent requirements when developing its policies for MD/DO presence on site.

In addition to requiring an MD or DO to be on-site for sufficient periods of time, consistent with the requirement at §485.618(e), the CAH must also ensure an MD/DO is available through direct radio, telephone or other form of electronic communication, such as video conferencing, for consultation, assistance in handling patient medical

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emergencies and referral of patients to other healthcare facilities. An MD/DO providing telemedicine services to the CAH may be used to fulfill the requirement for availability via telecommunications. Further, consistent with the requirements for CAH provision of emergency services at §485.618(d), unless a, PA, NP, or clinical nurse specialist with training in emergency care is immediately available via one of these telecommunication methods and available on site within the timeframe specified at §485.618(d)(1), an MD or DO must fulfill these requirements.

Survey Procedures §485.631(b)(2)

" Does the CAH have policies and procedures that address the minimum amount of time and frequency of MD or DO presence on-site at the CAH? Can the CAH demonstrate how its policy reflects the volume and type of services the CAH provides such that there is sufficient MD/DO presence on-site to support the services provided?

" Is there documentation showing that an MD or DO is on-site for the frequency and duration specified in the CAH's policies?

" Can the CAH demonstrate that an MD or DO is always available by telecommunications contact for consultation, assistance and/or patient referral?

FED - C0990 - RESPONSIBILITIES OF MD OR DO

Title RESPONSIBILITIES OF MD OR DO

Type Standard

CFR 485.631(c)

Regulation Definition

Physician Assistant, Nurse Practitioner, and Clinical Nurse Specialist Responsibilities

Interpretive Guideline

FED - C0991 - PA, NP & CLINICAL SPEC RESPONSIBILITIES

Title PA, NP & CLINICAL SPEC RESPONSIBILITIES

Type Standard

CFR 485.631(c)(1)

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Regulation Definition

The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH'S staff--

(i) Participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes; and

Interpretive Guideline

Survey Procedures §485.631(c)(1)(i)

" Interview any mid-level professional staff to ascertain their level of involvement in CAH policy development, execution, and periodic review.

" Does the CAH ensure that policies are updated to remain consistent with State standards of practice requirements for mid-level practitioners?

FED - C0993 - PA, NP, & CLINICAL SPEC RESPONSIBILITIES

Title PA, NP, & CLINICAL SPEC RESPONSIBILITIES

Type Standard

CFR 485.631(c)(1)(ii)

Regulation Definition

Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.

Interpretive Guideline

Survey Procedures §485.631(c)(1)(ii)

How does the CAH ensure that mid-level practitioners at the CAH participate with an MD/DO in the review of their patients' health records?

FED - C0995 - PA, NP, & CLINICAL SPEC RESPONSIBILITIES

Title PA, NP, & CLINICAL SPEC RESPONSIBILITIES

Type Standard

CFR 485.631(c)(2)(i)

Regulation Definition

The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

Interpretive Guideline

Survey Procedures §485.631(c)(2)(i)

" Review policies and procedures.

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" Interview mid-level practitioners to gauge their knowledge and application of CAH policies.

(i) Provides services in accordance with the CAH'S policies.

FED - C0997 - PA, NP, & CLINICAL SPEC RESPONSIBILITES

Title PA, NP, & CLINICAL SPEC RESPONSIBILITES

Type Standard

CFR 485.631(c)(2)(ii)

Regulation Definition	Interpretive Guideline
Arranges for, or refers patients to, needed services that cannot be furnished at the CAH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.	Survey Procedures §485.631(c)(2)(ii) Verify that there are policies and procedures for transferring patients to other facilities

FED - C0998 - PA, NP, & CLINICAL SPEC RESPONSIBILITIES

Title PA, NP, & CLINICAL SPEC RESPONSIBILITIES

Type Standard

CFR 485.631(c)(3)

Regulation Definition	Interpretive Guideline
Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the CAH is notified of the admission.	Interpretive Guidelines §485.631(c)(3) The CAH regulations do permit licensed mid-level practitioners, as allowed by the State, to admit patients to a CAH. However, CMS regulations do require that Medicare and Medicaid patients be under the care of an MD/DO if admitted by a mid-level practitioner and the patient has any medical or psychiatric problem that is present on admission or develops during hospitalization that is outside the scope of practice of the admitting practitioner. Evidence of being under the care of an MD/DO must be in the patient's medical record. If a CAH allows a mid-level practitioner to admit and care for patients, as allowed by State law, the governing body (or responsible individual) and medical staff would have to establish policies and bylaws to ensure patient safety. As applicable, the patient's medical record must demonstrate MD/DO responsibility/care.

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Survey Procedures §485.631(c)(3)

" Verify that admitting privileges are limited to those categories of practitioners as allowed by State law.

" Verify that patients are admitted only by those practitioners who are currently licensed and have been granted admitting privileges by the governing body (or responsible individual) in accordance with State laws and medical staff bylaws.

" Verify that an MD/DO is responsible for and is monitoring the care of each Medicare or Medicaid patient for all medical problems during the hospitalization.

" If mid-level practitioners admit patients, verify that every Medicare/Medicaid patient is being monitored by an MD/DO who is responsible for any medical problem outside the scope of practice of the admitting practitioners.

FED - C0999 - PERIODIC REVIEW OF CLINICAL PRIVILEGES

Title PERIODIC REVIEW OF CLINICAL PRIVILEGES

Type Standard

CFR 485.631(d)(1)
485.631(d)(2)
485.631(d)(3)

Regulation Definition

§485.631(d) Standard: Periodic review of clinical privileges and performance. The
CAH requires that-

(1) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialist, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH.

(2) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by-

Interpretive Guideline

Interpretive Guidelines §485.631(d)

Guidance is pending and will be updated in future release.

Survey Procedures §485.631(d)

Survey Procedures are pending and will be updated in future release.

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(i) One hospital that is a member of the network, when applicable;

(ii) One Quality Improvement Organization (QIO) or equivalent entity;

(iii) One other appropriate and qualified entity identified in the State rural health care plan;

(iv) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patient under an agreement between the CAH and a distant-site hospital, the distant-site hospital; or

(v) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, one of the entities listed in paragraphs (d)(2)(i) through (iii) of this section.

(3) The CAH staff consider the findings of the evaluation and make the necessary changes as specified in paragraphs (b) through (d) of this section.

FED - C1004 - PROVISION OF SERVICES

Title PROVISION OF SERVICES

Type Condition

CFR 485.635

Regulation Definition

§485.635 Condition of Participation: Provision of Services

Interpretive Guideline

Interpretive Guidelines §485.635

This condition establishes requirements related to patient care policies, required CAH services, and CAH services

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provided through agreements or arrangements. Assessment of the manner and degree of noncompliance with any one of the following standards in this condition is required in order to determine whether there is noncompliance with this condition.

FED - C1006 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

Type Standard

CFR 485.635(a)(1)

Regulation Definition

(1) The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

Interpretive Guideline

Interpretive Guidelines §485.635(a)(1)

The CAH must have written policies governing the health care services the CAH furnishes and these policies must be consistent with applicable State law. As discussed in relation to the requirements at §485.608, CMS does not interpret or enforce local law; that is the responsibility of State or local government. If surveyors identify practices related to delivery of health care services that they believe are not consistent with State law, they should refer the matter to the appropriate State authorities.

The regulation requires the CAH to furnish its health care services in accordance with its written policies. In other words, the CAH must not only have written policies, but must actually adhere to them in delivering services.

Survey Procedures §485.635(a)(1)

" Verify that the CAH has written policies covering the health care services that are furnished in the CAH.

" Observe staff delivering health care services to patients. Is the actual provision of services consistent with the CAH's written policies?

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FED - C1008 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

Type Standard

CFR 485.635(a)(2)
485.635(a)(4)

Regulation Definition

§485.635(a)(2) The policies are developed with the advice of members of the CAH's professional healthcare staff, including one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of §485.631(a)(1).

§485.635(a)(4) These policies are reviewed at least biennially by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

Interpretive Guideline

Interpretive Guidelines §485.635(a)(2) & (4)

The CAH's written policies governing patient care services must be developed with the advice of members of the CAH's professional healthcare staff. This advisory group must include:

o At least one MD or DO; and

o One or more physician assistants, nurse practitioners, or clinical nurse specialists, at least one of these non-physician practitioners if these professionals are included in the CAH's healthcare staff, as permitted at §485.631(a)(1). A CAH with no non-physician practitioners on staff is not required to obtain the services of an outside non-physician practitioner to serve on the advisory group.

The advisory group not only makes recommendations for new CAH patient care policies, but is also expected to review the existing patient care policies at least every 2 years and, if it concludes that changes are needed, recommend those changes. Policies must be reviewed and, as applicable, revised more frequently when required, for example, in response to a change in Federal or State regulations to which the CAH is subject.

The CAH must maintain documentation that provides evidence that the advisory group has conducted its reviews and made recommendations concerning patient care policies.

Although a CAH's patient care policies are developed and periodically reviewed with the advice of members of the CAH's professional healthcare staff, the final decision on the content of the written policies is made by the CAH's governing body or individual responsible for the CAH, consistent with the requirement at §485.627(a). If recommendations of the advisory group are rejected, the governing body must include in the record of its adoption of the final written policies its rationale for adopting a different policy than that which was recommended.

Survey Procedures §485.635(a)(2) & (4)

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o Review any meeting minutes for the group of healthcare professionals that advises the CAH's governing body or responsible individual on patient care policies to determine if the group's composition meets the regulatory requirements.

o Interview all staff listed as part of the policy development advisory group to determine if they had the opportunity to express opinions and make recommendations to the group, for the group's consideration as a group recommendation.

o Can the CAH provide documentation that the advisory group developed written recommendations on the CAH's patient care policies for consideration by the CAH's governing body/responsible individual?

o Is there evidence that the group reviewed the CAH's existing policies at least every 2 years and indicated whether or not it recommended any changes?

FED - C1010 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

Type Standard

CFR 485.635(a)(3)(i)

Regulation Definition

(i) A description of the services the CAH furnishes, including those furnished through agreement or arrangement.

Interpretive Guideline

Interpretive Guidelines §485.635(a)(3)(i)

The CAH's written patient care policies must describe the types of health care services that are available at the CAH, including whether those services are furnished by CAH staff or through agreements or arrangements. The types of health services described must include services provided both on-site and off-site.

Healthcare services provided through agreement or under arrangement include those provided through formal contracts, informal agreements, or lease arrangements. Services furnished under arrangement or by agreement may include both healthcare services provided on-site at the CAH by a contractor, as well as healthcare services provided to the CAH's patients outside the CAH. For example, the CAH may contract with a laboratory to provide certain laboratory services on-site, and others at an off-site laboratory; or it may contract with an imaging center for provision of certain advanced radiologic diagnostic services, such as MRI, to CAH inpatients who are temporarily moved to the center for the test and then returned to the CAH.

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The descriptions of the services provided may be brief but informative, for example, statements like "taking complete medical histories, providing complete physical examinations, laboratory tests including" (with a list of tests provided), radiologic tests and their interpretation, surgery (with a list of the types of surgery available) would satisfy this requirement.

Survey Procedures §485.635(a)(3)(i)

Verify that the CAH's healthcare policies identify and describe all healthcare services offered by the CAH, including services provided under arrangement or by agreement

FED - C1012 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

Type Standard

CFR 485.635(a)(3)(ii)

Regulation Definition	Interpretive Guideline
[The policies include the following:]	Interpretive Guidelines §485.635(a)(3)(ii)
(ii) Policies and procedures for emergency medical services.	The CAH's written patient care policies must include its policies and procedures for providing emergency services, addressing all of the requirements at 42 CFR 485.618. See the interpretive guidelines for §485.618. Survey Procedures §485.635(a)(3)(ii) Verify that written policies and procedures detail how the CAH plans to comply with the requirements of 42 CFR 485.618. Do the written policies and procedures address the following: " How the CAH provides 24 hour emergency care to its patients? " What equipment, supplies, medications, blood and blood products are maintained onsite and which are readily available for treating emergency cases by agreement at other facilities? " What types of personnel are available to provide emergency services and what are their required onsite response times?

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Do they address how the CAH coordinates with local emergency response systems?

FED - C1014 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

Type Standard

CFR 485.635(a)(3)(iii)

Regulation Definition

[The policies include the following:]

(iii) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.

Interpretive Guideline

Interpretive Guidelines §485.635(a)(3)(iii)

The written policies for the CAH's healthcare services must include guidelines, such as general instructions and protocols, for the medical management of patients' health problems. The guidelines may include directly or reference protocols that are documented elsewhere for the treatment of medical conditions that are commonly presented in the CAH.

Because nurse practitioners, clinical nurse specialists, and physician assistants may play a large role in patient care at a CAH, the CAH's policies must address the circumstances under which consultation with an MD or DO should occur and which situations require them to consult with or refer to an MD/DO for advice on how to treat a patient. The CAH's policies must also address the circumstances under which patient referral outside the CAH should occur.

The policies must also address maintenance of medical records, consistent with the requirements at §485.638. See interpretive guidelines for §485.638.

The policies must also address the CAH's procedures for periodical review and evaluation of its services, consistent with the requirements of §485.641. See interpretive guidelines for §485.641.

Survey Procedures §485.635(a)(3)(iii)

Verify that the CAH's written patient care policies:

" Address the circumstances under which consultation with other CAH professional healthcare staff, or referral outside the CAH should occur;

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" Address maintenance of medical records, in a manner consistent with the requirements at §485.638; and

" Address periodic evaluation of the CAH's healthcare services, in a manner consistent with the requirements at §485.641.

FED - C1016 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

Type Standard

CFR 485.635(a)(3)(iv)

Regulation Definition

[The policies include the following:]

(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

Interpretive Guideline

Interpretive Guidelines §485.635(a)(3)(iv)

The CAH must ensure that drugs and biologicals are managed in a manner that is safe and appropriate, and that its pharmacy system provides all drugs and biologicals prescribed by the CAH's practitioners in a timely manner for administration to its patients.

The CAH's written patient care policies must include rules governing pharmacy services within the CAH. The CAH's rules may be in the form of pharmacy services policies and procedures. These CAH rules must address storage, handling, dispensing, and administration of drugs and biologicals within the CAH. The rules must be in accordance with accepted professional principles of pharmacy and medication administration practices. Accepted professional principles include compliance with applicable Federal and State law and adherence to standards or guidelines for pharmaceutical services and medication administration issued by nationally recognized professional organizations, including, but not limited to: U.S. Pharmacopeia (www.usp.org), the American Society of Health-System Pharmacists (http://www.ashp.org/), the Institute for Safe Medication Practices (http://www.ismp.org/default.asp), the National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org); the Institute for Healthcare Improvement (http://www.ihi.org/ihi); or the Infusion Nurses Society (http://www.ins1.org).

The CAH's rules must address the following:

" Responsibility for pharmacy services

The CAH must identify the qualifications for and designate an individual who has overall responsibility for the CAH's pharmacy services, including development of the rules governing pharmacy services. The CAH and the responsible

individual must ensure adherence to State law requirements governing who may perform pharmacy services as well as requirements for supervision of pharmacy staff. The CAH and responsible individual are also responsible for assuring that pharmacy practices adhere to accepted professional principles. The CAH is expected to be able to identify the sources of accepted professional pharmacy practices that it relies upon in developing the CAH's pharmacy rules, policies and procedures.

" Storage of drugs and biologicals, including the location of storage areas, medication carts, and dispensing machines

Consistent with accepted professional principles, CAHs must demonstrate appropriate storage and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.

" Proper environmental conditions

Where the manufacturer's FDA-approved package insert specifies environmental conditions, such as temperature, humidity, exposure to light, etc., for storage of drugs, the CAH is expected to follow the labeled conditions. CAHs must exercise caution in dispensing or using any drug or biological that is not labeled to indicate proper storage conditions or that may have been stored under inadequate conditions.

" Security

The CAH must have policies and procedures that are consistent with State and Federal law to address who is authorized access to the pharmacy or drug storage area. Drugs and biologicals must be stored in a secure manner to prevent unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. For example, if medications are kept in a private office, or other area where patients and visitors are not allowed without the supervision or presence of a health care professional (for example, ambulatory infusion), they are generally considered secure. Areas restricted to authorized personnel only would generally be considered "secure areas."

CAHs are permitted flexibility in the storage of non-controlled drugs and biologicals when delivering care to patients, and in the safeguarding of drugs and biologicals to prevent tampering or diversion. An area in which staff are actively providing care to patients or preparing to receive patients, i.e., setting up for procedures before the arrival of a patient, would generally be considered a secure area. When a patient care area is not staffed, both controlled and non-controlled substances are expected to be locked.

Medication carts, anesthesia carts, epidural carts and other non-automated medication carts containing drugs or biologicals (hereafter, all referred to as "carts") must be secured when not in use. A CAH's policies and procedures are expected to address the security and monitoring of carts, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage and to ensure patient safety.

If a cart containing drugs or biologicals is in use and unlocked, someone with authorized access to the drugs and biologicals in the cart must be close by and directly monitoring the cart. That person could be a nurse, a physician, or other individual who in accordance with State and Federal law and CAH policy is authorized access to the drugs and biologicals in the cart. That individual must monitor the cart and be aware of other people's activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart.

" Handling drugs and biologicals

"Handling" includes reconstituting or mixing medications in accordance with directions contained in approved labeling provided by the drug's manufacturer. "Handling" also includes compounding or admixing of sterile intravenous preparations or of other drugs, either on- or off-site, using either CAH staff or a contracted pharmacy service. CAHs use many medications that need to be reconstituted, mixed or compounded. Whether furnishing the services via CAH staff or a contractor, the CAH is responsible for proper handling of drugs and biologicals.

Except in emergencies or when not feasible (for example, when the product's stability is short), only the pharmacy performs reconstituting, mixing, admixing or compounding.

" Compounding

All compounding of medications used or dispensed by the CAH must be performed consistent with accepted professional principles applicable to both sterile and non-sterile compounding.

Compounded medications, whether non-sterile or sterile, may be subject to physical and chemical contamination and unintended variations in strength. Microbial contamination and bacterial endotoxins are particularly hazardous with respect to compounded medications that are intended to be sterile.

A CAH pharmacy must be administered in accordance with accepted professional principles, and therefore must be able to demonstrate how it assures that all sterile and non-sterile compounded preparations dispensed and/or administered to the CAH's patients are being compounded consistent with accepted professional standards to ensure safety. The CAH must be able to provide evidence that the CAH's standard operating procedures for compounding, if

performed in-house, and for quality oversight of compounding, regardless of source, are consistent with accepted professional principles.

Compounding may take place in the CAH's pharmacy on-site and/or the CAH may obtain some or all of its compounded medications from external sources. Regardless of the source, if accepted standards for safe compounding are not met, compounded medications may contain less or more than the intended dose and/or may be chemically or microbiologically contaminated, with potentially serious adverse consequences for the patients who receive them.

" Use of Outside Compounders (also known as Outsourcing Facilities)

The Drug Quality and Security Act (DQSA), signed into law on November 27, 2013, contains provisions relating to the oversight of compounding of human drugs. The DQSA created a new section 503B in the FDCA under which a compounder may elect to become an "outsourcing facility." The law defines an "outsourcing facility" as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the FDCA. Facilities that elect to register as outsourcing facilities:

" Must comply with the FDA's Current Good Manufacturing Practice (CGMP) requirements, which contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The CGMP requirements make sure that a product is safe for use, and that it has the ingredients and strength it claims to have. The FDA's publishes the most current versions of its draft and final regulations and guidance related to compounding on its website: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm ;

" Will be inspected by FDA according to a risk-based schedule; and

" Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

In a January 2014 letter to purchasers of compounded medications (available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm380596.htm), the Commissioner of the FDA encouraged the use of registered outsourcing facilities and noted that,"[a]s a purchaser of compounded drugs, you can play an important role in improving the quality of compounded drugs by requiring compounding pharmacies that supply drugs to your facility to register as outsourcing facilities. Once they register,

you and the patients you serve can be assured that FDA will inspect these facilities on a risk-based schedule, hold them to CGMP requirements, monitor the adverse event reports they are required to submit to the agency, and require appropriate labeling."

FDA has posted a list of Registered Human Drug Compounding Outsourcing Facilities, including the end date of the last FDA inspection related to compounding, whether investigators observed any significant objectionable conditions, and whether other FDA actions were taken based on the last inspection, at: http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm378645.htm

Note that these registered outsourcing facilities are also popularly referred to as "503B pharmacies."

" Use of Compounding Pharmacies

If a CAH obtains compounded medications from a compounding pharmacy rather than a manufacturer or a registered outsourcing facility, then the CAH must demonstrate how it assures that the compounded medications it receives under this arrangement have been prepared in accordance with accepted professional principles for compounded drugs as well as applicable State or Federal laws or regulations. For example, does the contract with the vendor include provisions:

" Requiring the vendor to meet the requirements of Section 503A of the FDCA concerning pharmacy compounding of human drug products?

Note that these types of compounding pharmacies are also popularly referred to as "503A pharmacies" and generally are subject to oversight only by their State pharmacy board.

For Information - Not Required/Not to be Cited

ASHP Research and Education FoundationTM "Outsourcing Sterile Products Preparation: Contractor Assessment Tool"

The ASHP Research and Education FoundationTM offers a tool that CAHs may find useful for assessing vendors that provide compounded sterile preparations. http://www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx and click on "Start using Sterile Products Outsourcing Tool now."

" Dispensing drugs and biologicals

CAHs must comply with applicable State law that governs the qualifications, certification, or licensure of staff who dispense drugs and biologicals. There must be sufficient numbers and types of personnel to provide accurate and timely medication delivery.

Medications must be dispensed in a timely manner. The CAH must have a system that ensures medication orders get to the pharmacy promptly and medications are available for administration to patients when needed, including when the pharmacy is not open. Methods to accomplish this when the pharmacy is not open could include, but are not limited to, one or more of the following: automated dispensing units outside the pharmacy, night cabinets, contracted services after hours via telepharmacy contracting, on-call pharmacists, etc.

Concerns, issues or questions pharmacy staff have about any medication order must be clarified with the prescribing practitioner or another practitioner responsible for the care of the patient before dispensing.

A CAH may utilize a unit dose system, individual prescription, floor stock system or a combination of these systems, properly stored.

" Automated Dispensing Cabinets (ADCs) for medications are a secure option for medication storage since they ensure locked storage of medications and allow for electronic tracking of controlled substances and other drugs. These cabinets often have embedded security features, such as login and password or biometric identification so that they can only by accessed by authorized personnel.

" Policies and procedures must address who can access medications during after-hours.

Administration of drugs and biologicals to patients

CAHs must comply with applicable State law that governs the qualifications, certification, or licensure of staff who administer drugs and biologicals and must adhere to accepted standards of practice for medication administration. See the guidance for §485.635(d)(3) concerning medication administration by CAH nursing staff.

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Record keeping for the receipt and disposition of all scheduled drugs

The U.S. Department of Justice Drug Enforcement Administration (DEA) classifies drugs that are controlled in accordance with the Controlled Substances Act into five "schedules", ranging from Schedule I substances, which have a high potential for abuse and no currently accepted medical use in treatment, to Schedule V substances, which have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. The CAH is required to accurately track the receipt and disposition of all scheduled drugs used in the CAH. Components of a record system for scheduled drugs would include:

" Locked storage of scheduled drugs when not in use.

" Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs.

" The record system tracks movement of all scheduled drugs from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

" Any discrepancies in count are reconciled promptly. The CAH is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.

" Ensuring that outdated, mislabeled, or otherwise unusable drugs are not used for patient care

The CAH must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable drugs and biologicals are not available for patient use. This would include drugs that are the subject of a manufacturer's recall.

A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the FDA approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are inconsistent with the manufacturer's approved labeling.

A drug or biological is also outdated after its "beyond-use date" (BUD), which may be reached before the expiration date, but never later. The BUD takes into account the specific conditions and potential for deterioration and

microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a compounded medication.

The BUD is to be based on information provided by the manufacturer, whenever such information is available. The CAH must maintain and implement policies and procedures that provide clear and consistent direction to pharmacy staff regarding how to determine a BUD when complete BUD information is not available from the manufacturer.

For individual drug containers: each floor stock drug container is expected to be labeled with the name and strength of the drug, lot and control number equivalent, and expiration date. Appropriate accessory and cautionary statements are included as well as the expiration date and/or, if applicable, a BUD. In addition, where applicable, each patient's individual drug container is expected to be labeled with the patient's full name and quantity of the drug dispensed.

If the unit dose system is utilized, each single unit dose package is expected to be labeled with the name and strength of the drug, lot and control number equivalent, expiration date. and/or, if applicable, a BUD.

" Assessing Adverse Drug Reactions & Medication Administration Errors
In accordance with §485.635(a)(3)(v) the CAH must have a system for staff to report adverse drug reactions and medication administration errors. The pharmacy services is expected to assess all such reports to determine if problems or errors in pharmacy services caused or contributed to the adverse reaction or medication administration error. Where such problems or errors are identified, the CAH is expected to take effective action to address the identified issues.

Survey Procedures §485.635(a)(3)(iv)

" Has the CAH adopted pharmacy rules that were developed with the advice of the CAH's professional healthcare staff?

" Has the CAH identified the qualifications of and designated an individual who is responsible for developing and implementing the rules for the CAH's pharmacy services, consistent as applicable with State and Federal law?

" Review the qualifications of the responsible individual to verify that they satisfy the CAH's written criteria.

" Ask CAH practitioners, nursing and pharmacy staff whether the CAH's pharmacy service dispenses prescribed

drugs and biologicals in a timely manner. If there is evidence in medical records reviewed of late administration of prescribed medications, probe to determine whether delays are due to pharmacy dispensing delays.

" Ask the individual responsible for CAH pharmacy services what sources of accepted professional principles of pharmacy practice the CAH relies upon in developing and implementing its CAH pharmacy rules, policies and procedures. Is the source(s) a nationally recognized source?

" Are drugs and biologicals stored in a secure manner?

o Are drugs stored in areas not accessible to unauthorized personnel?

o When drugs or biologicals are kept in a patient care area during hours when patient care is not provided, are they locked up?

" Conduct a spot check of drug use and other inventory records to ensure that drugs are properly accounted for.

" Determine if the CAH has a system that tracks movement of all scheduled drugs from the point of entry into the CAH to the point of departure either through administration to the patient, destruction of the drug, or return to the manufacturer.

o Does this system provide documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs?

o Review records of scheduled drugs over a recent time period. Is there evidence of discrepancies, and if so, of efforts by the CAH to reconcile and address the discrepancies?

" Interview the person responsible for pharmacy services as well as other CAH staff to determine their understanding of the CAH's controlled drug policies.

" Verify that only a pharmacist or other personnel authorized in accordance with State and Federal law compound, label and dispense drugs or biologicals, regardless of whether the services are provided by CAH staff or under arrangement.

o Interview pharmacy and CAH staff to determine how drugs and biologicals are dispensed;

o Observe on-site dispensing operations;

" Review records to see if drugs and biologicals are removed from the pharmacy by unauthorized personnel;

" Do the CAH's pharmacy rules address ADCs, if used within the CAH? Are the ADCs being used in the manner prescribed by the CAH's rules?

" Can the CAH demonstrate that compounded medications used and/or dispensed by the hospital are being compounded consistent with standard operating procedures and quality assurance practices?

" Does the individual responsible for the pharmacy service, including compounding policies, practices and quality assurance within the CAH, and selecting and overseeing any external sources of compounded medications, have the expertise to conduct effective quality oversight?

" Can the individual responsible for the pharmacy services explain the risk level(s) of the CSPs being produced in-house and/or obtained from external sources?

" If any CSPs are produced in the CAH:

" Ask for one or more examples of situations in which a BUD had to be determined for a compounded sterile medication (CSP) based on the policy. Interview pharmacy personnel assigned to carry out this function within the CAH and/or to assess how this is done by external source(s) of CSPs. Is there evidence that the BUDs are determined consistent with the CAH's rules, policies and procedures?

" Interview staff who engage in sterile and non-sterile compounding. Are they knowledgeable about applicable levels of aseptic practices?

" Ask the individual responsible for pharmacy services to demonstrate how the following are accomplished to ensure that sterile compounding practices are consistent with standards for the risk level(s) of CSPs being produced for/dispensed to CAH patients:

" Verification of compounding accuracy and sterility.

" Environmental quality and controls, including environmental sampling; testing and monitoring; and cleaning and disinfection;

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" Personnel training and competency assessment, including but not limited to accuracy/precision in identifying and measuring ingredients; cleansing and garbing; aseptic manipulation skills; environmental quality and disinfection; appropriate work practices within and adjacent to the direct compounding area; verification/calibration of equipment; sterilization; and post-production quality checks.

" Review the CAH's procedures for maintaining the quality of CSPs during storage, transport and dispensing. Are CSPs packaged in a manner to protect package integrity and sterility? How are CSP-specific requirements with respect to motion, light exposure, temperature and potentially hazardous contents addressed? How does the CAH ensure that such information is effectively conveyed to non-pharmacy health care personnel and/or to patients/caregivers, if applicable?

" Review the pharmacy rules, policies and procedures for determining BUDs (for medications compounded in-house as well as from external sources).

" Can the CAH demonstrate that the policies and procedures are consistent with or more stringent than the applicable nationally accepted standards?

" Can it demonstrate that the pharmacy personnel assigned to determining BUDs when a manufacturer's instructions are not available have the expertise and technical support needed to properly conduct the assessments needed to make such determinations in a manner consistent with standards and hospital policies?

" Ask for one or more examples of situations in which a BUD had to be determined for a compounded sterile medication (CSP) based on the policy. Interview pharmacy personnel assigned to carry out this function within the CAH and/or to assess how this is done by external source(s) of CSPs. Is there evidence that the BUDs are determined consistent with the CAH's rules, policies and procedures?

" If the CAH obtains compounded products from an external source that is not an FDA registered outsourcing facility, can it demonstrate that it systematically evaluates and monitors whether these sources adhere to accepted professional principles for safe compounding?

" Does the CAH have a process for following up on adverse drug reactions and errors in medication administration reported by CAH staff in accordance with §485.635(a)(3)(v)? If any have been reported, did the CAH thoroughly assess and analyze them? Has the CAH taken effective preventive action to address identified issues?

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" Spot-check the labels of individual drug containers to verify that they contain the following minimal information:

o Each patient's individual drug container bears his/her full name and strength and quantity of the drug dispensed. Appropriate accessory and cautionary statements are included as well as the expiration date, and, when applicable, a BUD.

o Each floor stock container bears the name and strength of the drug, lot and control number of equivalent, expiration date, and, when applicable, a BUD.

" If the unit dose system is utilized, verify that each single unit dose package bears name and strength of the drug, lot and control number equivalent, expiration date, and, when applicable, a BUD.

" Spot-check patient-specific and floor stock medications to identify expired, mislabeled or unusable medications, including medications that are past their BUD.

FED - C1018 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

Type Standard

CFR 485.635(a)(3)(v)

Regulation Definition

[The policies include the following:]

(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

Interpretive Guideline

Interpretive Guidelines §485.635(a)(3)(v)

CAH staff must report all drug (medication) administration errors and all adverse drug reactions. This required reporting includes two distinct steps in the reporting of drug (medication) administration errors and adverse drug reactions. The first and highest priority reporting relates to the care of the patient, at time of occurrence. The second reporting step is related to the CAH-wide Quality Assurance review as addressed in §485.641(b).

" Medication administration error:

The National Coordinating Council Medication Error Reporting and Prevention definition of a medication error is "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product

labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use." A medication administration error is one that occurs in the phase of the medication process where the drug actually enters the patient by one of various possible routes, e.g., orally, intravenously, etc.

" Adverse drug reaction:

The American Society of Health-System Pharmacists (ASHP) defines an adverse drug reaction (ADR) as "Any unexpected, unintended, undesired, or excessive response to a drug that:

1. Requires discontinuing the drug (therapeutic or diagnostic)
2. Requires changing the drug therapy
3. Requires modifying the dose (except for minor dosage adjustments)
4. Necessitates admission to a hospital
5. Prolongs stay in a health care facility
6. Necessitates supportive treatment
7. Significantly complicates diagnosis
8. Negatively affects prognosis, or
9. Results in temporary or permanent harm, disability, or death.

Consistent with the definition, an allergic reaction (an immunologic hypersensitivity occurring as the result of unusual sensitivity to a drug) and an idiosyncratic reaction (an abnormal susceptibility to a drug that is peculiar to the individual) are also considered ADRs."

Patient Care

In the case of ADRs or medication administration errors that are not caught before they reach the patient, a "report" must be made to a practitioner responsible for the care of the patient.

For example, if a medication actually is administered to a patient when it should not be, or the wrong dose is administered, or the wrong route of administration is used, etc., or a medication that should have been administered to the patient has not been administered in a timely manner, then the medication administration error has reached the patient and must be reported to the responsible practitioner.

If, on the other hand the wrong dose of a drug is prepared for a patient, but a nurse catches this and does not give that dose to the patient, then a medication administration error has occurred, but the error has not reached the patient, and

thus does not need to be reported to the responsible practitioner.

Not every medication administration error that reaches the patient causes harm or has the potential to cause harm; it depends both on the drug and on the patient's condition.

In the case of all ADRs and any medication administration error that has harmed or has reached the patient and could potentially cause harm, the report to a practitioner must be made immediately after the staff identify the adverse reaction or (potentially) harmful error, to enable a timely assessment and intervention. The report must be made directly in a manner that confirms a practitioner received the report, for example, via a phone call. If the impact of the medication error that reached a patient is unknown, the error must be reported to a practitioner immediately. Documentation of the error or reaction, including notification to the practitioner, must be in the patient's medical record.

Medication administration errors that have reached the patient but result in no harm and do not have the potential to cause harm can be reported to a practitioner during usual working hours. For example, if an over-the counter analgesic dose is missed during the night shift, it can be reported first thing in the morning as no further intervention would be required by the practitioner. CAHs should provide clinical staff with expected guidance on how to respond to these situations.

Quality Assurance/Improvement Reporting:

Reduction of medication administration errors and ADRs may be facilitated by effective internal CAH reporting that can be used to assess vulnerabilities in the medication process and implement corrective actions to reduce or prevent reoccurrences. To facilitate reporting, the CAH must educate staff on medication administration errors and ADRs including the criteria for those errors and ADRs that are to be reported for quality assurance/improvement purposes, and how, to whom and when they should be reported.

Reporting for quality assurance/improvement purposes covers all identified medication errors, regardless of whether or not they reach the patient, and those ADRs meeting the criteria specified in the CAH's policies.

FED - C1020 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

Type Standard

CFR 485.635(a)(3)(vi)

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Regulation Definition	Interpretive Guideline
[The policies include the following:] (vi) Procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices. All patient diets, including therapeutic diets, must be ordered by the practitioner responsible for the care of the patients or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff in accordance with State law governing dietitians and nutrition professionals and that the requirement of § 483.25(i) of this chapter is met with respect to inpatients receiving post CAH SNF care.	Interpretive Guidelines §485.635(a)(3)(vi) Guidance is pending and will be updated in future release. Survey Procedures §485.635(a)(3)(vi) Survey Procedures are pending and will be updated in future release.

FED - C1022 - PATIENT CARE POLICIES

Title PATIENT CARE POLICIES

Type Standard

CFR 485.635(a)(4)

Regulation Definition	Interpretive Guideline
These policies are reviewed at least biennially by the group of professional personnel required under paragraph (a)(2) of this section and updated as necessary by the CAH.	Interpretive Guidelines §485.635(a)(4) Guidance is pending and will be updated in future release. Survey Procedures §485.635(a)(4) Survey Procedures are pending and will be updated in future release.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C1024 - PATIENT SERVICES

Title PATIENT SERVICES

Type Standard

CFR 485.635(b)(1)(i)

Regulation Definition

(1) General

(i) The CAH provides those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These CAH services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

Interpretive Guideline

Interpretive Guidelines §485.635(b)(1)(i)

This regulation addresses the minimum level of outpatient services (with the exception of emergency services - see §485.635(b)(4)) which a CAH must provide. Such services must be provided on-site at the CAH, but may be provided either by CAH staff or under an arrangement or contract. At a minimum, the CAH must provide those diagnostic and therapeutic services and supplies which are typically found in an ambulatory healthcare setting where patients first come into contact with the healthcare delivery system. The services required to be provided must, at a minimum, reflect the scope and complexity of services provided in a physician's office or in a hospital outpatient or emergency department that furnishes low intensity (i.e., less complex) services. Such services include, but are not limited to: taking a patient's medical history; conducting a physical examination of the patient; specimen collection, assessment of health status, and treatment for a variety of medical conditions. The extent of the CAH's outpatient services is expected to be sufficient to meet the needs of the patients it services for basic ambulatory care services. Further, the CAH's outpatient services must be integrated with its inpatient services.

For those outpatient services that fall only within the scope of practice of a physician or non-physician practitioner, in order to demonstrate compliance, a CAH physician or non-physician practitioner must be available to treat patients at the CAH when such outpatient services are provided. This requirement does not mean the CAH must have a practitioner physically present in the CAH 24 hours per day, seven days per week. See the discussion of required emergency services at §485.618(d) concerning required response times for a physician or non-physician practitioner to come to the CAH to provide medical care.

Survey Procedures §485.635(b)(1)(i)

" Does the CAH provide on-site outpatient services that are typical of those provided in a physician office or low intensity hospital outpatient or emergency department, including medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions?

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" Determine that the outpatient services are integrated with the appropriate CAH inpatient services in accordance with the needs of the patient care provided.

" Verify that the types and number of qualified personnel are appropriate for the scope and complexity of the outpatient services offered. Review personnel files or contracts to verify current licensure, certifications and training of staff consistent with applicable State laws.

" Verify that equipment, staff and facilities are adequate to provide the outpatient services and are in accordance with acceptable standards of practice.

FED - C1026 - PATIENT SERVICES

Title PATIENT SERVICES

Type Standard

CFR 485.635(b)(1)(ii)

Regulation Definition	Interpretive Guideline
(1) General]	Interpretive Guidelines §485.635(b)(1)(ii)
(ii) The CAH furnishes acute care inpatient services.	In accordance with §485.620(b), CAHs are required to have an average annual per acute inpatient length of stay that does not exceed 96 hours. Accordingly, CAHs are expected to provide less complex inpatient services in order to comply with the length of stay requirement. Furthermore, for each Medicare beneficiary, the CAH is required in accordance with Medicare payment law and regulations to have the practitioner who admits the beneficiary as an inpatient certify that the beneficiary may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the CAH. However, while it may be true that CAHs generally are not expected to handle patients requiring complex, specialized inpatient services, such as those services provided by trauma centers, or cardiac surgery centers, CAHs should be able to handle a range of patient needs requiring inpatient admission. CMS does not believe it is in the best interest of patients for them to routinely be transferred to a more distant hospital if instead their care can be provided locally without compromising quality or the length of stay requirements (78 FR 50749). Accordingly, acute inpatient services must be furnished to patients who present to the CAH for treatment so long as the CAH has an available inpatient bed and the treatment required to appropriately care for the patient is within the scope of services offered by the CAH. Given the resources of the CAH, the needs of the community it serves, and the variable nature of a CAH's inpatient census, a CAH may not be actively treating inpatients at all times. CAHs may experience significant seasonal

variations in the inpatient occupancy rates as well as variations that are a function of the size of the community in which the CAH is located.

A CAH is not required to maintain a minimum average daily census of patients receiving inpatient acute care services or maintain a minimum number of beds that are to be used for inpatient services. However, in determining compliance with this requirement factors to be considered include, but are not limited to, the following:

" What is the volume of emergency services the CAH provides on average quarterly and annually?

" What is the number of certified inpatient beds in the CAH?

" Are there dedicated observation beds in the CAH? If so, how many compared to the number of inpatient beds?

" What is the average acute care occupancy rate for the CAH's inpatient beds quarterly and annually?

" What is the volume of acute inpatient admissions in the CAH quarterly and annually?

" What is the volume of patients placed in observation status in the CAH quarterly and annually?

" What is the percentage of emergency department patients admitted to the CAH as an inpatient versus transferred to a hospital quarterly and annually?

" What is the range, volume and complexity of outpatient services the CAH provides?

While there is no specific formula for determining the number of patients a CAH is expected to admit, surveyors must be alert to disproportionate relationships among the CAH's various services. For example, if a CAH has only 4 certified beds and an average of 3 acute care inpatients per month, but has 18 observation beds that have an annual occupancy rate of 85%, has an ED staffed by physicians 24/7 and sees 9,000 ED patients/year, offers extensive and complex outpatient services, such as chemotherapy, advanced diagnostic imaging, sleep lab services, and same day surgery, but transfers to another hospital from the ED almost all patients who need inpatient admission, then these inpatient services would not be reasonably proportional to the overall mix and volume of services offered by the CAH. Based on data published by the Agency for Healthcare Research and Quality (AHRQ), in 2008 approximately 8.3 percent of emergency department (ED) visits in a rural "hospital" resulted in an inpatient admission, compared to 16 percent for non-rural hospital ED visits. Also, a higher percentage of rural ED patients were likely to be discharged - 91.7% compared to 84% for non-rural hospitals. The AHRQ rural hospital data included both hospitals

and CAHs, with CAHs accounting for 51 percent of rural EDs. Other published AHRQ data indicates that, in 2009, 3 percent of patients who lived in a rural area were transferred from the ED where they presented to a hospital, compared to 1.5 percent of all patients nationally who presented to an ED.

Given that a CAH may offer fewer services than even the average rural hospital and is expected to achieve a 96-hour average length of stay or less, there is no expectation that every CAH is expected to admit 8 percent of its ED patients. This benchmark can, however, provide a useful starting point for assessing compliance.

" Generally, if a CAH admits at least 8 percent of its ED patients annually, it would be considered compliant with the requirement to provide inpatient services and surveyors do not have to investigate further.

" If a CAH admits less than 8 percent of its ED patients annually, this is not in and of itself evidence of noncompliance. More investigation is needed to assess compliance by determining whether the volume of activity and number of staff the CAH has for its ED, other outpatient, and inpatient services are reasonably related to each other. There can be great variation among CAHs in their volume and types of activities, despite their relative similarity in size, making a "one size fits all" formula inappropriate. Researchers in one State with 79 CAHs found that they averaged 3,851 ED visits annually, but that visits for individual CAHs ranged from a low of 389, or a little more than one patient per day, to a high of 14,425, or about 40 patients per day. CAHs in this State averaged 19,705 other types of outpatient visits annually, but again the range was very large, from a low of 89 to a high of 86,367 per year. For inpatient admissions the annual average was 836, ranging from a low of 100 to a high of 3,838 . Presentation of the data found in this State is not intended to provide benchmarks for CAHs in other States, but rather to emphasize the tremendous range in the volume of activity among CAHs, even within one State.

" A couple of extreme but illustrative examples are presented below to indicate the types of factors to be considered when assessing whether the CAH satisfies the requirement to provide inpatient services:

" Example #1: A CAH has a very low volume of ED visits, such as 2 or fewer patients per day on average, discharges over 90% of its annual ED patients, has a total professional health care staff that consists of one physician who spends a limited amount of time on-site, and one nurse practitioner who works days five days per week. In this case it would not be unreasonable for the CAH to admit a patient for acute inpatient services only occasionally and transfer a majority of those ED patients who require inpatient services to a hospital.

" Example #2: A CAH has 50 ED visits per day on average, 4 certified inpatient beds, 2 inpatient admissions per month on average (all elective surgery patients who started as outpatient cases), 10 dedicated observation beds and places about 2 ED patients per day in observation; transfers out to a neighboring hospital an average of 15 ED

patients per week who require admission, has twenty physicians on staff, is performing an average of three thousand outpatient surgeries per year, provides outpatient chemotherapy, cardiology and advanced diagnostic imaging, and has a total of about 40,000 outpatient visits per year, not counting ED visits. This CAH's services are very skewed toward outpatient services, and the needs of its patient population for inpatient services do not appear to be met by the CAH. The CAH might arguably have the staff to provide a larger volume of inpatient services to many of the ED patients who require admission. The CAH would be expected to demonstrate to the surveyor why it could be reasonable for its inpatient capacity and admissions to be so disproportionately small compared to its outpatient services volume and capabilities, and in view of the needs of its ED patients for inpatient services. The surveyor would also review the medical records of a sample of ED patients transferred out to see if they required services the CAH's professional healthcare staff is not able to provide. (This case might also raise EMTALA issues related to on-call lists and appropriate transfers. See Appendix V)

" Example #3: A CAH has 25 ED visits per day, 25 certified beds, 23 of which, on average, are used for swing-bed services and are occupied by nursing home or skilled nursing facility residents. The CAH transfers out to a neighboring hospital an average of eight ED patients per week who require admission, and admits an average of one patient per month for acute inpatient services. The CAH has fifteen physicians on staff, is performing an average of 800 outpatient surgeries per year, provides outpatient chemotherapy, cardiology and advanced diagnostic imaging, and has a total of about 20,000 outpatient visits per year, not counting ED visits. In this situation the CAH's services are skewed towards outpatient and long-term care services and the needs of its patient population for inpatient services do not appear to be met by the CAH. The CAH would be expected to demonstrate to the surveyor why it could be reasonable for its inpatient acute care capacity and admissions to be so disproportionately small compared to its outpatient and long term care services and to the needs of its ED patients for inpatient services. The surveyor would also review the medical records of a sample of ED patients transferred out to see if they required services the CAH's professional healthcare staff is not able to provide. (This case might also raise EMTALA issues related to on-call lists and appropriate transfers. See Appendix V)

Survey Procedures §485.635(b)(1)(ii)

" Verify that the CAH is furnishing acute care inpatient services by reviewing data on the number of patients admitted over the prior year.

" Determine the percentage of ED visits that result in an admission to the CAH. If fewer than eight percent of ED visits lead to an inpatient admission, review data on transfers of ED patients, overall staffing, the volume and type of outpatient services offered, including observation services, and swing bed services to determine whether there is a reasonably proportionate relationship among the various services the CAH provides.

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" Review a sample of records of the patients the CAH transferred and determine if the transfers were appropriate based on the services available at the CAH.

FED - C1028 - LABORATORY SERVICES

Title LABORATORY SERVICES

Type Standard

CFR 485.635(b)(2)

Regulation Definition

The CAH provides basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include the following:

(i) Chemical examination of urine by stick or tablet method or both (including urine ketones).

(ii) Hemoglobin or hematocrit.

(iii) Blood glucose.

(iv) Examination of stool specimens for occult blood.

(v) Pregnancy tests.

(vi) Primary culturing for transmittal to a certified laboratory.

Interpretive Guideline

Interpretive Guidelines §485.635(b)(2)

Laboratory services that must be provided on-site at the CAH's main campus are the tests specified in the regulation, which would be considered the minimum necessary for diagnosis and treatment of a patient:

" Chemical examination of urine by stick or tablet method or both (including urine ketones);

" Hemoglobin or hematocrit;

" Blood glucose;

" Examination of stool specimens for occult blood;

" Pregnancy tests; and

" Primary culturing for transmittal to a certified laboratory.

These services may be provided by CAH staff or under arrangement or agreement with a laboratory, or through a combination of CAH staff and a laboratory under arrangement. Laboratory services, whether provided directly by the CAH or under an arrangement with a laboratory contractor, must have a current Clinical Laboratory Improvement Act (CLIA) certificate or waiver for all tests performed and meet the laboratory requirements specified in Part 493 of this chapter. Compliance with Part 493 is not assessed by CAH surveyors evaluating compliance with the CAH conditions of participation, but surveyors are expected to refer potential issues they may identify to the program responsible for CLIA certification.

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Given that the CAH must provide emergency services 24 hours a day, 7 days a week, the CAH must determine which laboratory services are to be immediately available to meet the emergency needs of patients and how the services are to be provided. The emergency laboratory services available should reflect the scope and complexity of the CAH's emergency services operations.

The provision of laboratory services that exceed the minimum tests specified is optional. The scope and complexity of the CAH's laboratory service must be adequate to support the clinical services the CAH offers to patients. Additional laboratory services may be offered directly or through arrangement. The CAH should have a written description of all the laboratory services that it provides, including those delivered on routine and stat basis.

The laboratory must have written policies and procedures for the collection, preservation, transportation, receipt, and reporting of tissue specimen results.

Patient laboratory results and all other laboratory clinical patient records are considered patient medical records and the CAH must comply with the requirements of the clinical records CoP at §485.638(a)(4)(ii).

Survey Procedures §485.635(b)(2)

" Ask the CAH to identify which laboratory services it offers. Are the required lab services provided at the CAH's main campus?

" Does the CAH have a CLIA certificate or waiver, as applicable, for all laboratory tests performed in CAH facilities?

" Verify that the CAH has a procedure in place for obtaining tests that are needed but unavailable at the CAH laboratory.

" If the CAH refers specimens to another laboratory for testing, does the CAH have documentation that the referral laboratory is CLIA certified for the appropriate tests?

" Has the CAH identified laboratory services that must be available to support the emergency services the CAH provides? Ask the staff who furnish emergency services whether these laboratory services are available whenever they provide emergency services.

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FED - C1030 - RADIOLOGY SERVICES

Title RADIOLOGY SERVICES

Type Standard

CFR 485.635(b)(3)

Regulation Definition

§485.635(b)(3) Radiology services. Radiology services furnished by the CAH are provided by personnel qualified under State law, and do not expose CAH patients or personnel to radiation hazards.

Interpretive Guideline

Interpretive Guidelines §485.635(b)(3)

Radiologic services encompass many different modalities used for the purpose of medical imaging. Each type of technology gives different information about the area of the body being studied or treated, related to possible disease, injury, or the effectiveness of medical treatment. All the modalities use some form of radiation, such as ionizing radiation (radiography, computed tomography, fluoroscopy), which has enough energy to potentially cause damage to DNA, and other forms of radiation (ultrasound, magnetic resonance imaging) to view the human body in order to diagnose, monitor, or treat medical conditions.

Radiological services furnished by the CAH may be provided by CAH staff or under arrangement. The CAH must maintain and have available diagnostic radiological services to support the services the CAH provides to meet the needs of its patients. These services must be available at all times the CAH provides services, including emergency services. The CAH has the flexibility to choose the types and complexity of radiologic services offered. They may offer only a minimal set of services or a more complex range of services (including nuclear medicine).

All radiological services provided by the CAH, including diagnostic, therapeutic, and nuclear medicine, must be provided in accordance with acceptable standards of practice and must meet professionally approved standards for safety. The scope and complexity of radiological services offered should be specified in writing and approved by the governing body (or responsible individual).

Acceptable standards of practice include maintaining compliance with appropriate Federal and State laws, regulations and guidelines governing radiological services, including facility licensure and/or certification requirements, as well as any standards and recommendations promoted by nationally recognized professions such as the American Medical Association, Radiological Society of North America, Alliance for Radiation Safety in Pediatric Imaging, American Society of Radiologic Technologists, American College of Cardiology, American College of Neurology, American College of Physicians, American College of Radiology, etc.

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Qualified Radiologic Personnel

There must be written policies that are developed and approved by the governing body or responsible individual and are consistent with State law, that designate which personnel are qualified to use the radiological equipment and administer procedures.

When telemedicine is used to provide teleradiology services, radiologists who interpret radiological tests must satisfy the telemedicine privileging requirements §485.616(c)(3).

In addition to radiologists, there are other types of healthcare personnel who, depending on State law and the scope and complexity of the CAH's radiologic services, may be involved in the delivery of radiologic services in the CAH, including radiologic technologists and medical physicists. Radiologic technologists perform diagnostic imaging examinations and administer radiation therapy treatments. They are educated in anatomy, patient positioning, examination techniques, equipment protocols, radiation safety, radiation protection and basic patient care.

Safety from Radiation Hazards

The CAH must adopt and implement policies and procedures that ensure safety from radiation hazards for patients and personnel. The CAH must implement and ensure compliance with its established safety standards. The policies must address at least the following:

" Adequate radiation shielding for patients, personnel and facilities, which includes:

o Shielding built into the CAH's physical plant, as appropriate;

o Types of personal protective shielding to be used, under what circumstances, for patients, including high risk patients as identified in radiologic services policies and procedures, and CAH personnel;

o Types of containers to be used for various radioactive materials, if applicable, when stored, in transport, in use, and when disposed;

o Clear signage identifying hazardous radiation areas;

" Labeling of all radioactive materials, including waste, with clear identification of all material(s);

" Transportation of radioactive materials between locations within the CAH;

" Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;

" Periodic testing of equipment for radiation hazards;

" Periodic checking of staff regularly exposed to radiation for the level of radiation exposure, via exposure meters or badge tests;

" Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and

" Disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste.

Radiologic Equipment Maintenance

The CAH must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted, and that problems identified are corrected in a timely manner. The CAH must ensure that equipment is inspected and maintained in accordance with Federal and State laws and regulations, as applicable, and the manufacturer's recommendations. The CAH must have a system in place to correct identified problems. The CAH must have evidence of its inspections and corrective actions.

Radiology Records

The CAH radiology records are to be treated in the same manner as any other part of a medical record. The medical records CoP at §485.638(a)(4)(ii) requires that the CAH maintain reports of physical examinations, diagnostic and laboratory test results, and consultative findings.

Survey Procedures §485.635(b)(3)

" Interview the person responsible for radiologic services.

" Ask what radiologic services the CAH offers at its main campus. At off-site locations ask how the CAH ensures patient needs for radiologic services are met, if applicable.

" Ask how the CAH ensures that radiologic services are provided consistent with acceptable standards of practice.

" Safety:

" Determine if the radiologic services staff is familiar with the policies and procedures related to safety.

" Verify that patient shielding (aprons, etc.) are properly maintained and routinely inspected by the CAH.

" Observe areas where radiologic testing is done and check for safety problems.

" Verify that hazardous materials are clearly labeled. Review records to verify that they are tracked, handled and stored properly in a safe manner with the requisite containers.

" Review records to verify that periodic tests of radiology personnel by exposure meters or test badges are performed.

" Equipment maintenance:

" Review the inspection records to verify that periodic inspections and maintenance are conducted in accordance with the manufacturer's recommendations.

" Determine whether any problems identified are properly corrected in a timely manner and the correction is maintained over time.

" Qualified Personnel:

" Are studies interpreted only by qualified staff approved to do so by the CAH's governing body or responsible individual?

" Determine which staff are using various pieces of radiological equipment and/or administering patient procedures. Review their personnel folders to determine if they meet the qualifications for tasks they perform, as established in the CAH's policies and consistent with state law.

" Ask staff to explain the protocol for the procedures/studies they administer. Ask to see the CAH's written protocols and verify that the staff is adhering to them.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C1032 - EMERGENCY PROCEDURES

Title EMERGENCY PROCEDURES

Type Standard

CFR 485.635(b)(4)

Regulation Definition	Interpretive Guideline
§485.635(b)(4) Emergency procedures. In accordance with the requirements of §485.618, the CAH provides medical services as a first response to common life-threatening injuries and acute illness.	Interpretive Guidelines §485.635(b)(4) Emergency services must be provided by the CAH at the CAH campus either by CAH staff or by individuals providing services under arrangement or agreement. The individuals providing the services must have the ability to recognize a patient's need for emergency care at all times. The CAH must provide medically appropriate initial interventions, treatment and stabilization of any patient who requires emergency services. Survey Procedures §485.635(b)(4) The survey procedures for §485.618 apply.

FED - C1034 - PROVIDED THROUGH AGREEMENTS OR ARRANGEMENTS

Title PROVIDED THROUGH AGREEMENTS OR ARRANGEMENTS

Type Standard

CFR 485.635(c)(1)
485.635(c)(5)

Regulation Definition	Interpretive Guideline
(1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including (5) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site	Interpretive Guidelines §485.635(c)(1)&(c)(5) All agreements for providing health care services to the CAH's patients must be with a provider or supplier that participates in the Medicare program, except in the case of an agreement with a distant-site telemedicine entity for the provision of telemedicine services. The agreements should describe routine procedures (e.g., for obtaining outside laboratory tests); and there should be evidence in the agreement or arrangement that the governing body (or responsible individual) is responsible for these services provided under agreement or arrangement. Individual

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telemedicine entity, the distant-site telemedicine entity is not required to be a Medicare-participating provider or supplier.

agreements or arrangements should be revised when the nature and scope of services provided has changed.

The governing body (or responsible individual) has the responsibility for ensuring that CAH services are provided according to acceptable standards of practice, irrespective of whether the services are provided directly by CAH employees or indirectly by agreement or arrangement. The governing body must take actions through the CAH'S QA program to: assess the services furnished directly by CAH staff and those services provided under agreement or arrangement, identify quality and performance problems, implement appropriate corrective or improvement activities, and to ensure the monitoring and sustainability of those corrective or improvement activities.

Survey Procedures §485.635(c)(1)&(c)(5)

" Determine whether the CAH verifies that every entity providing health care services to the CAH's patients under an agreement participates in Medicare, with the exception of a distant-site telemedicine entity providing telemedicine services under an agreement or arrangement.

FED - C1036 - AGREEMENTS AND ARRANGEMENTS

Title AGREEMENTS AND ARRANGEMENTS

Type Standard

CFR 485.635(c)(1)(i)
485.635(c)(2)

Regulation Definition

[The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including-]

(i) Services of doctors of medicine or osteopathy;

§485.635(c)(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

Interpretive Guideline

Interpretive Guidelines §485.635(c)(1)(i) & §485.635(c)(2)

In accordance with §485.631(a)(1), the CAH is required to have at least one doctor of medicine or osteopathy (MD or DO) on its staff who is responsible for the functions described in §485.631(b). CAHs are free to have additional MDs or DOs on staff, part- or full-time. MDs and DOs who have been credentialed and privileged to provide services on-site at the CAH are part of the CAH's professional healthcare staff, even if they are not at the CAH full-time; they would not be considered to be providing services under an arrangement and would not be covered by these regulatory provisions. These regulations also do not apply to MDs and DOs who provide telemedicine services to the CAH's patients, even when they are provided under arrangement. (See §485.616(c) and §485.635(c)(5) concerning telemedicine requirements.)

Under §485.635(c)(1)(i) & §485.635(c)(2), the CAH must have policies and procedures for referring patients it discharges who need additional specialized MD or DO services not available at the CAH. The policies and

procedures must at a minimum identify the services for which the CAH has referral arrangements or agreements, as well as the information to be provided to referred patients. MDs and DOs to whom the CAH refers its patients must participate in Medicare.

The CAH is not required to have referral arrangements in writing, but if it does not, then it must be able to document that patients it has referred to an outside MD or DO have been offered appointments and treatment.

Survey Procedures §485.635(c)(1)(i) & §485.635(c)(2)

" Verify that the CAH has arrangements with one or more MDs or DOs for referral of discharged CAH patients who need medical services not available at the CAH.

" Are the referral arrangements in writing? If not, can the CAH document that patients referred to an outside MD or DO have been offered appointments and treatment?

" Does the CAH have policies and procedures addressing referral of discharged patients? Are the CAH's practitioners and staff who handle the discharge of patients familiar with these policies and procedures?

FED - C1038 - AGREEMENTS AND ARRANGEMENTS

Title AGREEMENTS AND ARRANGEMENTS

Type Standard

CFR 485.635(c)(1)(ii)
485.635(c)(2)

Regulation Definition

[The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including-]

(ii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH; and

§485.635(c)(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

Interpretive Guideline

Interpretive Guidelines §485.635(c)(1)(ii) & §485.635(c)(2)

In accordance with §485.635(b)(2), the CAH is required to furnish, either directly by the CAH staff, under arrangement or agreement, or through a combination of CAH staff and a laboratory under arrangement basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). These services must be provided on-site at the CAH and may be provided either by CAH staff or under an arrangement with a laboratory. The CAH is also free to provide additional laboratory services on-site, beyond the minimum required services. The provision at §485.635(c)(1)(ii) does not apply to laboratory services provided on-site.

Instead, this provision addresses the requirement for the CAH to have an arrangement or agreement, as appropriate, with a laboratory that can provide additional or specialized clinical laboratory services that are not available at the CAH. The arrangement or agreement may provide either for the CAH to draw the specimens to be examined and send them to the outside laboratory. The CAH is not required to have a written agreement or arrangement, but if it does not, it is expected to be able to document that an outside laboratory to which it sends specimens provides the CAH with test results.

Laboratories that provide additional diagnostic and clinical laboratory services to a CAH under agreement or arrangement must have a current Clinical Laboratory Improvement Act (CLIA) certificate or waiver for all tests performed and meet the laboratory requirements specified in Part 493 of this chapter. The CAH is expected to have evidence of the outside laboratory to which it refers patients holding a current CLIA certificate or waiver.

The CAH must have policies and procedures for additional or specialized laboratory services provided under arrangement or agreement which address at least the following: the specific laboratory services provided under arrangement; and the collection, preservation, transportation, receipt, and reporting of tissue specimen results.

Likewise, although the CAH is expected to provide radiology services in accordance with §485.635(b)(3), it is also expected to have an arrangement or agreement, as appropriate, with other providers or suppliers of diagnostic imaging services, including advanced diagnostic imaging services, such as magnetic resonance imaging, computed tomography, etc. The CAH is not required to have a written agreement or arrangement, but if it does not, it is expected to be able to document that an outside diagnostic imaging facility to which it sends patients provides the CAH with the resulting studies and reports.

Patient diagnostic imaging studies and reports, laboratory results and all other laboratory clinical patient records must be included in the patient's medical record and meet all requirements at §485.638(a)(4)(ii).

Survey Procedures §485.635(c)(1)(ii) & §485.635(c)(2)

" Verify that the CAH has an agreement or arrangement with an outside laboratory and an outside diagnostic imaging facility for services not provided in the CAH.

" Ask the CAH how it ensures that the laboratory with which it has an agreement or arrangement holds the necessary CLIA certification.

" If the agreement or arrangement is not in writing, can the CAH document that it is sending specimens to an

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outside laboratory and patients to an outside diagnostic imaging facility when needed, and that it is receiving test results?

" Do policies and procedures address which imaging and lab services are provided under arrangement, as well as, for lab services, collection, preservation, transportation, receipt, and reporting of tissue specimen results?

FED - C1040 - AGREEMENTS AND ARRANGEMENTS

Title AGREEMENTS AND ARRANGEMENTS

Type Standard

CFR 485.635(c)(1)(iii)

Regulation Definition

[The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including-]

(iii) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.

Interpretive Guideline

Interpretive Guidelines §485.635(c)(1)(iii)

If the CAH does not provide all food and other services required to meet the nutritional needs of the CAH's inpatients using CAH staff, then the CAH must provide these services under an agreement or arrangement.

The CAH must assure that dietary services provided under an agreement or arrangement are provided in accordance with the CAH's policies adopted as required by §485.635(a)(3)(vii). Unless the CAH is a grandfathered co-located CAH (see §485.610(e)(1)) that has an arrangement with the co-located facility to provide food services to the CAH's inpatients, it is expected that the CAH's vendor provides dietary services on-site at the CAH in order to meet the needs of the CAH's inpatients. Surveyors assess compliance with the requirements of §485.635(a)(3)(vii) in the same manner, regardless of whether the services are provided by CAH staff or a vendor. In the case of a grandfathered co-located CAH that obtains food services from the co-located facility, surveyors must assess the food service operations in the co-located facility as part of the CAH survey.

Survey Procedures §485.635(c)(1)(iii)

" Verify that the CAH has an agreement or arrangement with a vendor to provide dietary services to inpatients if the CAH does not use its own staff to provide these services.

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FED - C1042 - AGREEMENTS AND ARRANGEMENTS

Title AGREEMENTS AND ARRANGEMENTS

Type Standard

CFR 485.635(c)(3)

Regulation Definition

§485.635(c)(3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.

Interpretive Guideline

Interpretive Guidelines §485.635(c)(3)

The CAH must maintain a list of all patient care services furnished by the CAH through arrangements or agreements. The list must be updated each time a contracted service is added or removed. For each service the list must include, at a minimum, the following information:

" The service(s) being offered;

" The individual(s) or entity providing the service(s);

" Whether the services are offered on- or off-site;

" Whether there is any limit on the volume or frequency of the services provided; and

" When the service(s) are available.

Survey Procedures §485.635(c)(3)

" Review the list of contracted services and verify that it contains all required information.

" Ask the CAH for evidence that the list is updated whenever there are changes.

" Ask various CAH staff during the course of the survey whether they work directly for the CAH or some other entity; check that services provided by staff employed by outside entities are on the list of contracted services.

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FED - C1044 - AGREEMENTS AND ARRANGEMENTS

Title AGREEMENTS AND ARRANGEMENTS

Type Standard

CFR 485.635(c)(4)(i)

Regulation Definition

§485.635(c)(4) The person principally responsible for the operation of the CAH under
§485.627(b)(2) of this chapter is also responsible for the following:

(i) Services furnished in the CAH whether or not they are furnished under arrangements or agreements.

(ii) Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.

Interpretive Guideline

Interpretive Guidelines §485.635(c)(4)

The person principally responsible for the operation of the CAH, in accordance with §485.627(b)(2), i.e., the CAH's Chief Executive Officer (CEO), is responsible for the operation of all patient care services furnished at the CAH. This includes services provided directly by CAH staff and services provided by the CAH under arrangement or agreement. It includes not only care provided directly to patients, but also services related to patient care, such as environmental cleaning, instrument cleaning and sterilization, laundry, pharmacy services, laboratory services, etc. (This requirement for the CEO to be responsible does not relieve the CAH's governing body of its ultimate responsibility for the CAH's total operation in those CAHs where there are both a governing body and a CEO.)

The CEO must take actions to assure that all services furnished by the CAH through a contractor comply with the applicable requirements of the CAH's CoPs. When assessing compliance of a service provided by a contractor with the CoPs, deficiencies cited under other CoPs warrant a citation of this requirement, because the CEO has failed to assure that the contractor provides services in a manner that allows the CAH to comply with the CoPs.

Survey Procedures §485.635(c)(4)(i)

" Ask the CAH's CEO to demonstrate how he or she provides oversight of all contracted services related to patient care.

" Ask for specific examples of how the CEO assures that services furnished in the CAH comply with the CoPs (e.g., policies and procedures, by-laws, etc.) that the individual responsible for its operations is responsible for all services provided through arrangements or agreements.

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FED - C1046 - NURSING SERVICES

Title NURSING SERVICES

Type Standard

CFR 485.635(d)(1)

Regulation Definition

Nursing services must meet the needs of patients.

(1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.

Interpretive Guideline

Interpretive Guidelines §485.635(d) & (d)(1)

In order to meet the needs of patients, nursing services must be a well-organized service of the CAH. The CAH designates an individual who is responsible for nursing services, including development of policies and procedures for nursing services. The designated individual is generally expected to be a registered nurse. Various titles may be used for the responsible nurse leader may have (e.g., director of nursing services, nurse executive, chief nursing officer, or nurse manager). The nurse leader is responsible for the overall management and evaluation of nursing care in the CAH, including, but not limited to:

" Development and maintenance of nursing policies and procedures;

" Supervision of nursing staff, either directly, or, depending on the size of the CAH, indirectly through other nursing managers; and

" Ongoing review and analysis of the quality of nursing care.

As required at §485.631(a)(5), the CAH must have a registered nurse, clinical nurse specialist, or licensed practical nurse on duty whenever the CAH has one or more inpatients (including patients in a swing bed receiving long term care services).

The CAH must also ensure that, for outpatient nursing services, appropriate nursing staff are available in accordance with State law and CAH policy.

For both inpatient and outpatient services there must be sufficient numbers of supervisory and non-supervisory nursing personnel with the appropriate education, experience, licensure (as applicable), competence and specialized qualifications to respond to the nursing needs of the patient population of each CAH department or nursing unit. Staffing schedules must be reviewed and revised as necessary to meet patient care needs and to make adjustments for

nursing staff absenteeism.

The CAH must have a procedure for assigning and coordinating the nursing care for every CAH patient. A registered nurse must either provide directly, or assign to other staff, the required nursing care for each CAH patient, including patients receiving swing bed services. The RN making the assignment must consider the specialized qualifications and competence of the CAH's available nursing staff in order to meet patients' nursing care needs. Nursing care duties may be assigned to appropriate personnel, such as a licensed practical nurse, nursing assistant or nurse's aide, so long as such assignment is consistent with state law and the individual has the qualifications and competence to perform the assigned tasks.

The CAH must ensure that all CAH nursing staff are adequately trained and oriented, aware of CAH nursing policies and procedures, supervised, and that their clinical activities are evaluated. If temporary outside agency nurses are employed to address temporary nurse staffing needs, determine how are these nurses oriented and supervised. (NOTE: Regular nursing services may be provided under arrangement instead of using CAH employees, but in this case the CAH is responsible for the ongoing training and supervision of these regular nursing staff.)

Survey Procedures §485.635(d)(1)

" Determine whether an RN has been designated responsible for nursing services at the CAH.

" Observe the nursing care in progress to determine the adequacy of staffing and to assess the delivery of care. Sources of information to use in the evaluation of the nursing services are: staffing schedules, nursing care plans for inpatients credentialing and training files (including contracted staff), and QA activities and reports.

" Interview the registered nurse responsible for nursing services and ask the following--

o How are the nursing needs of patients determined? Who makes this determination?

o How are staff assigned to provide nursing care to patients?

o How does the CAH ensure that care provided meets the needs of each patient?

o How are staff trained and oriented? If temporary outside agency nurses are used, how are they oriented and supervised?

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" Review nursing assignments in one or more inpatient units, the emergency department, and one other outpatient department. Did an RN make the assignments? Was the complexity of patient care needs and the competence and specialized qualifications of the nursing staff taken into consideration?

" Review written staffing schedules; do they adhere to the CAH's policies and procedures for staffing levels and types of nursing personnel?

" Verify that there is supervision of personnel performance and nursing care for each nursing unit.

" If there are temporary agency nurses providing services, interview one or more to determine if they are familiar with the nursing policies and procedures of the unit or department where they are working.

" Review personnel files to determine that nursing staff have required licenses and competencies.

FED - C1048 - NURSING SERVICES

Title NURSING SERVICES

Type Standard

CFR 485.635(d)(2)

Regulation Definition

A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.

Interpretive Guideline

Interpretive Guidelines §485.635(d)(2)

The nursing care of each patient of the CAH must be supervised by a registered nurse or a physician assistant where permitted by State law. Even where permitted under State law, a CAH is not required to have nursing care supervised by a physician assistant. This is simply an option for the CAH.

For inpatients, including patients receiving long term care services in swing beds, evaluation of their nursing care includes evaluating the care for each patient upon admission and, when appropriate, on an ongoing basis in accordance with accepted standards of nursing practice and CAH policy. Evaluation would include assessing the patient's care needs, patient's health status/conditioning, as well as the patient's response to interventions.

Nursing care plans are not developed for outpatients, so the focus of the evaluation would be on adherence to generally acceptable standards of nursing care practice, including requirements at §485.635(d)(3) for medication administration.

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Survey Procedures §485.635(d)(2)

" Determine that a registered nurse (or physician assistant where permitted by State law and CAH policy) supervises and evaluates the nursing care for each patient.

" Interview one or more registered nurses (or physician assistants, if applicable) who supervise and evaluate the nursing care for CAH patients.

FED - C1049 - NURSING SERVICES

Title NURSING SERVICES

Type Standard

CFR 485.635(d)(3)

Regulation Definition

§485.635(d)(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

Interpretive Guideline

Interpretive Guidelines §485.635(d)(3)

As required at §485.635(a)(3)(iv), the CAH must have written policies and procedures for the administration of all drugs and biologicals that adhere to accepted standards of practice and Federal and State laws. In accordance with §485.635(d)(3), all medication administration must be consistent with accepted standards of practice, as well as Federal and State laws. Examples of nationally recognized organizations with expertise in medication administration include, but are not limited to:

" National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org);

" Institute for Healthcare Improvement (http://www.ihi.org/ihi);

" U.S Pharmacopeia (www.usp.org);

" Institute for Safe Medication Practices, which offers guidelines specifically on timely medication administration, which can be found at: www.ismp.org/Newsletters/acutecare/articles/20110113.asp;

" Infusion Nurses Society (http://www.ins1.org).

In addition, the Centers for Disease Control and Prevention (CDC) publishes evidenced-based practice guidelines and recommendations on medication preparation and administration practices, designed to reduce the risk of infection associated with these activities.

Who May Administer Medications?

Drugs and biologicals, including intravenous (IV) medications, must be administered by, or under the supervision of, an MD or DO; an RN, or, where permitted by State law, a PA. Other personnel, such as LPN's, may administer medications when permitted by State law and CAH policy, so long as they are supervised by an MD, DO, RN or, where permitted by State law, a PA. The CAH's written policies must delineate the categories of clinical staff authorized to administer medication at the CAH.

Medication Orders

Drugs and biologicals, including intravenous (IV) medications, may only be administered in accordance with orders written and signed by a practitioner who is authorized by CAH policy, and in accordance with State law, to write orders and who is responsible for the care of the patient as specified under §485.631(b)(1)(iii).

Accepted standards of practice

Based on accepted standards of practice for medication administration, the CAH must assure compliance with the following requirements concerning:

" Minimum content of medication orders;

" Policies and procedures for verbal and standing orders;

" Self-administration of medications, if the CAH permits this;

" Training;

" Basic Safe Practices;

" Timing of Medication Administration;

" Assessment/Monitoring of Patients Receiving Medications;

" Intravenous (IV) medications; and

" Documentation

Content of the medication order

In accordance with accepted standards of practice, the minimum elements that must be present in orders for all drugs and biologicals to ensure safe preparation and administration include:

" Name of patient;

" Age and weight of patient, to facilitate dose calculation when applicable. Policies and procedures must address weight-based dosing for pediatric patients as well as in other circumstances identified in the CAH's policies. (NOTE: Dose calculations are based on metric weight (kg, or g for newborns). If a CAH permits practitioners to record weight in either pounds or using metric weight, the opportunity for error increases, since some orders would require conversion while others would not. Accordingly, CAHs must specify a uniform approach to be used by prescribing practitioners. For example, a CAH could require all prescribers to use pounds or ounces and have the electronic ordering system or the pharmacy convert to metric);

" Date and time of the order;

" Drug name;

" Exact strength or concentration, when applicable;

" Dose, frequency, and route;

" Dose calculation requirements, when applicable;

" Quantity and/or duration, when applicable;

" Specific instructions for use, when applicable; and

" Name of the prescriber.

Verbal and Standing Orders

Although the regulation requires medication administration be based on a written, signed order, this does not preclude the CAH from using:

" Verbal orders; or

" Standing orders.

In the case of both verbal and standing orders, a practitioner responsible for the care of the patient must authenticate the order in writing as soon as possible after the fact. The CAH must adopt policies and procedures regarding verbal and standing orders. (NOTE: CAHs that have a distinct part psychiatric and/or rehabilitation unit must follow the hospital CoPs for all services provided in those units, including the hospital requirements for verbal and standing orders.)

For verbal orders, CAH policies must, at a minimum, address the following:

" Describe situations in which verbal orders may be used, as well as limitations or prohibitions on their use;

" Provide a mechanism to establish the identity and authority of the practitioner issuing a verbal order;

" List the elements required for inclusion in the verbal order process;

" Establish protocols for clear and effective communication and verification of verbal orders. CMS expects nationally accepted read-back verification practice to be implemented for every verbal order;

" Identify the categories of clinical staff who are authorized to receive and act upon a verbal order; and

" Provide for prompt documentation in the medical record of the receipt of a verbal order.

For standing orders, CAH policies must, at a minimum, address the following:

" The process by which a standing order is developed; approved; monitored; evaluated and updated when needed;

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" For each standing order, which staff may initiate it and under what circumstances; (under no circumstances may a CAH use standing orders in a manner that requires any staff not authorized to write patient orders to make clinical decisions outside of their scope of practice in order to initiate such orders); and

" The requirements for subsequent authentication by a practitioner responsible for the care of the patient.

FED - C1050 - NURSING SERVICES

Title NURSING SERVICES

Type Standard

CFR 485.635(d)(4)

Regulation Definition

A nursing care plan must be developed and kept current for each inpatient.

Interpretive Guideline

Interpretive Guidelines §485.635(d)(4)

There must be a nursing care plan for every CAH inpatient. Nursing care planning starts upon admission. It includes planning the patient's care while in the CAH as well as planning for transfer to a hospital, to a post-acute care facility or for discharge. A nursing care plan is based on assessing the patient's nursing care needs (not solely those needs related to the admitting diagnosis). The assessment considers the patient's treatment goals and, as appropriate, physiological and psychosocial factors and patient discharge planning. The plan develops appropriate nursing interventions in response to the identified nursing care needs. One resource for information about nursing care plans is The American Nurses Association http://www.nursingworld.org/EspeciallyforYou/StudentNurses/Thenursingprocess.aspx.

The nursing care plan is kept current by ongoing assessments of the patient's needs and of the patient's response to interventions, and updating or revising the patient's nursing care plan in response to assessments. The nursing care plan is part of the patient's clinical record and must comply with the clinical records requirements at §485.638.

CAHs have the flexibility of developing the nursing care plan as part of a larger, coordinated interdisciplinary plan of care. This method may serve to promote communication among disciplines and reinforce an integrated, multi-faceted approach to a patient's care, resulting in better patient outcomes. The interdisciplinary plan of care does not minimize or eliminate the need for a nursing care plan. It does, however, serve to promote the collaboration between members of the patient's health care team.

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Survey Procedures §485.635(d)(4)

Select a representative sample of nursing care plans based on the number of inpatient records reviewed.

" Are the care plans created as soon as possible after admission for each patient?

" Are the care plans based on the nurse's assessment of the individual patient?

" Is there evidence that the care plans are reviewed on an ongoing basis?

" Is there evidence that the nursing care plan is revised as needed and is there documentation of nursing reassessment?

" Verify that there is evidence that the nursing care plans have been implemented.

FED - C1052 - REHABILITATION THERAPY SERVICES

Title REHABILITATION THERAPY SERVICES

Type Standard

CFR 485.635(e)

Regulation Definition

Physical therapy, occupational therapy, and speech-language therapy pathology services furnished at the CAH, if provided, are provided by staff qualified under State law, and consistent with the requirements for therapy services in §409.17 of this subpart.

Interpretive Guideline

Interpretive Guidelines §485.635(e)

Rehabilitation services are optional CAH services. If a CAH provides any rehabilitative services to its patients, either directly or under arrangement or agreement, either inpatient or outpatient, the services must be provided by staff qualified under State law, and consistent with the requirements for therapy services in §409.17. Rehabilitation services services can be initiated only upon the order of a practitioner responsible for the care of the patient. Physical therapy, occupational therapy, or speech-language pathology must be furnished in accordance with the regulation at 42 CFR 409.17, which specifies the following rehabilitation services plan of care requirements:

" Establishment of the plan: "The plan must be established before treatment begins by one of the following: (1) A physician; (2) A nurse practitioner, a clinical nurse specialist or a physician assistant; (3) The physical therapist furnishing the physical therapy services; (4) A speech-language pathologist furnishing the speech-language pathology services; (5) An occupational therapist furnishing the occupational therapy services."

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" Content of the plan: "The plan: (1) Prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual; and (2) Indicates the diagnosis and anticipated goals."

" Changes in the plan: "Any changes in the plan are implemented in accordance with the provider's policies and procedures."

Also in accordance with 42 CFR 409.17, rehabilitation services must be provided by qualified physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, and/or speech-language pathologists who meet the personnel qualifications defined in 42 CFR 484.4. CAHs must have policies and procedures consistent with State law.

Rehabilitation services must be provided according to national standards of practice as established by professional organizations such as, but not limited to, the American Physical Therapy Association, the American Occupational Therapy Association, and the American Speech-Language-Hearing Association.

Survey Procedures §485.635(e)

If the CAH provides rehabilitation services:

" Review clinical records of patients who received rehabilitation services. Determine whether the required care plan was developed and implemented.

" Review employee personnel files to verify the rehabilitation service providers (i.e., physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, and/or speech-language pathologists) have the necessary education, experience, training, and documented competencies to provide rehabilitation services.

" Ask the CAH what national standards of rehabilitation practice provide the basis for its rehabilitation services. Is there supporting documentation?

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FED - C1054 - PATIENT VISITATION RIGHTS

Title PATIENT VISITATION RIGHTS

Type Standard

CFR 485.635(f)

Regulation Definition

Patient visitation rights. A CAH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation….

Interpretive Guideline

Interpretive Guidelines §485.635(f)

Visitation plays an important role in the care of hospital patients, including CAHs. An article published in 2004 in the Journal of the American Medical Association (Berwick, D.M., and Kotagal, M.: "Restricted visiting hours in ICUs: time to change." JAMA. 2004; Vol. 292, pp. 736-737) discusses the health and safety benefits of open visitation for patients, families, and intensive care unit (ICU) staff and debunks some of the myths surrounding the issue (physiologic stress for the patient; barriers to provision of care; exhaustion of family and friends). The article ultimately concluded that "available evidence indicates that hazards and problems regarding open visitation are generally overstated and manageable," and that such visitation policies "do not harm patients but rather may help them by providing a support system and shaping a more familiar environment" as they "engender trust in families, creating a better working relationship between hospital staff and family members." CAHs that unnecessarily restrict patient visitation often miss an opportunity to gain valuable patient information from those who may know the patient best with respect to the patient's medical history, conditions, medications, and allergies, particularly if the patient has difficulties with recall or articulation, or is totally unable to recall or articulate this vital personal information. Many times visitors who may know the patient best act as an intermediary for the patient, helping to communicate the patient's needs to CAH staff.

Although visitation policies are generally considered to relate to visitors of inpatients, "visitors" also play a role for outpatients who wish to have a support person present during their outpatient visit. For example, a same-day surgery patient may wish to have a support person present during the pre-operative patient preparation or post-operative recovery. Or an outpatient clinic patient may wish to have a support person present during their examination by a physician. Accordingly, CAH visitation policies must address both the inpatient and outpatient settings.

CAHs are required to develop and implement written policies and procedures that address the patient's right to have visitors. If the CAH's policy establishes restrictions or limitations on visitation, such restrictions/limitations must be clinically necessary. Furthermore, the CAH's policy must include the reasons for any restrictions/limitations. The right of a patient to have visitors may be limited or restricted when visitation would interfere with the care of the

patient and/or the care of other patients. The regulation permits CAHs some flexibility, so that health care professionals may exercise their best clinical judgment when determining when visitation is, and is not, appropriate. Best clinical judgment takes into account all aspects of patient health and safety, including the benefits of visitation on a patient's care as well as potential negative impacts that visitors may have on other patients in the CAH.

Broad examples of clinically reasonable bases for a CAH to impose restrictions or limitations on visitors might include (but are not limited to) when:

" there may be infection control issues;

" visitation may interfere with the care of other patients;

" the CAH is aware that there is an existing court order restricting contact;

" visitors engage in disruptive, threatening, or violent behavior of any kind;

" the patient or patient's roommate needs rest or privacy;

" in the case of an inpatient substance abuse treatment program, there are protocols limiting visitation; and

" the patient is undergoing care interventions. However, while there may be valid reasons for limiting visitation during a care intervention, we encourage CAHs to try to accommodate the needs of any patient who requests that at least one visitor be allowed to remain in the room to provide support and comfort at such times.

It may also be reasonable to limit the number of visitors for any one patient during a specific period of time, as well as to establish minimum age requirements for child visitors. However, when a CAH adopts policies that limit or restrict patients' visitation rights, the burden of proof is upon the CAH to demonstrate that the visitation restriction is reasonably necessary to provide safe care.

CAHs are expected to provide a clear explanation in their written policy of the clinical rationale for any visitation restrictions or limitations reflected in that policy. CAHs are not required, however, to delineate each specific clinical reason for policies limiting or restricting visitation, given that it is not possible to anticipate every instance that may give rise to a clinically appropriate rationale for a restriction or limitation. If visitation policies differ by type of unit, e.g., separate policies for intensive care units, or for newborn nurseries, the CAH policy must address the clinical rationale for this differentiation explicitly.

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The CAH's policies and procedures are expected to address how CAH staff who play a role in facilitating or controlling visitor access to patients will be trained so as to assure appropriate implementation of the visitation policies and procedures and avoidance of unnecessary restrictions or limitations on patients' visitation rights.

Survey Procedures §485.635(f)

" Verify that the CAH has written policies and procedures that address the right of patients to have visitors.

" Review the policy to determine if there are limitations or restrictions on visitation. If there are, does the policy explain the clinical rationale for the restrictions or limitations? Is the rationale clear and reasonably related to clinical concerns?

" Is there documentation of how the CAH identifies and trains staff who play a role in facilitating or limiting/restricting access of visitors to patients?

" Are CAH staff aware of the visitation policies and procedures? Can staff on a given unit correctly describe the CAH's visitation policies for that unit?

FED - C1056 - PATIENT VISITATION RIGHTS

Title PATIENT VISITATION RIGHTS

Type Standard

CFR 482.635(f)(1)
482.635(f)(2)

Regulation Definition

§485.635(f) Standard: Patient visitation rights. A CAH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation. A CAH must meet the following requirements:

(1) Inform each patient (or support person, where

Interpretive Guideline

Interpretive Guidelines §482.635(f)(1)&(2)

CAHs are required to inform each patient (or the patient's support person, where appropriate) of his/her visitation rights. A patient's "support person" does not necessarily have to be the same person as the patient's representative designated under an advance directive who is legally responsible for making medical decisions on the patient's behalf. A patient's support person could be a family member, friend, or other individual who supports the patient during the course of the CAH stay. Not only may the support person visit the patient, but he or she may also exercise a patient's visitation rights on behalf of the patient with respect to other visitors, when the patient is unable to do so. CAHs must accept a patient's designation, orally or in writing, of an individual as the patient's support person.

appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, in advance of furnishing patient care whenever possible.

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

When a patient is incapacitated or otherwise unable to communicate his or her wishes, there is no advance directive designating a representative on file, and an individual provides an advance directive designating an individual as the patient's support person, (it is not necessary for the document to use this exact term), the CAH must accept this designation, provide the required notice of the patient's visitation rights, and allow the individual to exercise the patient's visitation rights on the patient's behalf.

When a patient is incapacitated or otherwise unable to communicate his or her wishes and no one has presented an advance directive designating them as the patient's support person, but an individual asserts that he or she, as the patient's spouse, domestic partner (including a same-sex domestic partner), parent or other family member, friend, or otherwise, is the patient's support person, the CAH is expected to accept this assertion, without demanding supporting documentation, provide the required notice of the patient's visitation rights, and allow the individual to exercise the patient's visitation rights on the patient's behalf. However, if more than one individual claims to be the patient's support person, it would not be inappropriate for the CAH to ask each individual for documentation supporting his/her claim to be the patient's support person.

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

" A refusal by the CAH of an individual's request to be treated as the patient's support person with respect to visitation rights must be documented in the patient's medical record must, along with the specific basis for the refusal.

The required notice of the patient's visitation rights must be provided, whenever possible, before the CAH provides patient care. The notice to patients must be in writing in a language or manner that the patient (or the patient's support person) 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 §485.608(a), CAHs are expected to comply with Title VI and may use this guidance to assist the CAH in ensuring patient's rights information is provided in a language and manner that the patient understands. Surveyors do not assess compliance with this guidance on limited English proficiency, but may refer concerns about possible noncompliance to the Office of Civil Rights in the applicable Department of Health and Human Services Regional Office.

The required visitation rights notice must address any clinically necessary or reasonable limitations or restrictions

imposed by CAH policy on visitation rights, providing the clinical reasons for such limitations/restrictions, including how they are aimed at protecting the health and safety of all patients. The information must be sufficiently detailed to allow a patient (or the patient's support person) to determine what the visitation hours are and what restrictions, if any, apply to that patient's visitation rights.

The notice must also inform the patient (or the patient's support person, where appropriate) of the patient's right to:

" Consent to receive visitors he or she has designated, either orally or in writing, including but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend;

" Receive the visitors he or she has designated, including but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend; and

" Withdraw or deny his/her consent to receive specific visitors, either orally or in writing.

The medical record must contain documentation that the required notice was provided to the patient or, if appropriate, the patient's support person.

Survey Procedures §485.635(f)(1) & (2)

" Determine whether the CAH's visitation policies and procedures require providing notice of the patient's visitation rights to each patient or, if appropriate, to a patient's support person and/or, as applicable, the patient's representative .

" Review the CAH's standard notice of visitation rights. Does it clearly explain the:

" CAH's visitation policy, including any limitations or restrictions, such as visiting hours, numbers of visitors, or unit-specific restrictions, etc., and the clinical rationale for such limitations or restrictions?

" right of the patient to have designated visitors, including but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and the right to withdraw or deny consent to visitation?

" Review a sample of medical records to determine if there is documentation that the required notice was provided and if it was provided in advance of care, unless circumstances made this not feasible.

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" Ask the CAH to identify how the required notice is provided. Ask staff responsible for providing the notice how they accomplish this. Ask the staff if they are familiar with the concept of a patient's "support person" and what it means.

" Ask a sample of current CAH patients or patients' support persons (where appropriate) whether they were provided notice of their right to have visitors. Ask if they were able to have visitors when they wanted to. If not, verify whether the restriction/limitation on visitors was addressed in the CAH's visitation policies and notice, or was inappropriate.

" Ask a sample of current CAH patients or patients' support persons (where appropriate) whether the CAH did not limit some or all visitors, contrary to the patient's wishes.

FED - C1058 - PATIENT VISITATION RIGHTS

Title PATIENT VISITATION RIGHTS

Type Standard

CFR 485.635(f)(3)
485.635(f)(4)

Regulation Definition

§485.635(f) Standard: Patient visitation rights. A CAH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation. A CAH must meet the following requirements:

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

(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

Interpretive Guideline

Interpretive Guidelines §485.635(f)(3)&(4)

The CAH's visitation policies and procedures may not use the race, color, national origin, religion, sex, gender identity, sexual orientation, or disability of either the patient (or the patient's support person, where appropriate) or the patient's visitors (including individuals seeking to visit the patient) as a basis for limiting, restricting, or otherwise denying visitation privileges.

The CAH's policies and procedures must ensure that all visitors (including individuals seeking to visit the patient) enjoy full and equal visitation privileges, consistent with the preferences the patient (or, where appropriate, the patient's support person) has expressed concerning visitors. In other words, it is permissible for the patient (or the patient's support person, where appropriate) to limit the visiting privileges of his/her visitors, including providing for more limited visiting privileges for some visitors than those for others. But it is not permissible for the CAH, on its own, to differentiate among visitors without any clinically necessary or reasonable basis. This includes visitors designated by the patient who have characteristics not addressed specifically in §485.635(f)(3), when those characteristics do not reasonably relate to a clinically reasonable basis for limiting or denying visitation. For

example, it would not be appropriate to prohibit a designated visitor based on that individual's style of dress, unless there was a clinically reasonable basis for doing so.

The CAH is responsible for ensuring that CAH staff treat all individuals seeking to visit patients equally, consistent with the preferences of the patient (or, where appropriate, the patient's support person) and do not use the race, color, national origin, religion, sex, gender identity, sexual orientation, or disability of either the patient (or the patient's support person, where appropriate) or the patient's visitors (including individuals seeking to visit the patient)as a basis for limiting, restricting, or otherwise denying visitation privileges. CAHs are expected to educate all staff who play a role in facilitating or controlling visitors on the CAH's visitation policies and procedures, and are responsible for ensuring that staff implement the CAH's policies correctly. CAHs are urged to develop culturally competent training programs designed to address the range of patients served by the CAH.

Survey Procedures §485.635(f)(3)&(4)

" Review the CAH's visitation policies and procedures to determine whether they restrict, limit, or otherwise deny visitation to individuals on a prohibited basis.

" Ask the CAH how it educates staff to assure that visitation policies are implemented in a non-discriminatory manner.

" Ask CAH staff who play a role in facilitating or controlling visitors to discuss their understanding of the circumstances under which visitors may be subject to restrictions/limitations. Are the restrictions/limitations appropriately based on the CAH's clinically-based policies?

" Ask CAH patients (or patients' support persons, where appropriate) whether the CAH has limited visitors against their wishes? If yes, verify whether the restriction/limitation on visitors was addressed in the CAH's visitation policies and in the patient notice, and whether it was appropriately based on a clinical rationale rather than impermissible discrimination.

FED - C1100 - CLINICAL RECORDS

Title CLINICAL RECORDS

Type Condition

CFR 485.638

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Regulation Definition

§485.638 Condition of Participation: Clinical Records

Interpretive Guideline

FED - C1102 - RECORDS SYSTEM

Title RECORDS SYSTEM

Type Standard

CFR 485.638(a)(1)

Regulation Definition

(1) The CAH maintains a clinical records system in accordance with written policies and procedures.

Interpretive Guideline

Interpretive Guidelines §485.638(a)(1)

The CAH must have a system of patient records, pertinent medical information, author identification, and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. The medical record system must correctly identify the author of every medical record entry. The medical record system must protect the security of all medical record entries. The medical record system must ensure that medical record entries are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner. All locations where medical records are stored or maintained must ensure the integrity, security and protection of the records.

The CAH must have a system in place that ensures that the identity of the author of each entry is correct. The author of every entry must take a specified action to identify himself/herself as the author (or responsible person) of the entry, the time and dating of the entry, that the entry is accurate, and that he/she takes responsibility for accuracy of the entry.

If the CAH uses computer entries there must be security system in place to ensure the integrity of the record system, to ensure that the author of each entry is correctly identified, to ensure that record entries are not altered or lost, that limits access to medical records to only authorized persons, and ensures that records are not released to unauthorized individuals. For the purposes of this regulation, electronic signatures comply with those medical record entries that include a requirements for a signature.

There should be a current list of authenticated signatures, as well as a list of computer codes and signature stamps (when used for authorship purposes) that have been authorized by the governing body and are protected by adequate safeguards. CAH policies and procedures should provide for appropriate sanctions for unauthorized or improper use

of computer codes or signature stamps.

The CAH must maintain a medical record for each inpatient and outpatient evaluated or treated in any part or location of the CAH. A unit record for both inpatients and outpatients may be used; however, when two different systems are used they must be appropriately cross referenced. When a patient reimbursement status changes from acute care services to swing bed services, a single medical record may be used for both stays as long as the record is sectioned separately. Both sections must include admission and discharge orders, progress notes, nursing notes, graphics, laboratory support documents, any other pertinent documents, and discharge summaries.

The medical record must be properly filed and retained. The CAH must have a medical recording system that ensures the prompt retrieval of any medical record, of any patient evaluated or treated at any location of the CAH within the past 6 years.

The medical record must be accessible. The CAH must have a medical record system that allows the medical record of any patient, inpatient or outpatient, evaluated and/or treated at any location of the CAH within the past 6 years to be accessible by appropriate staff, 24 hours a day, 7 days a week, whenever that medical record may be needed.

Survey Procedures §485.638(a)(1)

" Verify that a medical record is maintained for each person receiving care.

" Verify that written procedures ensure the integrity of authentication and protect the security of patient records.

" Verify that medical records are stored and maintained in locations where the records are secure, with protection from damage, flood, fire, theft, etc., and limits access to only authorized individuals.

" Verify that records are accurate, completed promptly, easily retrieved and readily accessible, as needed.

" Verify that there is an established system that addresses at least the following activities of the medical records services:

o Timely processing and retrieval of records;

o Protecting the confidentiality of medical information;

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o Compiling and retrieval of data of quality assurance activities.

" Verify that the system policies and procedures are reviewed and revised as needed.

" Verify that the CAH employs adequate medical record personnel who possess adequate education, skills, qualifications and experience to ensure the CAH complies with requirements of the medical records regulations and other appropriate Federal and State laws and regulations.

" Are medical records promptly completed in accordance with State law and CAH policy?

" Select a sample of past patients of the CAH (inpatient and/or outpatient). Request those patient's medical records. Can the CAH promptly retrieve those records?

FED - C1104 - RECORDS SYSTEM

Title RECORDS SYSTEM

Type Standard

CFR 485.638(a)(2)

Regulation Definition

The records are legible, complete, accurately documented, readily accessible, and systematically organized.

Interpretive Guideline

Interpretive Guidelines §485.638(a)(2)

All medical records must be accurately written. The CAH must ensure that all medical records accurately and completely document all orders, test results, evaluations, treatments, interventions, care provided and the patient's response to those treatments, interventions and care.

Survey Procedures §485.638(a)(2)

For CAH surveys that are conducted after the initial certification survey, examine a sample of records using an adequate sample size to evaluate the scope of services provided. In a very small CAH, look at all inpatient and outpatients records, if appropriate.

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FED - C1106 - RECORDS SYSTEM

Title RECORDS SYSTEM

Type Standard

CFR 485.638(a)(3)

Regulation Definition

A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

Interpretive Guideline

Interpretive Guidelines §485.638(a)(3)

The CAH must have one unified medical record service with a department head that has been appointed by the governing body (or responsible individual). The director of medical records must have responsibility for all medical records to include both inpatient and outpatient records.

Survey Procedures §485.638(a)(3)

" Verify that the CAH employs adequate medical record personnel.

" Review the organizational structure and policy statements and interview the person responsible for the service to ascertain that the medical records service is structured appropriately to meet the needs of the CAH and the patients.

FED - C1110 - RECORDS SYSTEM

Title RECORDS SYSTEM

Type Standard

CFR 485.638(a)(4)(i)

Regulation Definition

For each patient receiving health care services, the CAH maintains a record that includes, as applicable--

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history,

Interpretive Guideline

Interpretive Guidelines §485.638(a)(4)(i)

The medical record must include evidence of properly executed informed consent forms for any procedures or surgical procedures specified by the medical staff, or by Federal or State law, if applicable, that require written patient consent.

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assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

Informed consent means the patient or patient representative is given the information, explanations, consequences, and options needed in order to consent to a procedure or treatment.

A properly executed consent form contains at least the following:

" Name of patient, and when appropriate, patient's legal guardian;

" Name of CAH;

" Name of procedure(s);

" Name of practitioner(s) performing the procedures(s);

" Signature of patient or legal guardian;

" Date and time consent is obtained;

" Statement that procedure was explained to patient or guardian;

" Signature of professional person witnessing the consent;

" Name/signature of person who explained the procedure to the patient or guardian.

The medical record must contain information such as progress and nursing notes, documentation, records, reports, recordings, test results, assessments etc. to:

" Justify admission;

" Support the diagnosis;

" Describe the patient's progress;

" Describe the patient's response to medications; and

" Describe the patient's response to services such as interventions, care, treatments, etc.

The medical record must contain complete information/documentation regarding medical history, assessment of the health status and health care needs of the patient, and a summary of the episode, disposition, and instructions to the patient. This information and documentation is contained in a discharge summary.

A discharge summary discusses the outcome of the CAH stay, the disposition of the patient, and provisions for follow-up care. Follow-up care provisions include any post CAH appointment, how post CAH patient care needs are to be met, and any plans for post-CAH care by providers such as swing-bed services, home health, hospice, nursing homes, or assisted living. A discharge summary is required following any CAH acute care stay prior to and following a swing-bed admission and discharge.

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

The MD/DO may delegate writing the discharge summary to other qualified health care personnel such as nurse practitioners and physician assistants to the extent recognized under State law or a State's regulatory mechanism. The MD/DO may also delegate writing the discharge summary to another MD/DO who is familiar with the patient.

Survey Procedures §485.638(a)(4)(i)

" Verify that the medical staff have specified which procedures or treatments require a written informed consent.

" Verify that medical records contain consent forms for all procedures or treatment that are required by CAH policy.

" Verify that consent forms are properly executed.

" Examine a sample of patient records and/or facility records of requests for information contained in patient records to determine if there are signed and dated consent forms, when required, medical history, health status and care needs assessment, and discharge summary in each record, as needed.

" Review of sample of active and closed medical records for completeness and accuracy in accordance with Federal and State laws and regulations and CAH policy. The sample should be at least 10 percent of the average daily census, as appropriate.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C1114 - RECORDS SYSTEM

Title RECORDS SYSTEM

Type Standard

CFR 485.638(a)(4)(ii)

Regulation Definition

Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

Interpretive Guideline

Interpretive Guidelines §485.638(a)(4)(ii)

All or part of the history and physical exam (H & P) may be delegated to other practitioners in accordance with State law and CAH policy, but the MD/DO must sign the H & P and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant meeting these criteria may perform the H & P.

Survey Procedures §485.638(a)(4)(ii)

" Determine that the bylaws require a physical examination and medical history be done for each patient.

" For sampled records, does the appropriate practitioner sign reports of physical examinations, diagnostic and laboratory test results, and consultative findings?

FED - C1116 - RECORDS SYSTEM

Title RECORDS SYSTEM

Type Standard

CFR 485.638(a)(4)(iii)

Regulation Definition

All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's

Interpretive Guideline

Interpretive Guidelines §485.638(a)(4)(iii)

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

response to treatment; and

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);

" All nursing notes;

" All reports of treatment (including complications and CAH-acquired infections);

" All medication records (including unfavorable reactions to drugs);

" All radiology reports;

" All laboratory reports;

" All vital signs; and

" All other information necessary to monitor the patient's condition.

All medical records must be promptly completed. Every medical record must be complete with all documentation of orders, diagnosis, evaluations, treatments, test results, consents, interventions, discharge summary, and care provided along with the patient's response to those treatments, interventions, and care.

Survey Procedures §485.638(a)(4)(iii)

" 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 have access to the information necessary to monitor the patient's condition?

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C1118 - RECORDS SYSTEM

Title RECORDS SYSTEM

Type Standard

CFR 485.635(a)(4)(iv)

Regulation Definition

Dated signatures of the doctor of medicine or osteopathy or other health care professional.

Interpretive Guideline

Interpretive Guidelines §485.635(a)(4)(iv)

Entries in the medical record may be made only by individuals as specified in CAH and medical staff policies. All entries in the medical record must be timed, dated, and authenticated, and a method established to identify the author. The identification may include written signatures, initials, computer key, or other code.

When rubber stamps are authorized, the individual whose signature the stamp represents shall place in the administrative offices of the CAH a signed statement to the effect that he/she is the only one who has the stamp and uses it. There shall be no delegation to another individual.

A list of computer or other codes and written signatures must be readily available and maintained under adequate safeguards. There shall be sanctions for improper or unauthorized use of stamp, computer key, or other code signatures. The CAH must have policies and procedures in place and operational before an electronic medical record system would be deemed acceptable.

The parts of the medical record that are the responsibility of the MD/DO must be authenticated by this individual. When non-MD/DOs have been approved for such duties as taking medical histories or documenting aspects of physical examination, such information shall be appropriately authenticated by the responsible MD/DO. Any entries in the medical record by house staff or non-MD/DOs that require counter signing by supervisory or attending medical staff members shall be defined in the medical staff rules and regulations.

All entries in the medical record must be authenticated.

Authentication would include at a minimum:

" The CAH has a method to establish the identify of the author of each entry. This would include verification of the author of faxed orders/entries or computer entries.

" The author takes a specific action to verify that the entry is his/her entry or that he/she is responsible for the entry, that the entry is accurate.

" The timing of the entry is noted and correct.

Timing documents the time and date of each entry (orders, reports, notes etc.). Timing establishes when an order was given, when an activity happened or when an activity is to take place. Timing and dating entries are necessary for patient safety and quality of care. Timing and dating of entries establishes a baseline for future actions or assessments and establishes a timeline of events. Many patient interventions or assessments are based on time intervals or time lines of various signs, symptoms, or events. There must be a specific action by the author to indicate that the entry is, in fact, verified and accurate. Failure to disapprove an entry within a specific time period is not acceptable as authentication.

A system of auto-authentication in which a MD/DO or other practitioner authenticates a report before transcription is not consistent with these requirements. There must be a method of determining that the practitioner did, in fact, authenticate the document after it was transcribed.

Survey Procedures §485.635(a)(4)(iv)

" Verify that entries are authenticated.

" Verify that the department maintains a current list of authenticated signatures, written initials, codes, and stamps when such are used for authorship identification.

" Verify that computer or other code signatures are authorized by the CAH'S governing body and that a list of these codes is maintained under adequate safeguards by the CAH administration.

" Verify that the CAH'S policies and procedures provide for appropriate sanctions for unauthorized or improper use of the computer codes.

" Examine the CAH'S policies and procedures for using the system, and determine if documents are being authenticated after transcription.

" For sampled records, are there dated and authenticated signatures by appropriate MD/DOs and/or mid-level practitioners, as needed?

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C1120 - PROTECTION OF RECORD INFORMATION

Title PROTECTION OF RECORD INFORMATION

Type Standard

CFR 485.638(b)(1)

Regulation Definition

The CAH maintains the confidentially of record information and provides safeguards against loss, destruction, or unauthorized use.

Interpretive Guideline

Interpretive Guidelines §485.638(b)(1)

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

The right to confidentiality means safeguarding the content of information, including patient paper records, video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian. CAH staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to that individual.

Confidentiality applies to both central records and clinical record information that may be kept at dispersed locations.

Survey Procedures §485.638(b)(1)

" Verify that only authorized persons are permitted access to records maintained by the medical records department.

" Verify that the CAH has a policy to grant patients direct access to his/her medical record if the responsible official (e.g., practitioner responsible for patient's care) determines that direct access is not likely to have an adverse effect on the patient.

" Verify that medical records are released only for patient care evaluation, utilization review, treatment, quality assurance programs, in-house educational purposes, or in accordance with Federal or State law, court orders, or subpoenas.

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" Verify that copies of medical records are released outside the CAH only upon written authorization of the patient, legal guardian, or person with an appropriate "power of attorney" to act on the patient's behalf, or only if there is a properly executed subpoena or court order, or as mandated by statutes.

" Verify that precautions are taken to prevent unauthorized persons from gaining access to or altering patient records.

" Verify that adequate precautions are taken to prevent physical or electronic altering, damaging or deletion/destruction of patient records or information in patient records.

FED - C1122 - PROTECTION OF RECORD INFORMATION

Title PROTECTION OF RECORD INFORMATION

Type Standard

CFR 485.638(b)(2)

Regulation Definition

Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

Interpretive Guideline

Interpretive Guidelines §485.638(b)(2)

The CAH'S patient record system must ensure the security of patient records. The CAH must ensure that unauthorized individuals cannot gain access to patient records and that individuals cannot alter patient records. Patient records must be secure at all times and in all locations. This includes open patient records for patients who are currently inpatients in the CAH and outpatients in outpatient clinics.

Survey Procedures §485.638(b)(2)

" Observe the CAH'S security practices for patient records. Are patient records left unsecured or unattended? Are patient records unsecured or unattended in hallways, patient rooms, nurses stations, or on counters where an unauthorized person could gain access to patient records?

" If the CAH uses electronic patient records, are appropriate security safeguards in place? Is access to patient records controlled?

" Verify that the CAH has policies and procedures for the use and release of records and that these policies and

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procedures are enforced.

FED - C1124 - PROTECTION OF RECORD INFORMATION

Title PROTECTION OF RECORD INFORMATION

Type Standard

CFR 485.638(b)(3)

Regulation Definition	Interpretive Guideline
The patient's written consent is required for release of information not required by law.	

FED - C1126 - RETENTION OF RECORDS

Title RETENTION OF RECORDS

Type Standard

CFR 485.638(c)

Regulation Definition	Interpretive Guideline
The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.	Interpretive Guidelines §485.638(c) Medical records are retained in their original form or legally reproduced form in hard copy, microfilm, or computer memory banks. The CAH must be able to promptly retrieve the complete medical record of every individual evaluated or treated in any part or location of the CAH within the last 6 years. In accordance with Federal and State law and regulations, certain medical records may have retention requirements that exceed 6 years (for example: FDA, OSHA, EPA). Survey Procedures §485.638(c) Determine that records are retained for at least 6 years, or more if required by State or local laws.

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FED - C1140 - SURGICAL SERVICES

Title SURGICAL SERVICES

Type Condition

CFR 485.639

Regulation Definition

If a CAH provides surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual, of the CAH in accordance with the designation requirements under paragraph (a) of this section.

Interpretive Guideline

Interpretive Guidelines §485.639

The provision of surgical services is an optional CAH service. However, if a CAH provides surgical services to its patients, the services must be organized and staffed in such a manner to ensure the health and safety of patients. Surgical services that are performed in a safe manner would be performed in accordance with acceptable standards of practice. In accordance with acceptable standards of practice includes maintaining compliance with applicable Federal and State laws, regulations and guidelines governing surgical services or surgical service locations, as well as, any standards and recommendations promoted by or established by nationally recognized professional organizations (e.g., the American Medical Association, American College of Surgeons, Association of periOperative Registered Nurses, Association for Professionals in Infection Control and Epidemiology, etc.) Additionally, the CAH'S outpatient surgical services must be integrated with the CAH's inpatient surgical services.

When the CAH offers surgical services, the CAH must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the surgical services offered by the CAH in accordance with acceptable standards of practice.

The scope of surgical services provided by the CAH should be defined in writing and approved by the governing body or responsible individual.

Supervision in the OR

The operating room must be supervised by an experienced staff member authorized by State law. The supervisor's experience could include education, background working in surgical services, and specialized training in the provision of surgical services/management of surgical service operations. The CAH should address its required qualifications for the supervisor of the CAH'S operating rooms in its policies.
If the CAH utilizes LPN or operating room technicians as "scrub nurses," those personnel must be under the supervision of an RN who is immediately available to physically intervene and provide care, as required in State law.

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Policies and Procedures

Policies governing surgical care should contain:

" Aseptic surveillance and practice, including scrub techniques

" Identification of infected and non-infected cases

" Housekeeping requirements/procedures

" Patient care requirements

" Preoperative work-up

" Patient consents and releases

" Clinical procedures

" Safety practices

" Patient identification procedures

" Duties of scrub and circulating nurse

" Safety practices

" The requirement to conduct surgical counts in accordance with accepted standards of practice

" Scheduling of patients for surgery

" Personnel policies unique to the OR

" Resuscitative techniques

" DNR status

" Care of surgical specimens

" Malignant hyperthermia

" Appropriate protocols for all surgical procedures performed. These may be procedure-specific or general in nature and will include a list of equipment, materials, and supplies necessary to properly carry out job assignments.

" Sterilization and disinfection procedures

" Acceptable operating room attire

" Handling infections and biomedical/medical waste

Policies and procedures must be written, implemented and enforced. Surgical services' policies must be in accordance with acceptable standards of medical practice and surgical patient care.

Pre-Operative History and Physical (H & P)

A complete history and physical must be conducted in accordance with acceptable standards of practice, and the written document placed on the medical record, prior to surgery. All or part of the H & P may be delegated to other practitioners in accordance with State law and CAH policy, but the surgeon must sign the H & P and assume full responsibility for the H & P. This means that a nurse practitioner or a physician assistant, meeting these criteria, may perform the H & P.

In all circumstances, when an H & P has been conducted, but is not present on the chart prior to surgery, or in emergency situations where a complete H & P cannot be conducted prior to surgery, a brief admission note on the chart is necessary. The note should include at a minimum critical information about the patient's condition including pulmonary status, cardiovascular status, BP, vital signs, etc.

Informed Consent

A properly executed informed consent form contains at least the following:

" Name of patient, and when appropriate, patient's legal guardian;

" Name of CAH;

" Name of procedure(s);

" Name of practitioner(s) performing the procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues.);

" Signature of patient or legal guardian;

" Date and time consent is obtained;

" Statement that procedure was explained to patient or guardian;

" Signature of professional person witnessing the consent; and

" Name/signature of person who explained the procedure to the patient or guardian.

The responsible practitioner must disclose to the patient any information necessary to enable the patient to evaluate a proposed medical or surgical procedure before submitting to it. Informed consent requires that a patient have a full understanding of that to which he or she has consented. An authorization from a patient who does not understand what he/she is consenting to is not informed consent.

Patients must be given sufficient information to allow them to make intelligent choices from among the alternative courses of available treatment for their specific ailments.
Informed consent must be given despite a patient's anxiety or indecisiveness.

The responsible practitioner must provide as much information about treatment options as is necessary based on a patient's personal understanding of the practitioner's explanation of the risks of treatment and the probable consequences of the treatment.

Informed consent means the patient or patient representative is given (in a language or means of communication

he/she understands) the information needed in order to consent to a procedure or treatment.

An informed consent would include at least: an explanation of the nature and purpose of the proposed procedures, risks and consequences of the procedures, risks and prognosis if no treatment is rendered, the probability that the proposed procedure will be successful, and alternative methods of treatment (if any) and their associated risks and benefits. Furthermore, informed consent would include that the patient is informed as to who will actually perform surgical interventions that are planned. When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon's supervision, the patient must be informed of who these other practitioners are, as well as, what important tasks each will carry out.

Post-Operative Care/Recovery

Adequate provisions for immediate post-operative care means:

" Post operative care must be in accordance with acceptable standards of practice.

" The post-operative care area or recovery room is a separate area of the CAH. Access is limited to authorized personnel.

" Policies and procedures specify transfer requirements to and from the recovery room. Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the recovery room should include some of the following:

" Level of activity

" Respirations

" Blood pressure

" Level of consciousness

" Patient color

" If the patients are not transferred to the recovery room, determine that provisions are made for close observation until they have regained consciousness, e.g., direct observation by an RN in the patient's room.

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Operating Room Register

The register should include at least the following information:

" Patient's name

" Patient's CAH identification number

" Date of the operation

" Inclusive or total time of the operation

" Name of the surgeon and any assistant(s)

" Name of nursing personnel (scrub and circulating)

" Type of anesthesia used and name of person administering it

" Operation performed

" Pre and post-op diagnosis

" Age of patient

Operative Report

The operative report would include at least:

" Name and CAH identification number of the patient;

" Date and times of the surgery;

" Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision);

" Pre-operative and post-operative diagnosis;

" Name of the specific surgical procedure(s) performed;

" Type of anesthesia administered;

" Complications, if any;

" A description of techniques, findings, and tissues removed or altered;

" Surgeons or practitioners name(s) and a description of the specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner (significant surgical procedures include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues); and

" Prosthetic devices, grafts, tissues, transplants, or devices implanted, if any.

Survey Procedures §485.639

" Inspect all inpatient and outpatient operative rooms/suites. Request the use of proper attire for the inspection. Observe the practices to determine if the services are provided in accordance with acceptable standards of practice. Observe:

" That access to the operative and recovery area is limited to authorized personnel and that the traffic flow pattern adheres to accepted standards of practice;

" The conformance to aseptic and sterile technique by all individuals in the surgical area;

" That there is appropriate cleaning between surgical cases and appropriate terminal cleaning applied;

" That operating room attire is suitable for the kind of surgical case performed, that persons working in the operating suite must wear only clean surgical attire, that surgical attire is designed for maximum skin and hair coverage;

" That equipment is available for rapid and routine sterilization of operating room materials and that equipment is

monitored, inspected, tested, and maintained by the CAH'S biomedical equipment program; and

" That sterilized materials are packaged, handled, labeled, and stored in a manner that ensures sterility e.g., in a moisture and dust controlled environment and policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practice.

" Review the CAH'S organizational chart displaying the relationship of the operating room service to other services. Confirm that the operating room's organization chart indicates lines of authority and delegation of responsibility within the department or service.

" If LPNs and surgical technologists (STs) are performing circulating duties, verify that they do so in accordance with applicable State laws and approved medical staff policies and procedures.

" Verify in situations where LPNs and STs are permitted to circulate that a qualified RN supervisor is immediately available to respond to emergencies.

" Review policies and procedures, to ascertain whether they contain the minimum policies specified in the interpretive guidelines.

" Review a sample of medical records of surgical patients to determine if a complete history and physical examination by a surgeon is completed prior to surgery, except in an emergency, and in accordance with the methodology described above.

" Review a sample of medical records of surgical patients to verify that they contain consent forms. Ascertain that the completed forms contain at least the information specified in the interpretive guidelines.

" Check to determine that the operating room suite has available the items listed.

" On-call system

" Cardiac monitor

" Resuscitator

" Defibrillator

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" Aspirator (suction equipment)

" Tracheotomy set (a cricothyroidotomy set is not a substitute)

" Verify that all equipment is working and, as applicable, in compliance with the CAH'S biomedical equipment inspection, testing, and maintenance program.

" Verify that the CAH has provisions for post-operative care.
" Determine that there are policies and procedures that govern the recovery room area.

" Examine the OR register or equivalent record which lists all surgery performed by the surgery service. Determine that the register includes items specified in the interpretive guidelines.

" Review a sample of medical records of patients who had a surgical encounter. Verify that they contain a surgical report that is dated and signed by the responsible surgeon and includes the information specified in the interpretive guidelines.

FED - C1142 - DESIGNATION OF QUALIFIED PRACTITIONERS

Title DESIGNATION OF QUALIFIED PRACTITIONERS

Type Standard

CFR 485.639(a)(1)
485.639(a)(2)
485.639(a)(3)

Regulation Definition

The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by--

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(2) A doctor of dental surgery or dental medicine; or

Interpretive Guideline

Interpretive Guidelines §485.639(a)

Surgical privileges should be reviewed and updated at least every 2 years. A current roster listing each practitioner's specific surgical privileges must be available in the surgical suite and area/location where the scheduling of surgical procedures is done. A current list of surgeons suspended from surgical privileges or whose surgical privileges have been restricted must be retained in these area/locations.

The CAH must delineate the surgical privileges of all practitioners performing surgery and surgical procedures. The medical staff is accountable to the governing body for the quality of care provided to patients. The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure

(3) A doctor of podiatric medicine.

for applying the criteria to individuals requesting privileges. Surgical privileges are granted in accordance with the competencies of each practitioner. The medical staff appraisal procedures must evaluate each individual practitioner's training, education, experience, and demonstrated competence as established by the CAH'S QA program, credentialing process, the practitioner's adherence to CAH policies and procedures, and in accordance with scope of practice and other State laws and regulations.

The CAH must specify the surgical privileges for each practitioner that performs surgical tasks. This would include practitioners such as MD/DOs, dentists, oral surgeons, podiatrists, RN first assistants, nurse practitioners, surgical physician assistants, surgical technicians, etc. When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures and the degree of supervision (to include whether or not the supervising practitioner is in the same OR in line of sight) be delineated in that practitioner's surgical privileges and included on the surgical roster.

When practitioners whose scope of practice for conducting surgical procedures requires the supervision of an MD/DO surgeon, the term "supervision" would mean the supervising MD/DO surgeon is present in the same room, working with the same patient.

Surgery and all surgical procedures must be conducted by a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted surgical privileges in accordance with those criteria established by the governing body (or responsible individual), and who is working within the scope of those granted and documented privileges.

Survey Procedures §485.639(a)

" Review the CAH'S method for reviewing the surgical privileges of practitioners. This method should require a written assessment of the practitioner's training, experience, health status, and performance.

" Determine that a current roster listing each practitioner's specific surgical privileges is available in the surgical suite and the area where the scheduling of surgical procedures is done.

" Determine that a current list of surgeons suspended from surgical privileges or who have restricted surgical privileges is retained in these areas/locations.

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FED - C1144 - ANESTHETIC RISK AND EVALUATION

Title ANESTHETIC RISK AND EVALUATION

Type Standard

CFR 485.639(b)(1)
485.639(b)(2)
485.639(b)(3)

Regulation Definition

(1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

Interpretive Guideline

Interpretive Guidelines §485.639(b)

The pre-anesthesia evaluation must be performed prior to inpatient or outpatient surgery. The pre-anesthesia evaluation must be performed by an individual qualified to administer anesthesia. The pre-operative anesthetic evaluation should include:

" Notation of anesthesia risk

" Anesthesia, drug and allergy history

" Any potential anesthesia problems identified

" Patient's condition prior to induction of anesthesia

The post-anesthesia follow-up report must be written on all inpatients and outpatients prior to discharge from surgery and anesthesia services. The post-anesthesia evaluation must be written by the individual who is qualified to administer the anesthesia. An MD/DO may delegate the post-anesthesia assessment and the writing of the post-anesthesia follow-up report to practitioners qualified to administer anesthesia in accordance with State law and CAH policy. When delegation of the post-anesthesia follow-up report is permitted, the medical staff must address its delegation requirements and methods in its bylaws. The post-anesthesia follow-up report must be documented in the patient's medical record, whether the patient is an inpatient or outpatient of the CAH, and must include at a minimum:

" Cardiopulmonary status;

" Level of consciousness;

" Any follow-up care and/or observations; and

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" Any complications occurring during post-anesthesia recovery.

Survey Procedures §485.639(b)

" Review records to determine that each patient has a pre-anesthesia evaluation by an individual qualified to administer anesthesia. The evaluation must be performed prior to surgery.

" Review medical records to determine that a post-anesthesia follow-up report is written for each patient receiving anesthesia services, by the individual who administered the anesthesia prior to discharge from anesthesia services. Documentation should include those items specified in interpretive guidelines.

FED - C1145 - ADMINISTRATION OF ANESTHESIA

Title ADMINISTRATION OF ANESTHESIA

Type Standard

CFR 485.639(c)(1)

Regulation Definition

The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws.

(1) Anesthesia must be administered by only--

(i) A qualified anesthesiologist;

(ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(iii) A doctor of dental surgery or dental medicine;

(iv) A doctor of podiatric medicine;

Interpretive Guideline

Interpretive Guidelines §485.639(c)(1)

The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. The CAH must specify the anesthesia privileges for each practitioner that administers anesthesia, or who supervises the administration of anesthesia by another practitioner. The privileges granted must be in accordance with State law and CAH policy. The type and complexity of procedures for which the practitioner may administer anesthesia, or supervise another practitioner supervising anesthesia, must be specified in the privileges granted to the individual practitioner.

A dentist, oral surgeon, or podiatrist may administer anesthesia in accordance with State law, their scope of practice and CAH policy. The anesthesia privileges of each practitioner must be specified. Anesthesia privileges are granted in accordance with the practitioner's scope of practice, State law, the individual competencies of the practitioner and the practitioner's compliance with the CAH'S credentialing criteria.

When a CAH permits operating practitioners to supervise CRNA administering anesthesia, the medical staff must specify in the statement of privileges for each category of operating practitioner, the type and complexity of

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(v) A certified registered nurse anesthetist (CRNA), as defined in Sec. 410.69(b) of this chapter;

(vi) An anesthesiologist's assistant, as defined in Sec. 410.69(b) of this chapter; or

(vii) A supervised trainee in an approved educational program, as described in §§ 413.85 or 413.86 of this chapter.

procedures they may supervise.
A CRNA may administer anesthesia when under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed (unless supervision is exempted in accordance with §485.639(e)). An anesthesiologist's assistant may administer anesthesia when under the supervision of an anesthesiologist who is immediately available if needed. Available to immediately intervene includes at a minimum, that the supervising anesthesiologist or operating practitioner, as applicable, is:

" Physically located within the operative suite or in the labor and delivery unit; and

" Is prepared to immediately conduct hands-on intervention if needed; and

" Is not engaged in activities that could prevent the supervising practitioner from being able to immediately intervene and conduct hands-on interventions if needed

Survey Procedures §485.639(c)(1)

" Review the qualifications of individuals authorized to deliver anesthesia.

" Determine that there is documentation of current licensure or current certification status for all persons administering anesthesia.

FED - C1147 - ADMINISTRATION OF ANESTHESIA

Title ADMINISTRATION OF ANESTHESIA

Type Standard

CFR 485.639(c)(2)

Regulation Definition

In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

Interpretive Guideline

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FED - C1149 - DISCHARGE

Title DISCHARGE

Type Standard

CFR 485.639(d)

Regulation Definition

All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

Interpretive Guideline

Interpretive Guidelines §485.639(d)

Any exceptions to this requirement must be made by the attending practitioner and annotated on the clinical record.

Survey Procedures §485.639(d)

Verify that the CAH has policies and procedures in place to govern discharge procedures and instructions.

FED - C1150 - STATE EXEMPTION

Title STATE EXEMPTION

Type Standard

CFR 485.639(e)

Regulation Definition

(1) A CAH may be exempted from the requirement for MD/DO supervision of CRNAs as described in paragraph (c) (2) of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from MD/DO supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best

Interpretive Guideline

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interests of the State's citizens to opt-out of the current MD/DO supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

FED - C1200 - INFECTION PREVENT & CONTROL & ABT STEWAR PROG

Title INFECTION PREVENT & CONTROL & ABT STEWAR PROG

Type Condition

CFR 485.640

Regulation Definition

The CAH must have active facility-wide programs, for the surveillance, prevention, and control of HAIs and other infectious diseases and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in coordination with the facility-wide quality assessment and performance improvement (QAPI) program.

Interpretive Guideline

Interpretive Guidelines §485.640

Guidance is pending and will be updated in future release.

Survey Procedures §485.640

Survey Procedures are pending and will be updated in future release.

FED - C1204 - INFECTION PREVENT & CONTROL ORG & POLICIES

Title INFECTION PREVENT & CONTROL ORG & POLICIES

Type Standard

CFR 485.640(a)(1)

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Regulation Definition	Interpretive Guideline
Infection prevention and control program organization and policies. The CAH must demonstrate that: (1) An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed by the governing body, or responsible individual, as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership;	Interpretive Guidelines §485.640(a)(1) Guidance is pending and will be updated in future release. Survey Procedures §485.640(a)(1) Survey Procedures are pending and will be updated in future release.

FED - C1206 - INFECTION PREVENT & CONTROL POLICIES

Title INFECTION PREVENT & CONTROL POLICIES

Type Standard

CFR 485.640(a)(2)

Regulation Definition	Interpretive Guideline
The infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the CAH and between the CAH and other healthcare settings;	Interpretive Guidelines §485.640(a)(2) Guidance is pending and will be updated in future release. Survey Procedures §485.640(a)(2) Survey Procedures are pending and will be updated in future release.

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FED - C1208 - INFECTION PREVENT SURVEIL & CONTROL OF HAIs

Title INFECTION PREVENT SURVEIL & CONTROL OF HAIs

Type Standard

CFR 485.640(a)(3)

Regulation Definition	Interpretive Guideline
The infection prevention and control includes surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and that the program also addresses any infection control issues identified by public health authorities; and	Interpretive Guidelines §485.640(a)(3) Guidance is pending and will be updated in future release. Survey Procedures §485.640(a)(3) Survey Procedures are pending and will be updated in future release.

FED - C1210 - INFECTION PREVENT & CONTROL SCOPE & SEVERITY

Title INFECTION PREVENT & CONTROL SCOPE & SEVERITY

Type Standard

CFR 485.640(a)(4)

Regulation Definition	Interpretive Guideline
The infection prevention and control program reflects the scope and complexity of the CAH services provided.	Interpretive Guidelines §485.640(a)(4) Guidance is pending and will be updated in future release. Survey Procedures §485.640(a)(4) Survey Procedures are pending and will be updated in future release.

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FED - C1212 - ABT STEWARDSHIP PROGRAM ORG & POLICIES

Title ABT STEWARDSHIP PROGRAM ORG & POLICIES

Type Standard

CFR 485.640(b)(1)

Regulation Definition	Interpretive Guideline
The CAH must demonstrate that: (1) An individual (or individuals), who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body, or responsible individual, as the leader(s) of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership;	Interpretive Guidelines §485.640(b)(1) Guidance is pending and will be updated in future release. Survey Procedures §485.640(b)(1) Survey Procedures are pending and will be updated in future release.

FED - C1218 - FACILITY-WIDE ABT STEWARDSHIP PROGRAM

Title FACILITY-WIDE ABT STEWARDSHIP PROGRAM

Type Standard

CFR 485.640(b)(2)(i)

Regulation Definition	Interpretive Guideline
The facility-wide antibiotic stewardship program: (i) Demonstrates coordination among all components of the CAH responsible or antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services;	Interpretive Guidelines §485.640(b)(2)(i) Guidance is pending and will be updated in future release. Survey Procedures §485.640(b)(2)(i) Survey Procedures are pending and will be updated in future release.

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FED - C1219 - DOCUMENTATION OF ANTIBIOTIC USE

Title DOCUMENTATION OF ANTIBIOTIC USE

Type Standard

CFR 485.640(b)(2)(ii)

Regulation Definition	Interpretive Guideline
Documents the evidence-based use of antibiotics in all departments and services of the CAH; and	Interpretive Guidelines §485.640(b)(2)(ii) Guidance is pending and will be updated in future release. Survey Procedures §485.640(b)(2)(ii) Survey Procedures are pending and will be updated in future release.

FED - C1220 - DOCUMENTATION OF PROPER ABT USE

Title DOCUMENTATION OF PROPER ABT USE

Type Standard

CFR 485.640(b)(2)(iii)

Regulation Definition	Interpretive Guideline
Documents any improvements, including sustained improvements, in proper antibiotic use;	Interpretive Guidelines §485.640(b)(2)(iii) Guidance is pending and will be updated in future release. Survey Procedures §485.640(b)(2)(iii) Survey Procedures are pending and will be updated in future release.

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FED - C1221 - ABT STEWARD PROGRAM AND NATIONAL GUIDELINES

Title ABT STEWARD PROGRAM AND NATIONAL GUIDELINES

Type Standard

CFR 485.640(b)(3)

Regulation Definition	Interpretive Guideline
The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use; and	Interpretive Guidelines §485.640(b)(3) Guidance is pending and will be updated in future release. Survey Procedures §485.640(b)(3) Survey Procedures are pending and will be updated in future release.

FED - C1223 - ABT STEWARDSHIP PRGOGRAM SCOPE & SEVERITY

Title ABT STEWARDSHIP PRGOGRAM SCOPE & SEVERITY

Type Standard

CFR 485.640(b)(4)

Regulation Definition	Interpretive Guideline
The antibiotic stewardship program reflects the scope and complexity of the CAH services provided.	Interpretive Guidelines §485.640(b)(4) Guidance is pending and will be updated in future release. Survey Procedures §485.640(b)(4) Survey Procedures are pending and will be updated in future release.

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FED - C1225 - LEADERSHIP RESPONSIBILITIES

Title LEADERSHIP RESPONSIBILITIES

Type Standard

CFR 485.640(c)(1)(i)

Regulation Definition	Interpretive Guideline
(1) The governing body, or responsible individual, must ensure all of the following: (i) Systems are in place and operational for the tracking of all infection surveillance, prevention and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.	Interpretive Guidelines §485.640(c)(1)(i) Guidance is pending and will be updated in future release. Survey Procedures §485.640(c)(1)(i) Survey Procedures are pending and will be updated in future release.

FED - C1229 - LEADERSHIP RESPONSIBILITIES

Title LEADERSHIP RESPONSIBILITIES

Type Standard

CFR 485.640(c)(1)(ii)

Regulation Definition	Interpretive Guideline
(ii) All HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with the CAH's QAPI leadership.	Interpretive Guidelines §485.640(c)(1)(ii) Guidance is pending and will be updated in future release. Survey Procedures §485.640(c)(1)(ii) Survey Procedures are pending and will be updated in future release.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C1231 - LEADERSHIP RESPONSIBILITIES

Title LEADERSHIP RESPONSIBILITIES

Type Standard

CFR 485.640(c)(2)(i)

Regulation Definition	Interpretive Guideline
(2) The infection prevention and control professional(s) is responsible for: (i) The development and implementation of facility-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.	Interpretive Guidelines §485.640(c)(2)(i) Guidance is pending and will be updated in future release. Survey Procedures §485.640(c)(2)(i) Survey Procedures are pending and will be updated in future release.

FED - C1235 - LEADERSHIP RESPONSIBILITIES

Title LEADERSHIP RESPONSIBILITIES

Type Standard

CFR 485.640(c)(2)(ii)

Regulation Definition	Interpretive Guideline
(2) The infection prevention and control professional(s) is responsible for:] (ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.	Interpretive Guidelines §485.640(c)(2)(ii) Guidance is pending and will be updated in future release. Survey Procedures §485.640(c)(2)(ii) Survey Procedures are pending and will be updated in future release.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C1237 - LEADERSHIP RESPONSIBILITIES

Title LEADERSHIP RESPONSIBILITIES

Type Standard

CFR 485.640(c)(2)(iii)

Regulation Definition	Interpretive Guideline
(2) The infection prevention and control professional(s) is responsible for:]	Interpretive Guidelines §485.640(c)(2)(iii) Guidance is pending and will be updated in future release.
(iii) Communication and collaboration with the CAH's QAPI program on infection prevention and control issues.	Survey Procedures §485.640(c)(2)(iii) Survey Procedures are pending and will be updated in future release.

FED - C1239 - LEADERSHIP RESPONSIBILITIES

Title LEADERSHIP RESPONSIBILITIES

Type Standard

CFR 485.640(c)(2)(iv)

Regulation Definition	Interpretive Guideline
(2) The infection prevention and control professional(s) is responsible for:]	Interpretive Guidelines §485.640(c)(2)(iv) Guidance is pending and will be updated in future release.
(iv) Competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAH, on the practical applications of infection prevention and control guidelines, policies and procedures.	Survey Procedures §485.640(c)(2)(iv) Survey Procedures are pending and will be updated in future release.

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FED - C1240 - LEADERSHIP RESPONSIBILITIES

Title LEADERSHIP RESPONSIBILITIES

Type Standard

CFR 485.640(c)(2)(v)

Regulation Definition	Interpretive Guideline
(2) The infection prevention and control professional(s) is responsible for:] (v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by CAH personnel.	Interpretive Guidelines §485.640(c)(2)(v) Guidance is pending and will be updated in future release. Survey Procedures §485.640(c)(2)(v) Survey Procedures are pending and will be updated in future release.

FED - C1242 - LEADERSHIP RESPONSIBILITIES

Title LEADERSHIP RESPONSIBILITIES

Type Standard

CFR 485.640(c)(2)(vi)

Regulation Definition	Interpretive Guideline
(2) The infection prevention and control professional(s) is responsible for:] (vi) Communication and collaboration with the antibiotic stewardship program.	Interpretive Guidelines §485.640(c)(2)(vi) Guidance is pending and will be updated in future release. Survey Procedures §485.640(c)(2)(vi) Survey Procedures are pending and will be updated in future release.

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FED - C1244 - LEADERSHIP RESPONSIBILITIES

Title LEADERSHIP RESPONSIBILITIES

Type Standard

CFR 485.640(c)(3)(i)

Regulation Definition	Interpretive Guideline
(3) The leader(s) of the antibiotic stewardship program is responsible for: (i) The development and implementation of a facility-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.	Interpretive Guidelines §485.640(c)(3)(i) Guidance is pending and will be updated in future release. Survey Procedures §485.640(c)(3)(i) Survey Procedures are pending and will be updated in future release.

FED - C1246 - LEADERSHIP RESPONSIBILITIES

Title LEADERSHIP RESPONSIBILITIES

Type Standard

CFR 485.640(c)(3)(ii)

Regulation Definition	Interpretive Guideline
(3) The leader(s) of the antibiotic stewardship program is responsible for:] (ii) All documentation, written or electronic, of antibiotic stewardship program activities.	Interpretive Guidelines §485.640(c)(3)(ii) Guidance is pending and will be updated in future release. Survey Procedures §485.640(c)(3)(ii) Survey Procedures are pending and will be updated in future release.

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FED - C1248 - LEADERSHIP RESPONSIBILITIES

Title LEADERSHIP RESPONSIBILITIES

Type Standard

CFR 485.640(c)(3)(iii)

Regulation Definition	Interpretive Guideline
(3) The leader(s) of the antibiotic stewardship program is responsible for:]	Interpretive Guidelines §485.640(c)(3)(iii)
	Guidance is pending and will be updated in future release.
(iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as the CAH's infection prevention and control and QAPI programs, on antibiotic use issues.	Survey Procedures §485.640(c)(3)(iii)
	Survey Procedures are pending and will be updated in future release.

FED - C1250 - LEADERSHIP RESPONSIBILITIES

Title LEADERSHIP RESPONSIBILITIES

Type Standard

CFR 485.640(c)(3)(iv)

Regulation Definition	Interpretive Guideline
(3) The leader(s) of the antibiotic stewardship program is responsible for:]	Interpretive Guidelines §485.640(c)(3)(iv)
	Guidance is pending and will be updated in future release.
(iv) Competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAHs, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.	Survey Procedures §485.640(c)(3)(iv)
	Survey Procedures are pending and will be updated in future release.

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FED - C1400 - DISCHARGE PLANNING

Title DISCHARGE PLANNING

Type Condition

CFR 485.642

Regulation Definition	Interpretive Guideline
A Critical Access Hospital (CAH) must have an effective discharge planning process that focuses on the patient's goals and treatment preferences and includes the patient and his or her caregivers/support person(s) as active partners in the discharge planning for post-discharge care. The discharge planning process and the discharge plan must be consistent with the patient's goals for care and his or her treatment preferences, ensure an effective transition of the patient from the CAH to post-discharge care, and reduce the factors leading to preventable CAH and hospital readmissions.	Interpretive Guidelines §485.642 Guidance is pending and will be updated in future release. Survey Procedures §485.642 Survey Procedures are pending and will be updated in future release.

FED - C1404 - DISCHARGE PLANNING PROCESS

Title DISCHARGE PLANNING PROCESS

Type Standard

CFR 485.642(a)

Regulation Definition	Interpretive Guideline
The CAH's discharge planning process must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning and must provide a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, patient's representative, or patient's physician.	Interpretive Guidelines §485.642(a) Guidance is pending and will be updated in future release. Survey Procedures §485.642(a) Survey Procedures are pending and will be updated in future release.

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FED - C1406 - DISCHARGE PLANNING EVALUATION

Title DISCHARGE PLANNING EVALUATION

Type Standard

CFR 485.642(a)(1)

Regulation Definition	Interpretive Guideline
(1) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-CAH care will be made before discharge and to avoid unnecessary delays in discharge.	Interpretive Guidelines §485.642(a)(1) Guidance is pending and will be updated in future release. Survey Procedures §485.642(a)(1) Survey Procedures are pending and will be updated in future release.

FED - C1408 - DISCHARGE PLANNING EVALUATION

Title DISCHARGE PLANNING EVALUATION

Type Standard

CFR 485.642(a)(2)

Regulation Definition	Interpretive Guideline
(2) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-CAH services, including, but not limited to, hospice care services, post- CAH extended care services, home health services, and non-health care services and community based care providers, and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.	Interpretive Guidelines §485.642(a)(2) Guidance is pending and will be updated in future release. Survey Procedures §485.642(a)(2) Survey Procedures are pending and will be updated in future release.

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FED - C1410 - DISCHARGE PLANNING EVALUATION

Title DISCHARGE PLANNING EVALUATION

Type Standard

CFR 485.642(a)(3)

Regulation Definition	Interpretive Guideline
(3) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).	Interpretive Guidelines §485.642(a)(3) Guidance is pending and will be updated in future release. Survey Procedures §485.642(a)(3) Survey Procedures are pending and will be updated in future release.

FED - C1412 - DISCHARGE PLAN

Title DISCHARGE PLAN

Type Standard

CFR 485.642(a)(4)

Regulation Definition	Interpretive Guideline
(4) Upon the request of a patient's physician, the CAH must arrange for the development and initial implementation of a discharge plan for the patient.	Interpretive Guidelines §485.642(a)(4) Guidance is pending and will be updated in future release. Survey Procedures §485.642(a)(4) Survey Procedures are pending and will be updated in future release.

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FED - C1417 - DISCHARGE PLANNING

Title DISCHARGE PLANNING

Type Standard

CFR 485.642(a)(5)

Regulation Definition	Interpretive Guideline
(5) Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered nurse, social worker, or other appropriately qualified personnel.	Interpretive Guidelines §485.642(a)(5) Guidance is pending and will be updated in future release. Survey Procedures §485.642(a)(5) Survey Procedures are pending and will be updated in future release.

FED - C1420 - DISCHARGE PLANNING

Title DISCHARGE PLANNING

Type Standard

CFR 485.642(a)(6)

Regulation Definition	Interpretive Guideline
(6) The CAH's discharge planning process must require regular reevaluation of the patient's condition to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.	Interpretive Guidelines §485.642(a)(6) Guidance is pending and will be updated in future release. Survey Procedures §485.642(a)(6) Survey Procedures are pending and will be updated in future release.

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FED - C1422 - DISCHARGE PLANNING

Title DISCHARGE PLANNING

Type Standard

CFR 485.642(a)(7)

Regulation Definition	Interpretive Guideline
(7) The CAH must assess its discharge planning process on a regular basis. The assessment must include ongoing, periodic review of a representative sample of discharge plans, including those patients who were readmitted within 30 days of a previous admission, to ensure that the plans are responsive to patient post-discharge needs.	Interpretive Guidelines §485.642(a)(7) Guidance is pending and will be updated in future release. Survey Procedures §485.642(7) Survey Procedures are pending and will be updated in future release.

FED - C1425 - DISCHARGE PLANNING

Title DISCHARGE PLANNING

Type Standard

CFR 485.642(a)(8)

Regulation Definition	Interpretive Guideline
(8) The CAH must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The CAH must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.	Interpretive Guidelines §485.642(a)(8) Guidance is pending and will be updated in future release. Survey Procedures §485.642(a)(8) Survey Procedures are pending and will be updated in future release.

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FED - C1430 - DISCHARGE PLANNING

Title DISCHARGE PLANNING

Type Standard

CFR 485.642(b)

Regulation Definition	Interpretive Guideline
(b) Standard: Discharge of the patient and provision and transmission of the patient's necessary medical information. The CAH must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, postdischarge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.	

FED - C1500 - ORGAN, TISSUE, AND EYE PROCUREMENT

Title ORGAN, TISSUE, AND EYE PROCUREMENT

Type Condition

CFR 485.643

Regulation Definition	Interpretive Guideline
The CAH must have and implement written protocols that:	Interpretive Guidelines §485.643 The CAH must have written policies and procedures to address its organ procurement responsibilities.

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FED - C1503 - ORGAN, TISSUE, & EYE PROCUREMENT

Title ORGAN, TISSUE, & EYE PROCUREMENT

Type Standard

CFR 485.643(a)

Regulation Definition

§485.643(a) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;

Interpretive Guideline

Interpretive Guidelines §485.643(a)

The CAH must have a written agreement with an Organ Procurement Organization (OPO), designated under 42 CFR Part 486. At a minimum, the written agreement must address the following:

" The criteria for referral, including the referral of all individuals whose death is imminent or who have died in the CAH;

" Includes a definition of "imminent death";

" Includes a definition of "timely notification";

" Addresses the OPO's responsibility to determine medical suitability for organ donation;

" Specifies how the tissue and/or eye bank will be notified about potential donors using S notification protocols developed by the OPO in consultation with the CAH-designated tissue and eye bank(s);

" Provides for notification of each individual death in a timely manner to the OPO (or designated third party) in accordance with the terms of the agreement;

" Ensures that the designated requestor training program offered by the OPO has been developed in cooperation with the tissue bank and eye bank designated by the CAH;

" Permits the OPO, tissue bank, and eye bank access to the CAH'S death record information according to a designated schedule, e.g., monthly or quarterly;

" Includes that the CAH is not required to perform credentialing reviews for, or grant privileges to, members of

organ recovery teams as long as the OPO sends only "qualified, trained individuals" to perform organ recovery; and

" The interventions the CAH will utilize to maintain potential organ donor patients so that the patient organs remain viable.

CAHs must notify the OPO of every death or imminent death in the CAH. When death is imminent, the CAH must notify the OPO both before a potential donor is removed from a ventilator and while the potential donor's organs are still viable. The CAH should have a written policy, developed in coordination with the OPO and approved by the CAH'S medical staff and governing body, to define "imminent death." The definition for "imminent death" should strike a balance between the needs of the OPO and the needs of the CAH'S care givers to continue treatment of a patient until brain death is declared or the patient's family has made the decision to withdraw supportive measures. Collaboration between OPOs and CAHs will create a partnership that furthers donation, while respecting the perspective of CAH staff.

The definition for "imminent death" might include a patient with severe, acute brain injury who:

" Requires mechanical ventilation;

" Is in an intensive care unit (ICU) or emergency department; AND

" Has clinical findings consistent with a Glascow Coma Score that is less than or equal to a mutually-agreed-upon threshold; or

" MD/DOs are evaluating a diagnosis of brain death; or

" An MD/DO has ordered that life sustaining therapies be withdrawn, pursuant to the family's decision.

CAHs and their OPO should develop a definition of "imminent death" that includes specific triggers for notifying the OPO about an imminent death.

In determining the appropriate threshold for the Glasgow Coma Score (GCS), it is important to remember that if the threshold is too low, there may be too many "premature" deaths or situations where there is a loss of organ viability. Standards for appropriate GCS thresholds may be obtained from the CAH'S OPO or organizations such as the Association of Organ Procurement Organizations.

Note that a patient with "severe, acute brain injury" is not always a trauma patient. For example, post myocardial infarction resuscitation may result in a patient with a beating heart and no brain activity.

The definition agreed to by the CAH and the OPO may include all of the elements listed above or just some of the elements. The definition should be tailored to fit the particular circumstances in each CAH.

CAHs may not use "batch reporting" for deaths by providing the OPO with periodic lists of patient deaths, even if instructed to do so by the OPO. If the patient dies during a transfer from one CAH to another, it is the receiving CAH'S responsibility to notify the OPO.

"Timely notification" means a CAH must contact the OPO by telephone as soon as possible after an individual has died, has been placed on a ventilator due to a severe brain injury, or who has been declared brain dead (ideally within 1 hour). That is, a CAH must notify the OPO while a brain dead or severely brain-injured, ventilator-dependent individual is still attached to the ventilator and as soon as possible after the death of any other individual, including a potential non-heart-beating donor. Even if the CAH does not consider an individual who is not on a ventilator to be a potential donor, the CAH must call the OPO as soon as possible after the death of that individual has occurred.

Referral by a CAH to an OPO is timely if it is made:

" As soon as it is anticipated a patient will meet the criteria for imminent death agreed to by the OPO and CAH or as soon as possible after a patient meets the criteria for imminent death agreed to by the OPO and the CAH (ideally, within one hour); AND

" Prior to the withdrawal of any life sustaining therapies (i.e., medical or pharmacological support).

Whenever possible, referral should be made early enough to allow the OPO to assess the patient's suitability for organ donation before brain death is declared and before the option of organ donation is presented to the family of the potential donor. Timely assessment of the patient's suitability for organ donation increases the likelihood that the patient's organs will be viable for transplantation (assuming there is no disease process identified by the OPO that would cause the organs to be unsuitable), ensures that the family is approached only if the patient is medically suitable for organ donation, and ensures that an OPO representative is available to collaborate with the CAH staff in discussing donation with the family.

It is the OPO's responsibility to determine medical suitability for organ donation, and, in the absence of alternative

arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose.

Survey Procedures §485.643(a)

" Review the CAH'S written agreement with the OPO to verify that it addresses all required information.

" Verify that the CAH'S governing body has approved the CAH'S organ procurement policies.

" Review a sample of death records to verify that the CAH has implemented its organ procurement policies.

" Interview the staff to verify that they are aware of the CAH'S policies and procedures for organ, tissue and eye procurement.

" Verify that the organ, tissue and eye donation program is integrated into the CAH'S QA program.

FED - C1505 - ORGAN, TISSUE, & EYE PROCUREMENT

Title ORGAN, TISSUE, & EYE PROCUREMENT

Type Standard

CFR 485.643(b)

Regulation Definition

§485.643(b) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

Interpretive Guideline

Interpretive Guidelines §485.643(b)

The CAH must have an agreement with at least one tissue bank and at least one eye bank. The OPO may serve as a "gatekeeper" receiving notification about every CAH death and should notify the tissue bank chosen by the CAH about potential tissue and eye donors.

It is not necessary for a CAH to have a separate agreement with a tissue bank if it has an agreement with its OPO to provide tissue procurement services; not is it necessary for a CAH to have a separate agreement with an eye bank if its OPO provides eye procurement services. The CAH is not required to use the OPO for tissue or eye procurement but is free to have an agreement with the tissue bank or eye bank of its choice. The tissue banks and eye banks define "usable tissues" and "usable eyes."

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The requirements of this regulation may be satisfied through a single agreement with an OPO that provides services for organ, tissue and eye, or by a separate agreement with another tissue and/or eye bank outside the OPO, chosen by the CAH. The CAH may continue current successful direct arrangements with tissue and eye banks as long as the direct arrangement does not interfere with organ procurement.

Survey Procedures §485.643(b)

Verify that the CAH has an agreement with at least one tissue bank and one eye bank that specifies criteria for referral of all individuals who have died in the CAH. The agreement must also acknowledge that it is the OPO's responsibility to determine medical suitability for tissue and eye donation, unless the CAH has an alternative agreement with a different tissue and/or eye bank.

FED - C1507 - ORGAN, TISSUE, & EYE PROCUREMENT

Title ORGAN, TISSUE, & EYE PROCUREMENT

Type Standard

CFR 485.643(c)

Regulation Definition

Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to either donate or not donate organs, tissues, or eyes. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

Interpretive Guideline

Interpretive Guidelines §485.643(c)

It is the responsibility of the OPO to screen for medical suitability in order to select potential donors. Once the OPO has selected a potential donor, that person's family must be informed of the family's donation options.

Ideally, the OPO and the CAH will decide together how and by whom the family will be approached.

The individual designated by the CAH to initiate the request to the family must be a designated requestor.

A "designated requestor" is defined as a CAH-designated individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community. If possible, the OPO representative and a designated requestor should approach the family together.

The CAH must ensure that any "designated requestor" for organs, tissues or eyes has completed a training course

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either offered or approved by the OPO, which addresses methodology for approaching potential donor families.

Survey Procedures §485.643(c)

" Verify that the CAH ensures that the family of each potential donor is informed of its options to donate organs , tissues, or eyes, including the option to decline to donate.

" Review training schedules and personnel files to verify that all designated requestors have completed the required training.

" How does the CAH ensure that only designated requestors are approaching families to ask them to donate?

FED - C1509 - ORGAN, TISSUE, & EYE PROCUREMENT

Title ORGAN, TISSUE, & EYE PROCUREMENT

Type Standard

CFR 485.643(d)

Regulation Definition

Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the family of potential donors;

Interpretive Guideline

Interpretive Guidelines §485.643(d)

Using discretion does not mean a judgment can be made by the CAH that certain families should not be approached about donation. CAHs should approach the family with the belief that a donation is possible and should take steps to ensure the family is treated with respect and care. The staff's perception that a family's grief, race, ethnicity, religion or socioeconomic background would prevent donation should never be used as a reason not to approach a family.

All potential donor families must be approached and informed of their donation rights.

Survey Procedures §485.643(d)

" Interview a CAH-designated requestor regarding approaches to donation requests.

" Review the designated requestor training program to verify that it addresses the use of discretion.

" Review the facility complaint file for any relevant complaints.

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FED - C1511 - ORGAN, TISSUE, & EYE PROCUREMENT

Title ORGAN, TISSUE, & EYE PROCUREMENT

Type Standard

CFR 485.643(e)
485.643(f)

Regulation Definition

Ensure that the CAH works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes takes place.

§485.643(f) For purpose of these standards, the term "organ" means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

Interpretive Guideline

Interpretive Guidelines §485.643(e)

Appropriate staff, including all patient care staff, must be trained regarding donation issues and how to work with the OPO, tissue bank and eye bank. Those CAH staff who may have to contact or work with the OPO, tissue bank and eye bank staff, must have appropriate training on donation issues including their duties and roles.

The training program must be developed in cooperation with the OPO, tissue bank and eye bank, and should include, at a minimum:

" Consent process;

" Importance of using discretion and sensitivity when approaching families;

" Role of the designated requestor;

" Transplantation and donation, including pediatrics, if appropriate;

" Quality improvement activities; and

" Role of the organ procurement organization.

Training should be conducted with new employees annually, whenever there are policy/procedure changes, or when problems are determined through the CAH'S QA program.

CAHs must cooperate with OPOs, tissue banks and eye banks in regularly/periodically reviewing death records. This means that a CAH must develop policies and procedures which permit the OPO, tissue bank and eye bank access to death record information that will allow the OPO, tissue bank and eye bank to assess the CAH'S donor potential,

ensure that all deaths or imminent deaths are being referred to the OPO in a timely manner, and identify areas where the CAH, OPO, tissue bank and eye bank staff performance might be improved. The policies must address how patient confidentiality will be maintained during the review process.

The CAH must have policies and procedures, developed in cooperation with the OPO, that ensure that potential donors are maintained in a manner that maintain the viability of their organs. The CAH must have policies in place to ensure that potential donors are identified and declared dead within an acceptable time frame by an appropriate practitioner.

Survey Procedures §485.643(e)

" Review inservice training schedules and attendance sheets.

" How does the CAH ensure that all appropriate staff have attended an educational program regarding donation issues and how to work with the OPO, tissue bank, and eye bank?

" Verify by review of policies and records that the CAH works with the OPO, tissue bank, and eye bank in reviewing death records.

" Verify that the effectiveness of any protocols and policies is monitored as part of the CAH'S quality improvement program.

" Validate how often the reviews are to occur. Review the protocols that are in place to guide record reviews and analysis.

" Determine how confidentiality is ensured.

" Verify that there are policies and procedures in place to ensure coordination between the facility staff and the OPO staff in maintaining the potential donor.

" Determine by review, what policies and procedures are in place to ensure that potential donors are identified and declared dead by an appropriate practitioner within an acceptable timeframe.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C1600 - SPECIAL REQUIREMENTS FOR CAH PROVIDERS LTC

Title SPECIAL REQUIREMENTS FOR CAH PROVIDERS LTC

Type Condition

CFR 485.645

Regulation Definition

A CAH must meet the following requirements in order to be granted an approval from CMS to provide post-CAH SNF care, as specified in §409.30 of this chapter, and to be paid for SNF-level services, in accordance with paragraph (c) of this section.

Interpretive Guideline

Interpretive Guidelines §485.645

The swing-bed concept allows a CAH to use their beds interchangeably for either acute-care or post-acute care. A "swing-bed" is a change in reimbursement status. The patient swings from receiving acute-care services and reimbursement to receiving skilled nursing (SNF) services and reimbursement.

Medicare allows a CAH to operate swing-beds through the issuance of a "swing-bed approval." If the facility fails to meet the swing-bed requirements, and the facility does not develop and implement an accepted plan of correction, the facility loses the approval to operate swing-beds and receive swing-bed reimbursement. The facility does not go on a termination track. If the CAH continues to meet the CoP for the provider type, it continues to operate but loses swing-bed approval.

Swing-beds need not be located in a special section of the CAH. The patient need not change locations in the facility merely because his/her status changes unless the facility requires it.

The change in status from acute care to swing-bed status can occur within one facility or the patient can be transferred from another facility for swing-bed admission.

There must be discharge orders from acute inpatient care services and subsequent admission orders for swing-bed services, the same as if the patient had been transferred to a separately certified skilled nursing facility. The same clinical record may be used for a swing-bed patient, but it must include discharge orders from acute care and admission orders to swing-bed services, and the swing-bed services (which may be SNF or NF level services) must be clearly delineated within the clinical record.

There is no length of stay restriction for any CAH swing-bed patient. There is no Medicare requirement to place a swing-bed patient in a nursing home and there are no requirements for transfer agreements between CAHs and nursing homes. While there is no length of stay limit for patients in swing-bed status, the intended use for swing beds

is for a transitional time period to allow the patient to fully recover to return home or while awaiting placement into a nursing facility. The CAH should document in the patient's medical record efforts made for nursing facility placement.

Medicare coverage rules require that, in order to be eligible for coverage of post-hospital swing-bed care, a beneficiary must have a qualifying 3-day inpatient stay in a participating or qualified hospital or participating CAH prior to admission to a swing-bed.

There is no requirement for a CAH to use the MDS form for recording the patient assessment or for nursing care planning.

Swing-bed patients receive a SNF level of care, and the CAH is reimbursed for providing a SNF level of care, however swing-bed patients are not SNF patients. Swing-bed patients in CAHs are considered to be patients of the CAH.

NOTE: Swing-beds must not be confused with beds in a skilled nursing facility (SNF) or nursing facility (NF), including a distinct part SNF/NF, that shares the same building/campus as the CAH but is a separately certified provider with its own Medicare provider agreement.

FED - C1602 - ELIGIBILITY

Title ELIGIBILITY

Type Standard

CFR 485.645(a)(1)
485.645(a)(2)

Regulation Definition

A CAH must meet the following eligibility requirements:

(1) The facility has been certified as a CAH by CMS under §485.606(b) of this subpart; and

(2) The facility provides not more than 25 inpatient beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section.

Interpretive Guideline

Interpretive Guidelines §485.645(a) Eligibility

CAHs seeking swing-bed approval are screened prior to survey for their eligibility for swing-beds. However, the CMS RO makes the determination whether the CAH has satisfied the eligibility criteria, regardless of whether the SA or AO, as applicable, recommends approval of swing-bed status (this responsibility may not be delegated to the SA).

The eligibility criteria at 42 CFR 485.645(a) requires:

o The CAH has a Medicare provider agreement;

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o An initial CAH applicant may seek swing-bed approval. If the CAH applicant meets all Federal Requirements for participation, including those for swing-bed approval, the CAH applicant's approval for swing-bed services will be effective with the CAH's effective date of Medicare participation;

FED - C1604 - ELIGIBILITY

Title ELIGIBILITY

Type Standard

CFR 485.645(b)(1)
485.645(b)(2)

Regulation Definition

Facilities Participating as Rural Primary Care Hospitals (RPCHs) on September 30, 1997

These facilities must meet the following requirements:

(1) Notwithstanding paragraph (a) of this section, a hospital that participated in Medicare as a RPCH on September 30, 1997, and on that date had in effect an approval from CMS to use its inpatient facilities to provide post-hospital SNF care may continue in that status under the same terms, conditions, and limitations that were applicable at the time these approvals were granted..

(2) A CAH that was granted swing-bed approval under paragraph (b)(1) of this section may request that its application to be a CAH and swing-bed provider be reevaluated under paragraph (a) of this section. If this request is approved, the approval is effective not earlier than October 1, 1997. As of the date of approval, the CAH no longer has any status under paragraph (b)(1) of this section and may not request reinstatement under paragraph (b)(1) of this section.

Interpretive Guideline

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C1606 - PAYMENT

Title PAYMENT

Type Standard

CFR 485.645(c)

Regulation Definition	Interpretive Guideline
Payment for inpatient RPCH services to a CAH that has qualified as a CAH under the provisions in paragraph (a) of this section is made in accordance with §413.70 of this chapter. Payment for post-hospital SNF-level of care services is made in accordance with the payment provisions in §413.114 of this chapter.	

FED - C1608 - SNF SERVICES

Title SNF SERVICES

Type Standard

CFR 485.645(d)(1)

Regulation Definition	Interpretive Guideline
The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter: §485.645(d)(1) Resident Rights (§483.10(b)(7), (c)(1), (c)(2)(iii), (c)(6), (d), (e)(2) and (4), (f)(4)(ii) and (iii), (g)(8) and (17), (g)(18) introductory text, (h) of this chapter). " §483.10(b)(7) In the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the rights of the resident devolve to and are	Interpretive Guidelines §485.645(d)(1) Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines. Survey Procedures §485.645(d)(1) Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

exercised by the resident representative appointed under State law to act on the resident's behalf. The court-appointed resident representative exercises the resident's rights to the extent judged necessary by a court of competent jurisdiction, in accordance with State law.

" §483.10(c) Planning and implementing care. The resident has the right to be informed of, and participate in, his or her treatment, including:

(1) The right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition.

" §483.10(c)(2)(iii) The right to be informed, in advance, of changes to the plan of care.

" §483.10(c)(6) The right to request, refuse, and/or discontinue treatment, to participate in or refuse to participate in experimental research, and to formulate an advance directive.

" §483.10(d) Choice of attending physician. The resident has the right to choose his or her attending physician.

(1) The physician must be licensed to practice, and

(2) If the physician chosen by the resident refuses to or does not meet requirements specified in this part, the facility may seek alternate physician participation as specified in paragraphs (d)(4) and (5) of this section to assure provision of appropriate and adequate care and treatment.

(3) The facility must ensure that each resident remains informed of the name, specialty, and way of contacting the

physician and other primary care professionals responsible for his or her care.

(4) The facility must inform the resident if the facility determines that the physician chosen by the resident is unable or unwilling to meet requirements specified in this part and the facility seeks alternate physician participation to assure provision of appropriate and adequate care and treatment. The facility must discuss the alternative physician participation with the resident and honor the resident's preferences, if any, among options.

(5) If the resident subsequently selects another attending physician who meets the requirements specified in this part, the facility must honor that choice.

" §483.10(e)(2) The right to retain and use personal possessions, including furnishings, and clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

" §483.10(e)(4) The right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

" §483.10(f)(4)(ii) The facility must provide immediate access to a resident by immediate family and other relatives of the resident, subject to the resident's right to deny or withdraw consent at any time;

" §483.10(f)(4)(iii) The facility must provide immediate access to a resident by others who are visiting with the consent of the resident, subject to reasonable clinical and safety restrictions and the resident's right to deny or withdraw consent at any time;

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" §483.10(g)(8) The resident has the right to send and receive mail, and to receive letters, packages and other materials delivered to the facility for the resident through a means other than a postal service, including the right to:

(i) Privacy of such communications consistent with this section; and

(ii) Access to stationery, postage, and writing implements at the resident's own expense.

" §483.10(g)(17) The facility must-

(i) Inform each Medicaid-eligible resident, in writing, at the time of admission to the nursing facility and when the resident becomes eligible for Medicaid of-

(A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;

(B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and

(ii) Inform each Medicaid-eligible resident when changes are made to the items and services specified in §483.10(g)(17)(i)(A) and (B) of this section.

" §483.10(g)(18)[introductory text only] The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any

charges for services not covered under Medicare/Medicaid or by the facility's per diem rate.

" §483.10(h) Privacy and confidentiality. The resident has a right to personal privacy and confidentiality of his or her personal and medical records.

(1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident.

(2) The facility must respect the residents right to personal privacy, including the right to privacy in his or her oral (that is, spoken), written, and electronic communications, including the right to send and promptly receive unopened mail and other letters, packages and other materials delivered to the facility for the resident, including those delivered through a means other than a postal service.

(3) The resident has a right to secure and confidential personal and medical records.

(i) The resident has the right to refuse the release of personal and medical records except as provided at §483.70(i)(2) or other applicable federal or state laws.

(ii) The facility must allow representatives of the Office of the State Long-Term Care Ombudsman to examine a resident's medical, social, and administrative records in accordance with State law.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C1610 - ADMISSION, TRANSFER, & DISCHARGE RIGHTS

Title ADMISSION, TRANSFER, & DISCHARGE RIGHTS

Type Standard

CFR 485.645(d)(2)

Regulation Definition

Admission, Transfer and Discharge Rights (§483.5 definition of transfer & discharge, §483.15(c)(1), (c)(2), (c)(3), (c)(4), (c)(5), (c)(7), (c)(8), and (c)(9) of this chapter).

" §483.5 definition of transfer & discharge: Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.

" §483.15(c)(1) Transfer and discharge-(1) Facility requirements-

(i) The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless-

(A) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;

(B) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;

(C) The safety of individuals in the facility is endangered due to the clinical or behavioral status of the resident;

Interpretive Guideline

Interpretive Guidelines §485.645(d)(2)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(2)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

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(D) The health of individuals in the facility would otherwise be endangered;

(E) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. Non-payment applies if the resident does not submit the necessary paperwork for third party payment or after the third party, including Medicare or Medicaid, denies the claim and the resident refuses to pay for his or her stay. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or

(F) The facility ceases to operate.

(ii) The facility may not transfer or discharge the resident while the appeal is pending, pursuant to §431.230 of this chapter, when a resident exercises his or her right to appeal a transfer or discharge notice from the facility pursuant to §431.220(a)(3) of this chapter, unless the failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility. The facility must document the danger that failure to transfer or discharge would pose.

" §483.15(c)(2) Documentation. When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (c)(1)(i)(A) through (F) of this section, the facility must ensure that the transfer or discharge is documented in the resident's medical record and appropriate information is communicated to the receiving health care institution or provider.

(i) Documentation in the resident's medical record must include:

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(A) The basis for the transfer per paragraph (c)(1)(i) of this section.

(B) In the case of paragraph (c)(1)(i)(A) of this section, the specific resident need(s) that cannot be met, facility attempts to meet the resident needs, and the service available at the receiving facility to meet the need(s).

(ii) The documentation required by paragraph (c)(2)(i) of this section must be made by-

(A) The resident's physician when transfer or discharge is necessary under paragraph (c)(1)(A) or (B) of this section; and

(B) A physician when transfer or discharge is necessary under paragraph (c)(1)(i)(C) or (D) of this section.

(iii) Information provided to the receiving provider must include a minimum of the following:

(A) Contact information of the practitioner responsible for the care of the resident

(B) Resident representative information including contact information.

(C) Advance Directive information.

(D) All special instructions or precautions for ongoing care, as appropriate.

(E) Comprehensive care plan goals,

(F) All other necessary information, including a copy of the

resident's discharge summary, consistent with §483.21(c)(2), as applicable, and any other documentation, as applicable, to ensure a safe and effective transition of care.

" §483.15(c)(3) Notice before transfer. Before a facility transfers or discharges a resident, the facility must-

(i) Notify the resident and the resident's representative(s) of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. The facility must send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman.

(ii) Record the reasons for the transfer or discharge in the resident's medical record in accordance with paragraph (c)(2) of this section; and

(iii)Include in the notice the items described in paragraph (c)(5) of this section.

" §483.15(c)(4) Timing of the notice.

(i) Except as specified in paragraphs (c)(4)(ii) and (8) of this section, the notice of transfer or discharge required under this section must be made by the facility at least 30 days before the resident is transferred or discharged.

(ii)Notice must be made as soon as practicable before transfer or discharge when-

(A) The safety of individuals in the facility would be endangered under paragraph (c)(1)(i)(C) of this section;

(B) The health of individuals in the facility would be endangered, under paragraph (c)(1)(i)(D) of this section;

(C) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (c)(1)(i)(B) of this section;

(D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (c)(1)(i)(A) of this section; or

(E) A resident has not resided in the facility for 30 days.

" §483.15(c)(5) Contents of the notice. The written notice specified in paragraph (c)(3) of this section must include the following:

(i) The reason for transfer or discharge;

(ii) The effective date of transfer or discharge;

(iii) The location to which the resident is transferred or discharged;

(iv) A statement of the resident's appeal rights, including the name, address (mailing and email), and telephone number of the entity which receives such requests; and information on how to obtain an appeal form and assistance in completing the form and submitting the appeal hearing request;

(v) The name, address (mailing and email) and telephone number of the Office of the State Long-Term Care Ombudsman;

(vi) For nursing facility residents with intellectual and developmental disabilities or related disabilities, the mailing and email address and telephone number of the agency

responsible for the protection and advocacy of individuals with developmental disabilities established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (Pub. L. 106-402, codified at 42 U.S.C. 15001 et seq.); and

(vii) For nursing facility residents with a mental disorder or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with a mental disorder established under the Protection and Advocacy for Mentally Ill Individuals Act.

" §483.15(c)(7) Orientation for transfer or discharge. A facility must provide and document sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility. This orientation must be provided in a form and manner that the resident can understand.

" §483.15(c)(8) Notice in advance of facility closure. In the case of facility closure, the individual who is the administrator of the facility must provide written notification prior to the impending closure to the State Survey Agency, the Office of the State Long-Term Care Ombudsman, residents of the facility, and the resident representatives, as well as the plan for the transfer and adequate relocation of the residents, as required at §483.70(l).

" §483.15(c)(9) Room changes in a composite distinct part. Room changes in a facility that is a composite distinct part (as defined in §483.5) are subject to the requirements of §483.10(e)(7) and must be limited to moves within the particular building in which the resident resides, unless the resident voluntarily agrees to move to another of the composite distinct part's locations.

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

FED - C1612 - FREEDOM FROM ABUSE, NEGLECT & EXPLOITATION

Title FREEDOM FROM ABUSE, NEGLECT & EXPLOITATION

Type Standard

CFR 485.645(d)(3)

Regulation Definition

Freedom from abuse, neglect and exploitation (§483.12(a)(1), (a)(2), (a)(3)(i), (a)(3)(ii), (a)(4), (b)(1), (b)(2), (c)(1), (c)(2), (c)(3), and (c)(4) of this chapter).

" §483.12(a)(1) Freedom from abuse, neglect, and exploitation. The resident has the right to be free from abuse, neglect, misappropriation of resident property, and exploitation as defined in this subpart. This includes but is not limited to freedom from corporal punishment, involuntary seclusion and any physical or chemical restraint not required to treat the resident's medical symptoms.(a) The facility must-
(1) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;

" §483.12(a)(2) Ensure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident's medical symptoms. When the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints.
" §483.12(a)(3) Not employ or otherwise engage individuals who-
(i) Have been found guilty of abuse, neglect, exploitation, misappropriation of property, or mistreatment by a court of law;

Interpretive Guideline

Interpretive Guidelines §485.645(d)(3)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(3)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures

(ii) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, exploitation, mistreatment of residents or misappropriation of their property.

" §483.12(a)(4) Report to the State nurse aide registry or licensing authorities any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff.

" §483.12(b) The facility must develop and implement written policies and procedures that:

(1) Prohibit and prevent abuse, neglect, and exploitation of residents and misappropriation of resident property,

(2) Establish policies and procedures to investigate any such allegations,

" §483.12(c) In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must:

(1) Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, are reported immediately, but not later than 2 hours after the allegation is made, if the events that cause the allegation involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the allegation do not involve abuse and do not result in serious bodily injury, to the administrator of the facility and to other officials (including to the State Survey Agency and adult protective services where state law provides for jurisdiction in long-term care facilities) in accordance with State law through established procedures.

(2) Have evidence that all alleged violations are thoroughly

investigated.

(3) Prevent further potential abuse, neglect, exploitation, or mistreatment while the investigation is in progress.

(4) Report the results of all investigations to the administrator or his or her designated representative and to other officials in accordance with State law, including to the State Survey Agency, within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.

FED - C1616 - SOCIAL SERVICES

Title SOCIAL SERVICES

Type Standard

CFR 485.645(d)(4)

Regulation Definition

Social Services (§483.40(d) of this chapter).

" §483.40(d) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.

Interpretive Guideline

Interpretive Guidelines §485.645(d)(4)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(4)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

FED - C1620 - COMP ASSESSMENT, CARE PLAN & DISCHARGE

Title COMP ASSESSMENT, CARE PLAN & DISCHARGE

Type Standard

CFR 485.645(d)(5)

Aspen Federal Regulation Set: C 10.00 CRITICAL ACCESS HOSPITALS

Regulation Definition

§485.645(d)(5) Comprehensive assessment, comprehensive care plan, and discharge planning (§483.20(b), and §483.21(b) and (c)(2) of this chapter), except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under §483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in §413.343(b) of this chapter).

" §483.20(b) Comprehensive assessments-

(1) Resident assessment instrument. A facility must make a comprehensive assessment of a resident's needs, strengths, goals, life history and preferences, using the resident assessment instrument (RAI) specified by CMS. The assessment must include at least the following:

(i) Identification and demographic information.

(ii) Customary routine.

(iii) Cognitive patterns.

(iv) Communication.
(v) Vision.

(vi) Mood and behavior patterns.

(vii) Psychosocial well-being.

(viii) Physical functioning and structural problems.

(ix) Continence.

(x) Disease diagnoses and health conditions.

Interpretive Guideline

Interpretive Guidelines §485.645(d)(5)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(5)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

*NOTE: The CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under §483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in §413.343(b) of this chapter). Also, note that CAHs are not required to complete the PASARR. However, if a patient had a PASARR completed by a facility that was required to do so prior to admission into a CAH swing bed, the recommendations from the PASARR should be included in the CAHs comprehensive treatment plan for the patient.

(xi) Dental and nutritional status.

(xii) Skin condition.

(xiii) Activity pursuit.

(xiv) Medications.

(xv) Special treatments and procedures.

(xvi) Discharge planning.

(xvii) Documentation of summary information regarding the additional assessment performed on the care areas triggered by the completion of the Minimum Data Set (MDS).

(xviii) Documentation of participation in assessment. The assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members on all shifts.

(2) When required. Subject to the timeframes prescribed in §413.343(b) of this chapter, a facility must conduct a comprehensive assessment of a resident in accordance with the timeframes specified in paragraphs (b)(2) (i) through (iii) of this section. The timeframes prescribed in §413.343(b) of this chapter do not apply to CAHs.

(i) Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition. (For purposes of this section, "readmission" means a return to the facility following a temporary absence for hospitalization or for therapeutic leave.)

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(ii) Within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. (For purposes of this section, a "significant change" means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires interdisciplinary review or revision of the care plan, or both.)

(iii) Not less often than once every 12 months.

" §483.21(b) Comprehensive care plans.

(1) The facility must develop and implement a comprehensive person-centered care plan for each resident, consistent with the resident rights set forth at §483.10(c)(2) and §483.10(c)(3), that includes measurable objectives and timeframes to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The comprehensive care plan must describe the following:

(i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under §483.24, §483.25, or §483.40; and

(ii) Any services that would otherwise be required under §483.24, §483.25, or §483.40 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(c)(6).

(i) Any specialized services or specialized rehabilitative services the nursing facility will provide as a result of PASARR recommendations. If a facility disagrees with the findings of the PASARR, it must indicate its rationale in the resident's medical record.

(ii) In consultation with the resident and the resident's representative(s)-

(A) The resident's goals for admission and desired outcomes.

(B) The resident's preference and potential for future discharge. Facilities must document whether the resident's desire to return to the community was assessed and any referrals to local contact agencies and/or other appropriate entities, for this purpose.

(C) Discharge plans in the comprehensive care plan, as appropriate, in accordance with the requirements set forth in paragraph (c) of this section.

(2) A comprehensive care plan must be-

(i) Developed within 7 days after completion of the comprehensive assessment.

(ii) Prepared by an interdisciplinary team, that includes but is not limited to-

(A) The attending physician.

(B) A registered nurse with responsibility for the resident.

(C) A nurse aide with responsibility for the resident.

(D) A member of food and nutrition services staff.

(E) To the extent practicable, the participation of the resident and the resident's representative(s). An explanation must be included in a resident's medical record if the participation of the resident and their resident representative is determined not practicable for the development of the resident's care plan.

(F) Other appropriate staff or professionals in disciplines as determined by the resident's needs or as requested by the resident.

(iii) Reviewed and revised by the interdisciplinary team after each assessment, including both the comprehensive and quarterly review assessments.

(3) The services provided or arranged by the facility, as outlined by the comprehensive care plan, must-

(i) Meet professional standards of quality.

(ii) Be provided by qualified persons in accordance with each resident's written plan of care.

(iii) Be culturally-competent and trauma-informed.

" §483.21(c)(2) Discharge summary. When the facility anticipates discharge a resident must have a discharge summary that includes, but is not limited to, the following:

(i) A recapitulation of the resident's stay that includes, but is not limited to, diagnoses, course of illness/treatment or therapy, and pertinent lab, radiology, and consultation results.

(ii) A final summary of the resident's status to include items in

paragraph (b)(1) of §483.20, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or resident's representative.

(iii) Reconciliation of all pre-discharge medications with the resident's post-discharge medications (both prescribed and over-the-counter).

(iv) A post-discharge plan of care that is developed with the participation of the resident and, with the resident's consent, the resident representative(s), which will assist the resident to adjust to his or her new living environment. The post-discharge plan of care must indicate where the individual plans to reside, any arrangements that have been made for the resident's follow up care and any post-discharge medical and non-medical services.

FED - C1622 - SPECIALIZED REHABILITATIVE SERVICES

Title SPECIALIZED REHABILITATIVE SERVICES

Type Standard

CFR 485.645(d)(6)

Regulation Definition

Specialized Rehabilitative Services (§483.65 of this chapter).

" §483.65 (a) Provision of services. If specialized rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, respiratory therapy, and rehabilitative services for a mental disorder and intellectual disability or services of a lesser intensity as set forth at §483.120(c), are required in the resident's comprehensive plan of care, the facility must-

(1) Provide the required services; or

Interpretive Guideline

Interpretive Guidelines §485.645(d)(6)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(6)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

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(2) In accordance with §483.70(g), obtain the required services from an outside resource that is a provider of specialized rehabilitative services and is not excluded from participating in any federal or state health care programs pursuant to section 1128 and 1156 of the Act.

(b) Qualifications. Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.

FED - C1624 - DENTAL SERVICES

Title DENTAL SERVICES

Type Standard

CFR 485.645(d)(7)

Regulation Definition

Dental Services (§483.55(a)(2), (3), (4), and (5) and (b) of this chapter).

" §483.55 Dental services. The facility must assist residents in obtaining routine and 24-hour emergency dental care.

(a) Skilled nursing facilities. A facility-

(2) May charge a Medicare resident an additional amount for routine and emergency dental services;

(3) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility;

Interpretive Guideline

Interpretive Guidelines §485.645(d)(7)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(7)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

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(4) Must if necessary or if requested, assist the resident-

(i) In making appointments; and

(ii) By arranging for transportation to and from the dental services location; and

(5) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay.

(b) Nursing facilities. The facility-

(1) Must provide or obtain from an outside resource, in accordance with §483.70(g), the following dental services to meet the needs of each resident:

(i) Routine dental services (to the extent covered under the State plan); and

(ii) Emergency dental services;

(2) Must, if necessary or if requested, assist the resident-

(i) In making appointments; and

(ii) By arranging for transportation to and from the dental services locations;

(3) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not

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occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay;

(4) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility; and

(5) Must assist residents who are eligible and wish to participate to apply for reimbursement of dental services as an incurred medical expense under the State plan.

FED - C1626 - NUTRITION

Title NUTRITION

Type Standard

CFR 485.645(d)(8)

Regulation Definition

Nutrition (§483.25(g)(1) and (g)(2) of this chapter).

" §483.25(g) Assisted nutrition and hydration. (Includes naso-gastric and gastrostomy tubes, both percutaneous endoscopic gastrostomy and percutaneous endoscopic jejunostomy, and enteral fluids). Based on a resident's comprehensive assessment, the facility must ensure that a resident-

(1) Maintains acceptable parameters of nutritional status, such as usual body weight or desirable body weight range and electrolyte balance, unless the resident's clinical condition demonstrates that this is not possible or resident preferences

Interpretive Guideline

Interpretive Guidelines §485.645(d)(8)

Refer to Appendix PP of the State Operations Manual (SOM) for interpretive guidelines.

Survey Procedures §485.645(d)(8)

Refer to Appendix PP of the State Operations Manual (SOM) for survey procedures.

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indicate otherwise;

(2) Is offered sufficient fluid intake to maintain proper hydration and health.

FED - C2400 - COMPLIANCE WITH 489.24

Title COMPLIANCE WITH 489.24

Type Standard

CFR 489.20(l)

Regulation Definition

[The provider agrees,] in the case of a hospital as defined in §489.24(b), to comply with §489.24.

Interpretive Guideline

The term "hospital" is defined in §489.24 (b) as including critical access hospitals as defined in §1861 (mm)(1) of the Act. Therefore, a critical access hospital that operates a dedicated emergency department (as that term is defined below) is subject to the requirements of EMTALA.

42 CFR §489.20 (l) of the provider's agreement requires that hospitals comply with 42 CFR §489.24, Special responsibilities of Medicare hospitals in emergency cases. Hospitals are required to adopt and enforce a policy to ensure compliance with the requirements of §489.24. Non-compliance with EMTALA requirements will lead CMS to initiate procedures for termination from the Medicare program. Non-compliance may also trigger the imposition of civil monetary penalties by the Office of the Inspector General.

Surveyors review the following documents to help determine if the hospital is in compliance with the requirement(s):
o Review the bylaws, rules, and regulations of the medical staff to determine if they reflect the requirements of §489.24 and the related requirements at §489.20.
o Review the emergency department policies and procedure manuals for procedures related to the requirements of §489.24 and the related requirements at §489.20.

If a hospital violates §489.24, surveyors are to cite a corresponding violation of §489.20(l), tag C2400.

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FED - C2401 - RECEIVING AN INAPPROPRIATE TRANSFER

Title RECEIVING AN INAPPROPRIATE TRANSFER

Type Standard

CFR 489.20(m)

Regulation Definition

[The provider agrees,] in the case of a hospital as defined in §489.24(b), to report to CMS or the State survey agency any time it has reason to believe it may have received an individual who has been transferred in an unstable emergency medical condition from another hospital in violation of the requirements of §489.24(e).

Interpretive Guideline

A hospital (recipient) that suspects it may have received an improperly transferred (transfer of an unstable individual with an emergency medical condition who was not provided an appropriate transfer according to §489.24(e)(2)), individual is required to promptly report the incident to CMS or the State Agency (SA) within 72 hours of the occurrence. If a recipient hospital fails to report an improper transfer, the hospital may be subject to termination of it's provider agreement according to 42 CFR§ 489.53(a).

Surveyors are to look for evidence that the recipient hospital knew, or suspected the individual had been to a hospital prior to the recipient hospital, and had not been transferred in accordance with §489.24(e). Evidence may be obtained in the medical record or through interviews with the individual, family members or staff.

Review the emergency department log and medical records of patients received as transfers. Look for evidence that:
o The hospital had agreed in advance to accept the transfers;
o The hospital had received appropriate medical records;
o All transfers had been effected through qualified personnel, transportation equipment and medically appropriate life support measures; and
o The hospital had available space and qualified personnel to treat the patients.

FED - C2402 - POSTING OF SIGNS

Title POSTING OF SIGNS

Type Standard

CFR 489.20(q)

Regulation Definition

[The provider agrees,] in the case of a hospital as defined in

Interpretive Guideline

Section 1866(a)(1)(N)(iii) of the Social Security Act requires the posting of signs which specify the rights of

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§489.24(b), to post conspicuously in any emergency department or in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments (that is, entrance, admitting area, waiting room, treatment area) a sign (in a form specified by the Secretary) specifying the rights of individuals under section 1867 of the Act with respect to examination and treatment for emergency medical conditions and women in labor; and to post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital or rural primary care hospital (e.g., critical access hospital) participates in the Medicaid program under a State plan approved under Title XIX.

individuals with EMCs and women in labor.

To comply with the requirements hospital signage must at a minimum:
o Specify the rights of individuals with EMCs and women in labor who come to the emergency department for health care services;
o Indicate whether the facility participates in the Medicaid program;
o The wording of the sign(s) must be clear and in simple terms and language(s) that are understandable by the population served by the hospital; and
o The sign(s) must be posted in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment (e.g., entrance, admitting area, waiting room, treatment area).

FED - C2403 - HOSPITAL MUST MAINTAIN RECORDS

Title HOSPITAL MUST MAINTAIN RECORDS

Type Standard

CFR 489.20(r)(1)

Regulation Definition

[The provider agrees,] in the case of a hospital as defined in §489.24(b), (including both the transferring and receiving hospitals), to maintain medical and other records related to individuals transferred to or from the hospital for a period of 5 years from the date of transfer.

Interpretive Guideline

The medical records of individuals transferred to or from the hospital must be retained in their original or legally reproduced form in hard copy, microfilm, microfiche, optical disks, computer disks, or computer memory for a period of 5 years from the date of transfer.

FED - C2404 - ON CALL PHYSICIANS

Title ON CALL PHYSICIANS

Type Standard

CFR 489.20(r)(2) and 489.24(j)(1-2)

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Regulation Definition	Interpretive Guideline
§489.20(r)(2) [The hospital (including both the transferring and receiving hospitals), must maintain] a list of physicians who are on call for duty after the initial examination to provide further evaluation and/or treatment necessary to stabilize an individual with an emergency medical condition.	§489.20 (r)(2) Section 1866 (a)(1)(iii) of the Act states, as a requirement for participation in the Medicare program, that hospitals must maintain a list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an EMC. The on call list identifies and ensures that the emergency department is prospectively aware of which physicians, including specialists and subspecialists are available to provide care. A hospital can meet its responsibility to provide adequate medical personnel to meet its anticipated emergency needs by using on call physicians either to staff or to augment its emergency department, during which time the capability of its emergency department includes the services of its on call physicians. CMS does not have requirements regarding how frequently on call physicians are expected to be available to provide on call coverage. Nor is there a pre-determined ratio CMS uses to identify how many days a hospital must provide medical staff on call coverage based on the number of physicians on staff for that particular specialty. In particular, CMS has no rule stating that whenever there are at least three physicians in a specialty, the hospital must provide 24 hour / 7 day coverage in that specialty. Generally, in determining EMTALA compliance, CMS will consider all relevant factors, including the number of physicians on staff, other demands on these physicians, the frequency with which the hospital's patient typically require services of on call physicians, and the provisions the hospital has made for situations in which a physician in the specialty is not available or the on call physicians is unable to respond. On call coverage is a decision made by hospital administrators and the physicians who provide on call coverage for the hospital. Each hospital has the discretion to maintain the on call list in a manner that best meet the needs of the hospital's patients who are receiving services required under EMTALA in accordance with the resources available to the hospital, including the availability of on call physicians. The best practice for hospitals, which offer particular services to the public, should be available through on call coverage of the emergency department. Physicians group names are not acceptable for identifying the on call physician. Individual physician names are to be identified on the list. §489.24(j)(1) Hospitals have the ultimate responsibility for ensuring adequate on call coverage. Hospitals participating in the Medicare Program must maintain a list of physicians on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an EMC. Hospitals have an EMTALA obligation to provide on call coverage for patients in need of specialized treatment if the hospital has the capacity to treat the individual.
§489.24(j)(1) Each hospital must maintain an on-call list of physicians on its medical staff in a manner that best meets the needs of the hospital's patients who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians.	
§489.24(j)(2)(i) The hospital must have written policies and procedures in place to respond to situations in which a particular specialty is not available or the on-call physician cannot respond because of circumstances beyond the physician's control.	
§489.24(j)(2)(ii) The hospital must have written policies and procedures in place to provide that emergency services are available to meet the needs of patients with emergency medical conditions if it elects to permit on-call physicians to schedule elective surgery during the time that they are on call or to permit on-call physicians to have simultaneous on-call duties.	

No physician is required to be on call at all times. On call coverage should be provided for within reason depending upon the number of physicians in a specialty. A determination about whether a hospital is in compliance with these regulations must be based on the facts in each individual case. The surveyor will consider all relevant factors including the number of physicians on staff, the number of physicians in a particular specialty, other demands on these physicians, the frequency with which the hospital's patients typically require services of on call physicians, vacations, conferences, days off and the provisions the hospital has made for situations in which a physician in the specialty is not available or the on call physician is unable to respond.

If a staff physician is on call to provide emergency services or to consult with an emergency room physician in the area of his or her expertise, that physician would be considered to be available at the hospital. A determination as to whether the on call physician must physically assess the patient in the emergency department is the decision of the treating emergency physician. His or her ability and medical knowledge of managing that particular medical condition will determine whether the on call physician must come to the emergency department.

When a physician is on call for the hospital and seeing patients with scheduled appointments in his private office, it is generally not acceptable to refer emergency cases to his or her office for examination and treatment of an EMC. The physician must come to the hospital to examine the individual if requested by the treating emergency physician. If, however, if it is medically appropriate to do so, the treating emergency physician may send an individual needing the services of the on call physician to the physician's office if it is part of a hospital-owned facility (department of the hospital sharing the same Medicare provider number as the hospital) and on the hospital campus. In determining if a hospital has appropriately moved an individual from the hospital to the on call physician's office, surveyors may consider whether (1) all persons with the same medical condition are moved in such circumstances, regardless of their ability to pay for treatment; (2) there is bona fide medical reason to move the patient; and (3) appropriate medical personnel accompany the patient.

If a physician who is on call does not come to the hospital when called, but rather repeatedly or typically directs the patient to be transferred to another hospital where the physician can treat the individual, the physician may have violated EMTALA. Surveyors are to assess all facts of the case prior to making a recommendation to the RO as to whether the physician violated EMTALA. Surveyors are to consider the individual needs and the physician circumstances, which may have an impact upon the case. Each case is to be viewed on its own merit and specific facts.

For physicians taking call simultaneously at more than one hospital, the hospitals must have policies and procedures to follow when the on call physician is not available to respond because he has been called to the other hospital to evaluate an individual. Hospital policies may include, but are not limited to procedures for back up on call physicians,

or the implementation of an appropriate EMTALA transfer according to 42 CFR §489.24(e). The policies and procedures a hospital adopts to meet its EMTALA obligation is at the hospital's discretion, as long as they meet the needs of the individuals who present for emergency care taking into account the capability of the hospital and the availability of on call physicians.

The decision as to whether the on call physician responds in person or directs a non-physician practitioner (physician assistant, nurse practitioner, orthopedic tech) as his or her representative to present to the dedicated ED is made by the responsible on call physician, based on the individual's medical need and the capabilities of the hospital and applicable State scope of practice laws, hospital bylaws, and rules and regulations. The on call physician is ultimately responsible for the individual regardless of who responds to the call. In the event that the treating physician disagrees with the on-call physician's decision to send a representative and requests the appearance of the on-call physician, then both the hospital and an on-call physician who fails or refuses to appear in a reasonable period of time may be subject to sanctions for violations of the EMTALA statutory requirements.

There is no EMTALA prohibition against the treating physician consulting on a case with another physician, who may or may not be on the hospital's or CAH's on-call list, by telephone, video conferencing, transmission of test results, or any other means of communication. CMS is aware that it is increasingly common for hospitals/CAHs to use telecommunications to exchange imaging studies, laboratory results, EKG's, real-time audio and video images of patients, and/or other clinical information with a consulting physician not on the hospital/CAH premises. Such practices may contribute to improved patient safety and efficiency of care. In some cases it may be understood by the hospitals/CAHs and physicians who establish such remote consulting arrangements that the physician consultant is not available for an in-person assessment of the individual at the treating physician's hospital/CAH.

However, if a physician:
o is on a hospital's or CAH's on-call list; and
o has been requested by the treating physician to appear at the hospital; and
o fails or refuses to appear within a reasonable period of time,

then the hospital and the on-call physician may be subject to sanctions for violation of the EMTALA statutory requirements.

It is only when the treating physician requests an in-person appearance by the on-call physician that a failure by the latter to appear in person may constitute an EMTALA violation.

It is an entirely separate issue, outside the scope of EMTALA enforcement, whether or not insurers or other third

party payers, including Medicare, will provide reimbursement to physicians who provide remote consultation services. Hospitals and/or physicians interested in Medicare reimbursement policy for telemedicine or telehealth services should consult Medicare Benefit Policy Manual, Pub 100-2, Chapter 18, Section §270).

Physicians that refuse to be included on a hospital's on call list but take calls selectively for patients with whom they or a colleague at the hospital have established a doctor-patient relationship while at the same time refusing to see other patients (including those individuals whose ability to pay is questionable) may violate EMTALA. If a hospital permits physicians to selectively take call while the hospital's coverage for that particular service is not adequate, the hospital would be in violation of its EMTALA obligation by encouraging disparate treatment.

If a physician on call does not fulfill his obligation to the hospital, but the hospital arranges for another staff physician in that specialty to assess the individual, and no other EMTALA requirements are violated, then the hospital may not be in violation of the regulation. However, in this circumstance, the physician who has agreed to take call and does not come to the hospital when called may have violated the regulation.

CMS allows hospitals flexibility in the utilization of their medical personnel. Allowing exemptions to medical staff members (senior physicians) would not by itself violate EMTALA.

Surveyors are to review the hospital policies or medical staff bylaws with respect to response time of the on call physician. If a physician on the list is called by the hospital to provide emergency screening or treatment and either refuses or fails to arrive within the response time established by hospital policies or medical staff bylaws, the hospital and that physician may be in violation of EMTALA. Hospitals are responsible for ensuring that on call physicians respond within a reasonable period of time. The expected response time should be stated in minutes in the hospitals policies. Terms such as "reasonable" or "prompt" are not enforceable by the hospital and therefore inappropriate in defining physician's response time. Note the time of notification and the response (or transfer) time.

§489.24(j)(2)(i)
The medical staff by-laws or policies and procedures must define the responsibility of the on call physicians to respond, examine and treat patients with an EMC.

Physicians, including specialists and subspecialists (e.g., neurologists) are not required to be on call at all times or required to be on call in their specialty for emergencies whenever they are visiting their own patients in the hospital. The hospital must have policies and procedures (including back-up call schedules or the implementation of an appropriate EMTALA transfer) to be followed when a particular specialty is not available or the on call physician cannot respond because of situations beyond his or her control. The hospital is ultimately responsible for providing

adequate on call coverage to meet the needs of its patients.

§489.24(j)(2)(ii)
Physicians are not prohibited from performing surgery while on call. The only exception applies to Critical Access Hospital (CAH) staff. On call physicians who are reimbursed for being on call at CAHs cannot provide services at any other provider or facility. However, a hospital may have its own internal policy prohibiting elective surgery by on call physicians to better serve the needs of its patients seeking treatment for a potential emergency medical condition. When a physician has agreed to be on call at a particular hospital during a particular period of time, but has also scheduled elective surgery during that time, that physician and the hospital should have planned back-up in the event that he/she is called while performing elective surgery and is unable to respond to the situation or the implementation of an appropriate EMTALA transfer according to §489.24(e).

Physicians can be on call simultaneously at other hospitals to maximize patient access to care. When the on call physician is simultaneously on call at more than one hospital in the geographic area, all hospitals involved must be aware of the on call schedule as each hospital independently has an EMTALA obligation. The medical staff by laws or policies and procedures must define the responsibilities of the on call physicians to respond, examine and treat individuals with emergency medical conditions, and the hospital must have policies and procedures to be followed when a particular specialty is not available or the on call physician cannot respond because of situations beyond his or her control as the hospital is ultimately responsible for providing adequate on call coverage to meet the needs of its individuals.

FED - C2405 - EMERGENCY ROOM LOG

Title EMERGENCY ROOM LOG

Type Standard

CFR 489.20(r)(3)

Regulation Definition

[The provider agrees,] in the case of a hospital as defined in §489.24(b) (including both the transferring and receiving hospitals), to maintain a central log on each individual who comes to the emergency department, as defined in §489.24(b), seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred, or discharged.

Interpretive Guideline

The purpose of the central log is to track the care provided to each individual who comes to the hospital seeking care for an emergency medical condition.

Each hospital has the discretion to maintain the log in a form that best meets the needs of the hospital. The central log includes, directly or by reference, patient logs from other areas of the hospital that may be considered dedicated emergency departments, such as pediatrics and labor and delivery where a patient might present for emergency services or receive a medical screening examination instead of in the "traditional" emergency department. These

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§489.24 The provisions of this regulation apply to all hospitals that participate in Medicare and provide emergency services.

additional logs must be available in a timely manner for surveyor review. The hospital may also keep its central log in an electronic format.

Review the emergency department log covering at least a 6 month period that contains information on all individuals coming to the emergency department and check for completeness, gaps in entries or missing information.

Hospitals with an emergency department are required under EMTALA to do the following:
o To provide an appropriate MSE to any individual who comes to the emergency department;
o Provide necessary stabilizing treatment to an individual with an EMC or an individual in labor;
o Provide for an appropriate transfer of the individual if either the individual requests the transfer or the hospital does not have the capability or capacity to provide the treatment necessary to stabilize the EMC (or the capability or capacity to admit the individual);
o Not delay examination and/or treatment in order to inquire about the individual's insurance or payment status;
o Accept appropriate transfers of individuals with emergency medical conditions if the hospital has the specialized capabilities not available at the transferring hospital and has the capacity to treat those individuals;
o Obtain or attempt to obtain written and informed refusal of examination, treatment or an appropriate transfer in the case of an individual who refuses examination, treatment or transfer; and
o Not take adverse action against a physician or qualified medical personnel who refuses to transfer an individual with an emergency medical condition, or against an employee who reports a violation of these requirements.

FED - C2406 - MEDICAL SCREENING EXAM

Title MEDICAL SCREENING EXAM

Type Standard

CFR 489.24(a) and 489.24(c)

Regulation Definition

(a) Applicability of provisions of this section.
(1) In the case of a hospital that has an emergency department, if an individual (whether or not eligible for Medicare benefits and regardless of ability to pay) "comes to the emergency department", as defined in paragraph (b) of this section, the hospital must-
(i) Provide an appropriate medical screening examination within the capability of the hospital's emergency department,

Interpretive Guideline

§489.24(a)
A "hospital with an emergency department" is defined in §489.24(b) as a hospital with a dedicated emergency department. An EMTALA obligation is triggered for such a hospital when an individual comes by him or herself, with another person, to a hospital's dedicated emergency department (as that term is defined above) and a request is made by the individual or on the individual's behalf, or a prudent layperson observer would conclude from the individual's appearance or behavior a need, for examination or treatment of a medical condition. In such a case, the hospital has incurred an obligation to provide an appropriate medical screening examination for the individual and stabilizing treatment or an appropriate transfer. The purpose of the medical screening examination is to determine whether or not

including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition exists. The examination must be conducted by an individual(s) who is determined qualified by hospital bylaws or rules and regulations and who meets the requirements of §482.55 of this chapter concerning emergency services personnel and direction; and
(ii) If an emergency medical condition is determined to exist, provide any necessary stabilizing treatment, as defined in paragraph (d) of this section, or an appropriate transfer as defined in paragraph (e) of this section. If the hospital admits the individual as an inpatient for further treatment, the hospital's obligation under this section ends, as specified in paragraph (d)(2) of this section.

(2)(i) When a waiver has been issued in accordance with section 1135 of the Act that includes a waiver under section 1135(b)(3) of the Act, sanctions under this section for an inappropriate transfer or for the direction or relocation of an individual to receive medical screening at an alternate location do not apply to a hospital with a dedicated emergency department if the following conditions are met:
(A) The transfer is necessitated by the circumstances of the declared emergency in the emergency area during the emergency period.
(B) The direction or relocation of an individual to receive medical screening at an alternate location is pursuant to an appropriate State emergency preparedness plan or, in the case of a public health emergency that involves a pandemic infectious disease, pursuant to a State pandemic preparedness plan.
(C) The hospital does not discriminate on the basis of an individual's source of payment or ability to pay.
(D) The hospital is located in an emergency area during an emergency period, as those terms are defined in section

an emergency medical condition exits.

If an individual who is not a hospital patient comes elsewhere on hospital property (that is, the individual comes to the hospital but not to the dedicated emergency department), an EMTALA obligation on the part of the hospital may be triggered if either the individual requests examination or treatment for an emergency medical condition or if a prudent layperson observer would believe that the individual is suffering from an emergency medical condition. The term "hospital property" means the entire main hospital campus as defined in §413.65(a), including the parking lot, sidewalk and driveway or hospital departments, including any building owned by the hospital that are within 250 yards of the hospital.

If an individual is registered as an outpatient of the hospital and they present on hospital property but not to a dedicated emergency department, the hospital does not incur an obligation to provide a medical screening examinations for that individual if they have begun to receive a scheduled course of outpatient care. Such an individual is protected by the hospital conditions of participation that protect patient's health and safety and to ensure that quality care is furnished to all patients in Medicare-participating hospital. If such an individual experiences an EMC while receiving outpatient care, the hospital does not have an obligation to conduct an MSE for that patient. As discussed in greater detail below, such a patient has adequate protections under the Medicare COPs and state law.

If an individual is initially screened in a department or facility on-campus outside of the ED, the individual could be moved to another hospital department or facility on-campus to receive further screening or stabilizing treatment without such movement being regarded as a transfer, as long as (1) all persons with the same medical condition are moved in such circumstances, regardless of their ability to pay for treatment; (2) there is bona fide medical reason to move the individual; and (3) appropriate medical personnel accompany the individual. The same is also true for an individual who presents to the dedicated emergency department (e.g., patient with an eye injury in need of stationary ophthalmology equipment located in the eye clinic) and must be moved to another hospital-owned facility or department on-campus for further screening or stabilizing treatment. The movement of the individual between hospital departments is not considered an EMTALA transfer under this section, since the individual is simply being moved from one department of a hospital to another department or facility of the same hospital.

Hospitals should not move individuals to off-campus facilities or departments (such as an urgent care center or satellite clinic) for a MSE. If a individual comes to a hospital-owned facility or department, which is off-campus and operates under the hospital's Medicare provider number, §1867 (42 C.F.R.
§489.24) will not apply to that facility and/or department unless it meets the definition of a dedicated emergency department.

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1135(g)(1) of the Act.
(E) There has been a determination that a waiver of sanctions is necessary.
(ii) A waiver of these sanctions is limited to a 72-hour period beginning upon the implementation of a hospital disaster protocol, except that, if a public health emergency involves a pandemic infectious disease (such as pandemic influenza), the waiver will continue in effect until the termination of the applicable declaration of a public health emergency, as provided under section 1135(e)(1)(B) of the Act.

(c) Use of dedicated emergency department for nonemergency services. If an individual comes to a hospital's dedicated emergency department and a request is made on his or her behalf for examination or treatment for a medical condition, but the nature of the request makes it clear that the medical condition is not of an emergency nature, the hospital is required only to perform such screening as would be appropriate for any individual presenting in that manner, to determine that the individual does not have an emergency medical condition.

If, however, such a facility does not meet the definition of a dedicated ED, it must screen and stabilize the patient to the best of its ability or execute an appropriate transfer if necessary to another hospital or to the hospital on whose Medicare provider number it is operated. Hospital resources and staff available at the main campus are likewise available to individuals seeking care at the off campus facilities or departments within the capability of the hospital. Movement of the individual to the main campus of the hospital is not considered a transfer since the individual is simply being moved from one department of a hospital to another department or facility of the same hospital. In addition, a transfer from such an entity (i.e., an off-campus facility that meets the definition of a dedicated ED) to a nonaffiliated hospital (i.e., a hospital that does not own the off-campus facility) is allowed where the facility at which the individual presented cannot stabilize the individual and the benefits of transfer exceed the risks of transfer. In other words, there is no requirement under EMTALA that the individual be always transferred back to the hospital that owns and operates the off-campus dedicated ED. Rather, the requirement of EMTALA is that the individual be transferred to an appropriate facility for treatment.

If a request were made for emergency care in a hospital department off the hospital's main campus that does not meet the definition of a dedicated emergency department, EMTALA would not apply. However, such an off-campus facility must have policies and procedures in place as how to handle patients in need of immediate care. For example, the off-campus facility policy may direct the staff to contact the emergency medical services/911 (EMS) to take the patient to an emergency department (not necessarily the emergency department of the hospital that operates the off-campus department, but rather the closest emergency department) or provide the necessary care if it is within the hospital's capability. Therefore, a hospital off-campus facility that does not meet the definition of a dedicated emergency department does not have an EMTALA obligation and not required to be staffed to handle potential EMC.

Medicare hospitals that do not provide emergency services must meet the standard of §482.12 (f), which requires hospitals to have written policies and procedures for the appraisal of emergencies, initial treatment within its capability and capacity, and makes an appropriate referral to a hospital that is capable of providing the necessary emergency services.

If a hospital has an EMTALA obligation, it must screen individuals to determine if an EMC exists. It is not appropriate to merely "log in" an individual and not provide a MSE. An MSE is the process required to reach, with reasonable clinical confidence, the point at which it can be determined whether the individual has an EMC or not. An MSE is not an isolated event. It is an ongoing process that begins, but typically does not end, with triage.

Triage entails the clinical assessment of the individual's presenting signs and symptoms at the time of arrival at the hospital, in order to prioritize when the individual will be seen by a physician or other qualified medical personnel (QMP)

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Individuals coming to the emergency department must be provided a MSE appropriate to the individuals' presenting signs and symptoms, as well as the capability and capacity of the hospital. Depending on the individual's presenting signs and symptoms, an appropriate MSE can involve a wide spectrum of actions ranging from a simple process involving only a brief history and physical examination to a complex process that also involves performing ancillary studies and procedures such as (but not limited to) lumbar punctures, clinical laboratory tests, CT scans, and/or other diagnostic tests and procedures. The medical record must reflect continued monitoring according to the individual's needs until it is determined whether or not the individual has an EMC and, if he/she does, until he/she is stabilized or appropriately transferred. There should be evidence of this ongoing monitoring prior to discharge or transfer.

The MSE must be the same MSE that the hospital would perform on any individual coming to the hospital's dedicated emergency department with those signs and symptoms, regardless of the individual's ability to pay for medical care. If a hospital applies in a nondiscriminatory manner (i.e. a different level of care must not exist based on payment status, race, national origin, etc.) a screening process that is reasonably calculated to determine whether an EMC exists, it has met its obligations under EMTALA. If the MSE is appropriate and does not reveal an EMC, the hospital has no further obligation under 42 CFR §489.24.

Regardless of a positive or negative individual outcome, a hospital would be in violation of the anti-dumping statute if it fails to meet any of the medical screening requirements under 42 CFR §489.24. The clinical outcome of an individual's condition is not a proper basis for determining whether an appropriate screening was provided or whether a person transferred was stable. However, the outcome may be a "red flag" indicating that a more thorough investigation is needed. Do not make decisions base on clinical information that was not available at the time of stabilizing or transfer. If an individual was misdiagnosed, but the hospital utilized all of its resources, a violation of the screening requirement did not occur.

It is not impermissible under EMTALA for a hospital to follow normal registration procedures for individuals who come to the emergency department. For example, a hospital may ask the individual for an insurance card, so long as doing so does not delay the medical screening examination. In addition, the hospital may seek other information (not payment) from the individual's health plan about the individual such as medical history. And, in the case of an individual with an emergency medical condition, once the hospital has conducted the medical screening examination and has initiated stabilizing treatment, it may seek authorization for all services from the plan, again, as long as doing so does not delay the implementation of the required MSE and stabilizing treatment.

A hospital that is not in a managed care plan's network of designated providers cannot refuse to screen and treat (or appropriately transfer, if the medical benefits of the transfer outweigh the risks or if the individual requests the

transfer) individuals who are enrolled in the plan who come to the hospital if that hospital participates in the Medicare program.

Once an individual has presented to the hospital seeking emergency care, the determination of whether an EMC exists is made by the examining physician(s) or other qualified medical personnel of the hospital.

Medicare participating hospitals that provide emergency services must provide a medical screening examination to any individual regardless of diagnosis (e.g., labor, AIDS), financial status (e.g., uninsured, Medicaid), race, and color, national origin (e.g. Hispanic or Native American surnames), and/or disability, etc.

A hospital, regardless of size or patient mix, must provide screening and stabilizing treatment within the scope of its abilities, as needed, to the individuals with emergency medical conditions who come to the hospital for examination and treatment.

"Labor" is defined to mean the process of childbirth beginning with the latent or early phase of labor and continuing through the delivery of the placenta. A woman experiencing contractions is in true labor, unless a physician , certified nurse-midwife, or other qualified medical person acting within his or her scope of practice as defined in hospital medical staff bylaws and State law, certifies that, after a reasonable time of observation, the woman is in false labor.

An infant that is born alive is a "person" and an "individual" under 1 U.S.C. 8(a) and the screening requirement of EMTALA applies to "any individual" who comes to the emergency department. If an infant was born alive in a dedicated emergency department, and a request was made on that infant's behalf for screening for a medical condition, (or if a prudent layperson would conclude, based on the infant's appearance or behavior, that the infant needed examination or treatment for a (medical condition) the hospital and physician could be liable for violating EMTALA for failure to provide such a medical screening examination.

If an infant is born alive elsewhere on the hospital's campus (i.e., not in the hospital's dedicated emergency department) and a prudent layperson observer would conclude, based on the born-alive infant's appearance or behavior, that the infant was suffering from an emergency medical condition, the hospital and its medical staff are required to perform a medical screening examination on the infant to determine whether or not an emergency medical condition exists. Whether in the DED or elsewhere on the hospital's campus, if the physician or other authorized qualified medical personnel performing the medical screening examination determines that the infant is suffering from an emergency medical condition, the hospital has an obligation under EMTALA to provide stabilizing treatment or an appropriate transfer. If the hospital admits the infant, its obligation under EMTALA ends.

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A minor (child) can request an examination or treatment for an EMC. The hospital is required by law to conduct the examination if requested by an individual or on the individual's behalf to determine if an EMC exists. Hospital personnel should not delay the MSE by waiting for parental consent. If after screening the minor, it is determined than no EMC is present, the staff can wait for parental consent before proceeding with further examination and treatment.

On-campus provider-based entities (such as rural health clinics or physician offices) are not subject to EMTALA, therefore it would be inappropriate to move individuals to these facilities for a MSE or stabilizing treatment under this Act.

If an individual is not on hospital property (which includes a hospital owned and operated ambulance), this regulation is not applicable. Hospital property includes ambulances owned and operated by the hospital, even if the ambulance is not on the hospital campus. An individual in a non-hospital owned ambulance, which is on hospital property is considered to have come to the hospital's emergency department. An individual in a non- hospital owned ambulance not on the hospital's property is not considered to have come to the hospital's emergency department when the ambulance personnel contact "Hospital A" by telephone or telemetry communications. If an individual is in an ambulance, regardless of whether the ambulance is owned by the hospital, a hospital may divert individuals when it is in "diversionary" status because it does not have the staff or facilities to accept any additional emergency patients at that time. However, if the ambulance is owned by the hospital, the diversion of the ambulance is only appropriate if the hospital is being diverted pursuant to community-wide EMS protocols. Moreover, if any ambulance (regardless of whether or not owned by the hospital) disregards the hospital's instructions and brings the individual on to hospital campus, the individual has come to the hospital and the hospital has incurred an obligation to conduct a medical screening examination for the individual.

Hospitals that deliberately delay moving an individual from an EMS stretcher to an emergency department bed do not thereby delay the point in time at which their EMTALA obligation begins. Furthermore, such a practice of "parking" patients arriving via EMS, refusing to release EMS equipment or personnel, jeopardizes patient health and adversely impacts the ability of the EMS personnel to provide emergency response services to the rest of the community. Hospitals that " park " patients may also find themselves in violation of 42 CFR 482.55, the Hospital Condition of Participation for Emergency Services, which requires that hospitals meet the emergency needs of patients in accordance with acceptable standards of practice.

On the other hand, this does not mean that a hospital will necessarily have violated EMTALA and/or the hospital CoPs if it does not, in every instance, immediately assume from the EMS provider all responsibility for the individual, regardless of any other circumstances in the ED. For example, there, may be situations when a hospital does not have the capacity or capability at the time of the individual's presentation to provide an immediate medical screening

examination (MSE) and, if needed, stabilizing treatment or an appropriate transfer. So, if the EMS provider brought an individual to the dedicated ED at a time when ED staff was occupied dealing with multiple major trauma cases, it could under those circumstances be reasonable for the hospital to ask the EMS provider to stay with the individual until such time as there were ED staff available to provide care to that individual. However, even if a hospital cannot immediately complete an appropriate MSE, it must still assess the individual's condition upon arrival to ensure that the individual is appropriately prioritized, based on his/her presenting signs and symptoms, to be seen by a physician or other QMP for completion of MSE. The hospital should also assess whether the EMS provider can appropriately monitor the individual's condition..

Should a hospital, which is not in diversionary status, fail to accept a telephone or radio request for transfer or admission, the refusal could represent a violation of other Federal or State requirements (e.g., Hill-Burton). If you suspect a violation of related laws, refer the case to the responsible agency for investigation.

The following two circumstances will not trigger EMTALA:
o The use of a hospital's helipad by local ambulance services or other hospitals for the transport of individuals to tertiary hospitals located throughout the State does not trigger an EMTALA obligation for the hospital that has the helipad on its property when the helipad is being used for the purpose of transit as long as the sending hospital conducted the MSE prior to transporting the individual to the helipad for medical helicopter transport to a designated recipient hospital. The sending hospital is responsible for conducting the MSE prior to transfer to determine if an EMC exists and implementing stabilizing treatment or conducting an appropriate transfer. Therefore, if the helipad serves simply as a point of transit for individuals who have received a MSE performed prior to transfer to the helipad, the hospital with the helipad is not obligated to perform another MSE prior to the individual's continued travel to the recipient hospital. If, however, while at the helipad, the individual's condition deteriorates, the hospital at which the helipad is located must provide another MSE and stabilizing treatment within its capacity if requested by medical personnel accompanying the individual.

o If as part of the EMS protocol, EMS activates helicopter evacuation of an individual with a potential EMC, the hospital that has the helipad does not have an EMTALA obligation if they are not the recipient hospital, unless a request is made by EMS personnel, the individual or a legally responsible person acting on the individual's behalf for the examination or treatment of an EMC.

Hospitals are not relieved of their EMTALA obligation to screen, provide stabilizing treatment and or an appropriate transfer to individuals because of prearranged community or State plans that have designated specific hospitals to care for selected individuals (e.g., Medicaid patients, psychiatric patients, pregnant women). Hospitals located in those States which have State/local laws that require particular individuals, such as psychiatric or indigent individuals,

to be evaluated and treated at designated facilities/hospitals may violate EMTALA if the hospital disregards the EMTALA requirements and does not conduct an MSE and provide stabilizing treatment or conduct an appropriate transfer prior to referring the individual to the State/local facility. If, after conducting the MSE and ruling out an EMC (or after stabilizing the EMC) the sending hospital needs to transfer an individual to another hospital for treatment, it may elect to transfer the individual to the hospital so designated by these State or local laws. Hospitals are also prohibited from discharging individuals who have not been screened or who have an emergency medical condition to non-hospital facilities for purposes of compliance with State law. The existence of a State law requiring transfer of certain individuals to certain facilities is not a defense to an EMTALA violation for failure to provide an MSE or failure to stabilize an EMC therefore hospitals must meet the federal EMTALA requirements or risk violating EMTALA.

If a screening examination reveals an EMC and the individual is told to wait for treatment, but the individual leaves the hospital, the hospital did not "dump" the individual unless:
o The individual left the emergency department based on a "suggestion" by the hospital;
o The individual's condition was an emergency, but the hospital was operating beyond its capacity and did not attempt to transfer the individual to another facility, or
o If a individual leaves a hospital Against Medical Advice (AMA) or LWBS, on his or her own free will (no coercion or suggestion) the hospital is not in violation of EMTALA.

Hospital resources and staff available to inpatients at the hospital for emergency services must likewise be available to individuals coming to the hospital for examination and treatment of an EMC because these resources are within the capability of the hospital. For example, a woman in labor who presents at a hospital providing obstetrical services must be treated with the resources available whether or not the hospital normally provides unassigned emergency obstetrical services.

The MSE must be conducted by an individual(s) who is determined qualified by hospital by-laws or rules and regulations and who meets the requirements of §482.55 concerning emergency services personnel and direction. The designation of the qualified medical personnel (QMP) should be set forth in a document approved by the governing body of the hospital. If the rules and regulations of the hospital are approved by the board of trustees or other governing body, those personnel qualified to perform the medical screening examinations may be set forth in the rules and regulations, or the hospital by-laws. It is not acceptable for the hospital to allow informal personnel appointments that could frequently change.

Refer to Tag C2407 for stabilizing treatment and inpatients and Tag C2409 for an appropriate transfer for EMTALA.

EMTALA does not apply to hospital inpatients. The existing hospital CoPs protect individuals who are already patients of a hospital and who experience an EMC. Hospitals that fail to provide treatment to these patients may be subject to further enforcement actions.

If the surveyor discovers during the investigation that a hospital did not admit an individual in good faith with the intention of providing treatment (i.e., the hospital used the inpatient admission as a means to avoid EMTALA requirements), then the hospital is considered liable under EMTALA and actions may be pursued.

§489.24 (a)(2)
Pursuant to section 1135(b) of the Social Security Act (Act), under certain emergency circumstances EMTALA sanctions may be waived. Specifically, waivers of sanctions are permitted with respect to:
o The inappropriate transfer of an individual who has not been stabilized. Pursuant to the Act the inappropriate transfer must arise out of the circumstances of the emergency; or
o The direction or relocation of an individual to receive a medical screening examination (MSE) at an alternate location pursuant to an appropriate State emergency preparedness plan or State pandemic preparedness plan. If a State emergency preparedness plan or pandemic preparedness plans has been activated in the emergency area, then the direction or relocation of individuals for MSEs is considered to be pursuant to a state plan.

Section 1135(g)(1) of the Act defines "emergency area" as a geographical area in which, and an "emergency period" as the period during which, there exists:
o An emergency or disaster declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act; and
o A public health emergency declared by the Secretary pursuant to section 319 of the Public Heath Service Act.

The waiver of sanction applies only to hospitals:
o With dedicated emergency departments; and
o Located in an emergency area during an emergency period; and
o When the Secretary has exercised his waiver authority pursuant to section 1135 of the Act..

In addition, the Act and the regulations at §489.24(a)(2) limit the duration of the waiver from EMTALA enforcement to 72 hours in most cases. The 72- hour period begins with the implementation of a hospital disaster protocol. In the case of an infectious pandemic disease, however, the waiver continues past the 72 hours and remains in effect until termination of the declaration of a public health emergency as described in section 1135(e)(1)(B) of the Act.

When all of the above conditions exist, then the Regional Office (RO) may issue an advisory notice that hospitals

with dedicated emergency departments in the emergency area will not, during the emergency period, be subject to EMTALA sanctions for:
o Redirecting individuals seeking an MSE when a State emergency preparedness plan or a pandemic preparedness plan has been activated in the emergency area; or
o Inappropriate transfers arising out of the circumstances of the emergency.

The RO notice will also indicate that the waiver of sanctions will be for the 72-hour period starting with each hospital's activation of its hospital disaster protocol. However, the 72- hour period may not in any case start before the effective date of the Secretary ' s public health emergency declaration. In the case of an infectious pandemic disease, however, the RO notice will indicate that the waiver may continue past the 72-hour period and remain in effect until termination of the declaration of public health emergency as described in section 1135(e)(1)(B) of the Act.

EMTALA complaints alleging violations by a hospital in an emergency area during an emergency period related to failure to provide an MSE or an inappropriate transfer must first be reviewed by the RO to determine whether a waiver of sanctions was in effect. The review may require some preliminary investigation, usually by telephone. If the review indicates a waiver was in effect for that hospital at the time of the complaint, then the RO will not authorize the State Agency to conduct an EMTALA investigation of the complaint.

§489.24(c)
Any individual with a medical condition that presents to a hospital's ED must receive an MSE that is appropriate for their medical condition. The objective of the MSE is to determine whether or not an emergency medical condition exists. This does not mean that all EMTALA screenings must be equally extensive. If the nature of the individual's request makes clear that the medical condition is not of an emergency nature, the MSE is reflective of the individual presenting complaints or symptoms. A hospital may, if it chooses, have protocols that permit a QMP (e.g., registered nurse) to conduct specific MSE(s) if the nature of the individual's request for examination and treatment is within the scope of practice of the QMP (e.g., a request for a blood pressure check and that check reveals hat the patient's blood pressure is within normal range). Once the individual is screened and it is determined the individual has only presented to the ED for a non-emergency purpose, the hospital's EMTALA obligation ends for that individual at the completion of the MSE. Hospitals are not obligated under EMTALA to provide screening services beyond those needed to determine that there is no EMC.

For a hospital to be exempted from its EMTALA obligations to screen individuals presenting at its emergency department for non-emergency tests (e.g., individual has consulted with physician by telephone and the physician refers the individual to a hospital emergency department for a non-emergency test) the hospital must be able to document that it is only being asked to collect evidence, not analyze the test results, or to otherwise examine or treat

the individual. Furthermore, a hospital may be exempted from its EMTALA obligations to screen individuals presenting to its dedicated emergency department if the individual had a previously scheduled appointment.

If an individual presents to an ED and requests pharmaceutical services (medication) for a medical condition, the hospital generally would have an EMTALA obligation. Surveyors are encouraged to ask probing questions of the hospital staff to determine if the hospital in fact had an EMTALA obligation in this situation (e.g., did the individual present to the ED with an EMC and informed staff they had not taken their medication? Was it obvious from the nature of the medication requested that it was likely that the patient had an EMC?). The circumstances surrounding why the request is being made would confirm if the hospital in fact has an EMTALA obligation. If the individual requires the medication to resolve or provide stabilizing treatment of an EMC, then the hospital has an EMTALA obligation. Hospitals are not required by EMTALA to provide medication to individuals who do not have an EMC simply because the individual is unable to pay or does not wish to purchase the medication from a retail pharmacy or did not plan appropriately to secure prescription refills.

If an individual presents to a dedicated emergency department and requests services that are not for a medical condition, such as preventive care services (immunizations, allergy shots, flu shots) or the gathering of evidence for criminal law cases (e.g., sexual assault, blood alcohol test), the hospital is not obligated to provide a MSE under EMTALA to this individual.

Attention to detail concerning blood alcohol testing (BAT) in the ED is instrumental when determining if a MSE is to be conducted. If an individual is brought to the ED and law enforcement personnel request that emergency department personnel draw blood for a BAT only and does not request examination or treatment for a medical condition, such as intoxication and a prudent lay person observer would not believe that the individual needed such examination or treatment, then the EMTALA's screening requirement is not applicable to this situation because the only request made on behalf of the individual was for evidence. However, if for example, the individual in police custody was involved in a motor vehicle accident or may have sustained injury to him or herself and presents to the ED, a MSE would be warranted to determine if an EMC exists.

When law enforcement officials request hospital emergency personnel to provide clearance for incarceration, the hospital has an EMTALA obligation to provide a MSE to determine if an EMC exists. If no EMC is present, the hospital has met its EMTALA obligation and no further actions are necessary for EMTALA compliance.

Surveyors will evaluate each case on its own merit when determining a hospital's EMTALA obligation when law enforcement officials request screening or BAT for use as evidence in criminal proceedings.

This principle also applies to sexual assault cases.

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FED - C2407 - STABILIZING TREATMENT

Title STABILIZING TREATMENT

Type Standard

CFR 489.24(d)(1-3)

Regulation Definition

(1) General. Subject to the provisions of paragraph (d)(2) of this section, if any individual (whether or not eligible for Medicare benefits) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either-
(i) within the capabilities of the staff and facilities available at the hospital, for further medical examination and treatment as required to stabilize the medical condition.
(ii) For for transfer of the individual to another medical facility in accordance with paragraph (e) of this section.

(2) Exception: Application to inpatients.
(i) If a hospital has screened an individual under paragraph (a) of this section and found the individual to have an emergency medical condition, and admits that individual as an inpatient in good faith in order to stabilize the emergency medical condition, the hospital has satisfied its special responsibilities under this section with respect to that individual
(ii) This section is not applicable to an inpatient who was admitted for elective (nonemergency) diagnosis or treatment.
(iii) A hospital is required by the conditions of participation for hospitals under Part 482 of this chapter to provide care to its inpatients in accordance with those conditions of participation.

(3) Refusal to consent to treatment.
A hospital meets the requirements of paragraph (d)(1)(i) of

Interpretive Guideline

§489.24(d)(1)(i)
A hospital is obligated to provide the services specified in the statute and this regulation regardless of whether a hospital will be paid. After the medical screening has been implemented and the hospital has determined that an emergency medical condition exists, the hospital must provide stabilizing treatment within its capability and capacity.

Capabilities of a medical facility mean that there is physical space, equipment, supplies, and specialized services that the hospital provides (e.g., surgery, psychiatry, obstetrics, intensive care, pediatrics, trauma care).

Capabilities of the staff of a facility means the level of care that the personnel of the hospital can provide within the training and scope of their professional licenses. This includes coverage available through the hospitals on call roster.

The capacity to render care is not reflected simply by the number of persons occupying a specialized unit, the number of staff on duty, or the amount of equipment on the hospital's premises. Capacity includes whatever a hospital customarily does to accommodate patients in excess of its occupancy limits §489.24 (b). If a hospital has customarily accommodated patients in excess of its occupancy limits by whatever mean (e.g., moving patients to other units, calling in additional staff, borrowing equipment from other facilities) it has, in fact, demonstrated the ability to provide services to patients in excess of its occupancy limits.

A hospital may appropriately transfer (see Tag C2409) an individual before the sending hospital has used and exhausted all of its resources available if the individual requests the transfer to another hospital for his or her treatment and refuses treatment at the sending hospital.

To comply with the MSE and stabilization requirements of §1867 all individuals with similar medical conditions are to be treated consistently. Compliance with local, State, or regionally approved EMS transport of individuals with an emergency is usually deemed to indicate compliance with §1867; however a copy of the protocol should be obtained and reviewed at the time of the survey.

this section with respect to an individual if the hospital offers the individual the further medical examination and treatment described in that paragraph and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of the examination and treatment, but the individual (or a person acting on the individual's behalf) does not consent to the examination or treatment. The medical record must contain a description of the examination, treatment, or both if applicable, that was refused by or on behalf of the individual. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of the person acting on his or her behalf). The written document should indicate that the person has been informed of the risks and benefits of the examination or treatment, or both.

If community wide plans exist for specific hospitals to treat certain EMCs (e.g., psychiatric, trauma, physical or sexual abuse), the hospital must meet its EMTALA obligations (screen, stabilize, and or appropriately transfer) prior to transferring the individual to the community plan hospital. An example of a community wide plan would be a trauma system hospital. A trauma system is a comprehensive system providing injury prevention services and timely and appropriate delivery of emergency medical treatment for people with acute illness and traumatic injury. These systems are designed so that patients with catastrophic injuries will have the quickest possible access to an established trauma center or a hospital that has the capabilities to provide comprehensive emergency medical care. These systems ensure that the severely injured patient can be rapidly cared for in the facility that is most appropriately prepared to treat the severity of injury.

Community plans are designed to provide an organized, pre-planned response to patient needs to assure the best patient care and efficient use of limited health care resources. Community plans are designed to augment physician's care if the necessary services are not within the capability of the hospital but does not mandate patient care nor transfer patterns. Patient health status frequently depends on the appropriate use of the community plans. The matching of the appropriate facility with the needs of the patient is the focal point of this plan and assures every patient receives the best care possible. Therefore, a sending hospital's appropriate transfer of an individual in accordance with community wide protocols in instances where it cannot provide stabilizing treatment would be deemed to indicate compliance with §1867.

If an individual seeking care is a member of a managed health care plan (e.g., HMO, PPO or CMP), the hospital is obligated to comply with the requirements of §489.24 regardless of the individual's payor source or financial status. The hospitals is obligated to provide the services necessary to determine if an EMC is present and provide stabilizing treatment if indicated. This is true regardless if the individual is enrolled in a managed care plan that restricts its enrollees' choice of health care provider. EMTALA is a requirement imposed on hospitals, and the fact that an individual who comes to the hospital is enrolled in a managed care plan that does not contract with that hospital has no bearing on the obligation of the hospital to conduct an MSE and to at lease initiate stabilizing treatment. A managed health care plan may only state the services for which it will pay or decline payment, but that does not excuse the hospital from compliance with EMTALA.

42 CFR §489.24 (b) defines stabilized to mean
" ... that no material deterioration of the condition is likely, within reasonable medical probability, to result from, or occur during, the transfer of the individual from a facility, or with respect to an "emergency medical condition" as defined in this section under paragraph (1) of that definition, that a woman has delivered the child and the placenta."

The regulation sets the standard determining when a patient is stabilized.

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If a hospital is unable to stabilize an individual within its capability, an appropriate transfer should be implemented. To be considered stable the emergency medical condition that caused the individual to seek care in the dedicated ED must be resolved, although the underlying medical condition may persist. For example, an individual presents to a hospital complaining of chest tightness, wheezing, and shortness of breath and has a medical history of asthma. The physician completes a medical screening examination and diagnoses the individual as having an asthma attack that is an emergency medical condition. Stabilizing treatment is provided (medication and oxygen) to alleviate the acute respiratory symptoms. In this scenario the EMC was resolved and the hospital's EMTALA obligation is therefore ended, but the underlying medical condition of asthma still exists. After stabilizing the individual, the hospital no longer has an EMTALA obligation. The physician may discharge the individual home, admit him/her to the hospital, or transfer (the "appropriate transfer" requirement under EMTALA does not apply to this situation since the individual has been stabilized) the individual to another hospital depending on his/her needs. The preceding example does not reflect a change in policy, rather it is a clarification as to when an appropriate transfer is to be implemented to decrease hospitals risk of being in violation of EMTALA due to inappropriate transfers.

An individual will be deemed stabilized if the treating physician or QMP attending to the individual in the emergency department/hospital has determined, within reasonable clinical confidence, that the emergency medical condition has been resolved.

For those individuals whose EMCs have been resolved the physician or QMP has several options:
o Discharge home with follow-up instructions. An individual is considered stable and ready for discharge when, within reasonable clinical confidence, it is determined that the individual has reached the point where his/her continued care, including diagnostic work-up and/or treatment, could be reasonably performed as an outpatient or later as an inpatient, provided the individual is given a plan for appropriate follow-up care as part of the discharge instructions. The EMC that caused the individual to present to the dedicated ED must be resolved, but the underlying medical condition may persist. Hospitals are expected within reason to assist/provide discharged individuals the necessary information to secure the necessary follow-up care to prevent relapse or worsening of the medical condition upon release from the hospital; or
o Inpatient admission for continued care.

Hospitals are responsible for treating and stabilizing, within their capacity and capability, any individual who presents him/herself to a hospital with an EMC. The hospital must provide care until the condition ceases to be an emergency or until the individual is properly transferred to another facility. An inappropriate transfer or discharge of an individual with an EMC would be a violation of EMTALA.

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If a hospital is alleged to have violated EMTALA by transferring an unstable individual without implementing an appropriate transfer according to §489.24(e), and the hospital believes that the individual was stable (EMC resolved) the burden of proof is the responsibility of the transferring hospital. When interpreting the facts the surveyor should assess whether or not the individual was stable. Was it reasonable to believe that the transferring hospital should have been knowledgeable of the potential complications during transport? To determine whether the individual was stable and treated appropriately surveyors will request that the QIO physician review the case.

If the treating physician is in doubt that an individual's EMC is stabilized the physician should implement an appropriate transfer (see Tag C2409) to prevent a potential violation of EMTALA, if his/her hospital cannot provide further stabilizing treatment.

If a physician is not physically present at the time of transfer, then the qualified medical personnel (as determined by hospital bylaws or other board-approved documents) must consult with a physician to determine if an individual with an EMC is to be transferred to another facility for further stabilizing treatment.

The failure of a receiving facility to provide the care it maintained it could provide to the individual when the transfer was arranged should not be construed to mean that the individual's condition worsened as a result of the transfer.

In the case of psychiatric emergencies, if an individual expressing suicidal or homicidal thoughts or gestures, if determined dangerous to self or others, would be considered to have an EMC.

Psychiatric patients are considered stable when they are protected and prevented from injuring or harming him/herself or others. The administration of chemical or physical restraints for purposes of transferring an individual from one facility to another may stabilize a psychiatric patient for a period of time and remove the immediate EMC but the underlying medical condition may persist and if not treated for longevity the patient may experience exacerbation of the EMC. Therefore, practitioners should use great care when determining if the medical condition is in fact stable after administering chemical or physical restraints.

A hospital's EMTALA obligation ends when a physician or qualified medical person has made a decision:
o That no emergency medical condition exists (even though the underlying medical condition may persist);
o That an emergency medical condition exists and the individual is appropriately transferred to another facility; or
o That an emergency medical condition exists and the individual is admitted to the hospital for further stabilizing treatment.

§489.24(d)(1)(ii)

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When a hospital has exhausted all of its capabilities in attempting to resolve the EMC, it must effect an appropriate transfer of the individual (see Tag C2409).

42 CFR §489.24 (b) defines transfer to mean
" ... the movement (including the discharge) of an individual outside a hospital's facilities at the direction of any person employed by (or affiliated or associated, directly or indirectly, with) the hospital, but does not include such a movement of an individual who has been declared dead or leaves the facility without the permission of any such person."

If an individual is admitted as an inpatient, EMCs must be stabilized either by the hospital to which an individual presents or the hospital to which the individual is transferred. If a woman is in labor, the hospital must deliver the baby and the placenta or transfer appropriately. She may not be transferred unless she, or a legally responsible person acting on her behalf, requests a transfer and a physician or other qualified medical personnel, in consultation with a physician, certifies that the benefits to the woman and/or the unborn child outweigh the risks associated with the transfer.

If the individual's condition requires immediate medical stabilizing treatment and the hospital is not able to attend to that individual because the emergency department is operating beyond its capacity, then the hospital should transfer the individual to a hospital that has the capability and capacity to treat the individual's EMC.

§489.24(d)(2)(i)
A hospital's EMTALA obligation ends when the individual has been admitted in good faith for inpatient hospital services whether or not the individual has been stabilized. An individual is considered to be "admitted" when the decision is made to admit the individual to receive inpatient hospital services with the expectation that the patient will remain in the hospital at least overnight. Typically, we would expect that this would be documented in the patient's chart and medical record at the time that a physician signed and dated the admission order. Hospital policies should clearly delineate, which practitioners are responsible for writing admission orders.

A hospital continues to have a responsibility to meet the patient emergency needs in accordance with hospital CoPs at 42 CFR Part 482. The hospital CoPs protect individuals who are admitted, and they do not permit the hospital to inappropriately discharge or transfer any patient to another facility. The hospital CoPs that are most relevant in this case are as follows: emergency services, governing body, discharge planning, quality assurance and medical staff.

Hospitals are responsible for assuring that inpatients receive acceptable medical care upon admission. Hospital services for inpatients should include diagnostic services and therapeutic services for medical diagnosis, treatment,

and care of the injured, disabled or sick persons with the intention of treating patients.

If during an EMTALA investigation there is a question as to whether an individual was admitted so that a hospital could avoid its EMTALA obligation, the SA surveyor is to consult with RO personnel to determine if the survey should be expanded to a survey of the hospital CoPs. After completion of the survey, the case is to be forwarded to the RO for violation determination. If it is determined that the hospital admitted the individual solely for the purpose of avoiding its EMTALA obligation, then the hospital is liable under EMTALA and may be subject to further enforcement action.

§489.24(d)(2)(i)
Individuals admitted to the hospital for elective medical services are not protected by EMTALA. The hospital CoPs protect all classifications of inpatients, elective and emergent.

§489.24(d)(2)(ii)
If an inpatient develops an EMC, the hospital is required to meet the patient's emergency needs in accordance with acceptable standards of practice. The hospital CoPs protects patients who are admitted, and the hospital may not discharge or transfer any patient to another facility inappropriately. The protective CoPs are found at 42 C.F.R. Part 482. The five CoPs that are most relevant in affording patients protection in cases when patients with an EMC is admitted are as follows:
o Emergency services (§482.55)
o Governing body (§482.12)
o Discharge planning (§482.43)
o Quality assessment and performance improvement (§482.21)
o Medical staff (§482.22)
If a hospital is noncompliant with any of the above COPs, the hospital will be subject to enforcement action.

§489.24(d)(3)
The medical record should reflect that screening, further examination, and or treatment were offered by the hospital prior to the individual's refusal.

In the event an individual refuses to consent to further examination or treatment, the hospital must indicate in writing the risks/benefits of the examination and/or treatment; the reasons for refusal; a description of the examination or treatment that was refused; and the steps taken to try to secure the written, informed refusal if it was not secured.

Hospitals may not attempt to coerce individuals into making judgments against their interest by informing them that

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they will have to pay for their care if they remain but that their care will be free or at a lower cost if they transfer to another hospital.

An individual may only refuse examination, treatment, or transfer on behalf of a patient if the patient is incapable of making an informed choice for him/herself.

FED - C2408 - DELAY IN EXAMINATION OR TREATMENT

Title DELAY IN EXAMINATION OR TREATMENT

Type Standard

CFR 489.24(d)(4-5)

Regulation Definition

(4) Delay in treatment.
(i) A participating hospital may not delay providing an appropriate medical screening examination required under paragraph (a) of this section or further medical examination and treatment required under paragraph (d)(1) of this section in order to inquire about the individual's method of payment or insurance status.

(ii)A participating hospital may not seek, or direct an individual to seek, authorization from the individual's insurance company for screening or stabilization services to be furnished by a hospital, physician, or nonphysician practitioner to an individual until after the hospital has provided the appropriate medical screening examination required under paragraph (a) of this section, and initiated any further medical examination and treatment that may be required to stabilize the emergency medical condition under paragraph (d)(1) of this section.

(iii) An emergency physician or nonphysician practitioner is not precluded from contacting the individual's physician at any time to seek advice regarding the individual's medical history

Interpretive Guideline

§489.24:(d)(4)(i),(ii),(iii)and (iv)
Hospitals should not delay providing a medical screening examination or necessary stabilizing treatment by inquiring about an individual's ability to pay for care. All individuals who present to a hospital and request an MSE for a medical condition (or have a request for an MSE made on their behalf) must receive that screening examination, regardless of the answers the individual may give to the insurance questions asked during the registration process. In addition, a hospital may not delay screening or treatment to any individual while it verifies the information provided.

Hospitals may follow reasonable registration processes for individuals presenting with an EMC. Reasonable registration processes may include asking whether an individual is insured and, if so, what the insurance is, as long as this inquiry do not delay screening, treatment or unduly discourage individuals from remaining for further evaluation. The registration process permitted in the dedicated ED typically consists of collecting demographic information, insurance information, whom to contact in an emergency and other relevant information.

If a managed care member comes to a hospital that offers emergency services, the hospital must provide the services required under the EMTALA statute without regard for the individual's insurance status or any prior authorization requirement of such insurance.

This requirement applies equally to both the referring and the receiving (recipient) hospital. Therefore, it may be a violation if the receiving hospital delays acceptance of the transfer of an individual with an unstabilized EMC pending receipt or verification of financial information. It would not be a violation if the receiving hospital delayed acceptance of the transfer of an individual with a stabilized EMC pending receipt or verification of financial information because EMTALA protections no longer apply once a patient is stabilized.

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and needs that may be relevant to the medical treatment and screening of the patient, as long as this consultation does not inappropriately delay services required under paragraph (a) or paragraphs (d)(1) and (d)(2) of this section.

Hospitals may follow reasonable registration processes for individuals for whom examination or treatment is required by this section, including asking whether an individual is insured and, if so, what that insurance is, as long as that inquiry does not delay screening or treatment. Reasonable registration processes may not unduly discourage individuals from remaining for further evaluation.

A hospital meets the requirements of paragraph (d)(1)(ii) of this section with respect to an individual if the hospital offers to transfer the individual to another medical facility in accordance with paragraph (e) of this section and informs the individual (or a person acting on his or her behalf) of the risks and benefits to the individual of the transfer, but the individual (or a person acting on the individual's behalf) does not consent to the transfer. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of a person acting on his or her behalf). The written document must indicate the person has been informed of the risks and benefits of the transfer and state the reasons for the individual's refusal. The medical record must contain a description of the proposed transfer that was refused by or on behalf of the individual.

If a delay in screening was due to an unusual internal crisis whereby it was simply not within the capability of the hospital to provide an appropriate screening examination at the time the individual came to the hospital (e.g., mass casualty occupying all the hospital's resources for a time period), surveyors are to interview hospital staff members to elicit the facts surrounding the circumstances to help determine if there was a violation of EMTALA.

§489.24(d)(5)
For individuals who refuse to consent to a transfer, the hospital staff must inform the individual of the risks and benefits and document the refusal and, if possible, place a signed informed consent to refusal of the transfer in the individual's medical record.

If an individual or the individual's representative refuses to be transferred and also refuses to sign a statement to that effect, the hospital may document such refusals as they see fit.

FED - C2409 - APPROPRIATE TRANSFER

Title APPROPRIATE TRANSFER

Type Standard

CFR 489.24(e)(1-2)

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Regulation Definition	Interpretive Guideline
(1) General If an individual at a hospital has an emergency medical condition that has not been stabilized (as defined in paragraph (b) of this section), the hospital may not transfer the individual unless - (i) The transfer is an appropriate transfer (within the meaning of paragraph (e)(2) of this section); and (ii)(A) The individual (or a legally responsible person acting on the individual's behalf) requests the transfer, after being informed of the hospital's obligations under this section and of the risk of transfer. The request must be in writing and indicate the reasons for the request as well as indicate that he or she is aware of the risks and benefits of the transfer. (B) A physician (within the meaning of section 1861(r)(1) of the Act) has signed a certification that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual or, in the case of a woman in labor, to the woman or the unborn child, from being transferred. The certification must contain a summary of the risks and benefits upon which it is based; or (C) If a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as determined by the hospital in its bylaws or rules and regulations) has signed a certification described in paragraph (e)(1)(ii)(B) of this section after a physician (as defined in section 1861(r)(1) of the Act) in consultation with the qualified medical person, agrees with the certification and subsequently countersigns the certification. The certification must contain a summary of the risks and benefits upon which it is based.	§489.24 (e)(1)(i) If an individual's EMC has not been resolved prior to transferring the individual to another hospital the sending hospital has an EMTALA obligation, and must meet the four requirements of an "appropriate" transfer. These requirements are found in §489(e)(2): o §489.24(2)(i), the transferring hospital provides medical treatment within its capacity that minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child; o §489.24(e)(2)(ii), the receiving facility has agreed to accept the patient, has space and qualified personnel available for the treatment; o §489.24(e)(2)(iii), the transferring hospital sends to the receiving facility all medical records related to the emergency medical condition which are available at the time of transfer and; o §489.24(e)(2)(iv), the transfer is effected through qualified personnel and transportation equipment. §489.24 (e)(1)(ii)(A) and (B) Section 1861 (r)(i) of the Act defines physicians as: A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action. (This provision is not to be construed to limit the authority of a doctor or medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism). The regulation at §489.24 (e)(1) requires an express written certification. Physician certification cannot simply be implied from the findings in the medical record and the fact that the patient was transferred. The certification must state the reason(s) for transfer. The narrative rationale need not be a lengthy discussion of the individual's medical condition reiterating facts already contained in the medical record, but it should give a complete picture of the benefits to be expected from appropriate care at the receiving (recipient) facility and the risks associated with the transfer, including the time away from an acute care setting necessary to effect the transfer. The risks and benefits certification should be specific to the condition of the patient upon transfer. This rationale may be on the certification form or in the medical record. In cases where the individual's medical record does not include a certification, give the hospital the opportunity to retrieve the certification. Certifications may not be backdated. Document the hospital's response. Women in Labor o Regardless of practices within a State, a woman in labor may be transferred only if she or her representative requests the transfer and if a physician or other qualified medical personnel signs a certification that the benefits

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(2) A transfer to another medical facility will be appropriate only in those cases in which -
(i) The transferring hospital provides medical treatment within its capacity that minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child;
(ii) The receiving facility
(A) Has available space and qualified personnel for the treatment of the individual; and
(B) Has agreed to accept transfer of the individual and to provide appropriate medical treatment.

(iii) The transferring hospital sends to the receiving facility all medical records (or copies thereof) related to the emergency condition which the individual has presented that are available at the time of the transfer, including available history, records related to the individual's emergency medical condition, observations of signs or symptoms, preliminary diagnosis, results of diagnostic studies or telephone reports of the studies, treatment provided, results of any tests and the informed written consent or certification (or copy thereof) required under paragraph (e)(1)(ii) of this section, and the name and address of any on-call physician (described in paragraph (g) of this section) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment. Other records (e.g., test results not yet available or historical records not readily available from the hospital's files) must be sent as soon as practicable after transfer; and

(iv) The transfer is effected through qualified personnel and transportation equipment, as required, including the use of necessary and medically appropriate life support measures during the transfer.

outweigh the risks. If the hospital does not provide obstetrical services, the benefits of a transfer may outweigh the risks. A hospital cannot cite State law or practice as the basis for transfer.
o Hospitals that are not capable of handling high-risk deliveries or high-risk infants often have written transfer agreements with facilities capable of handling high-risk cases. The hospital must still meet the screening, treatment, and transfer requirements.

The certification that the benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the risk of the transfer is not required for transfers of individuals who no longer have an emergency medical condition.

The date and time of the physician certification should closely match the date and time of the transfer.

§489.24 (e)(1)(ii)(C)
A QMP may sign the certification of benefits versus risks of a transfer only after consultation with the physician who authorizes the transfer. If a QMP determines that the transfer to another facility is in the best interest of the individual and signs the certification of benefits versus risks, a physician's countersignature must be obtained within the established timeframe according to hospital policies and procedures.

§489.24 (e)(2)(i)
This is the first requirement of an appropriate transfer.

The provision of treatment to minimize the risks of transfer is merely one of the four requirements of an appropriate transfer. If the patient requires treatment, it must be sufficient to minimize the risk likely to occur or result from the transfer.

Note: The four requirements of an "appropriate" transfer are applied only if the transfer is to another medical facility. In other words, the hospital has the alternative of either (1) providing treatment to stabilize the emergency medical condition and subsequently admitting, discharging or transferring the individual, or (2) appropriately transferring an unstabilized individual to another medical facility if the emergency medical condition still exists. There is no "third" option of simply "referring" the individual away after performing step one (treatment to minimize the risk of transfer) of the four transfer requirements of an appropriate transfer.

If an individual is moved to another part of the hospital, the transfer requirements are not applicable because technically the patient has not been transferred.

If an individual is moved to a diagnostic facility located at another hospital with the intention of returning to the first hospital, an appropriate transfer (within the meaning of paragraph (e)(2) of this subsection) must still be effectuated. It is reasonable to expect the recipient hospital with the diagnostic capability to communicate (e.g., telephonic report or documentation within the medical record) with the transferring hospital its findings of the medical condition and a status report of the individual during and after the procedure. Implementing an appropriate transfer back to the sending hospital is not necessary.

Surveyor Probes
After the investigation of the transferring hospital, call or go to the receiving (recipient) facility and determine whether the receiving (recipient) facility verifies the transferring hospital's information. In cases of discrepancy, obtain the medical record from the transferring and receiving hospitals and the ambulance service for review. Review each hospital's information. If you determine that it is necessary to conduct a complaint investigation at the receiving (recipient) hospital, notify the RO to request an extension of the investigation timeframe.

Review the transfer logs for the entire hospital, not merely the emergency department. Examine the following for appropriate transfers:
o Transfers to off-site testing facilities and return;
o Death or significant adverse outcomes;
o Refusals of examination, treatment, or transfer;
o Patients leaving against medical advice (AMA);
o Returns to the emergency department within 48 hours; and
o Emergency department visits where the individual is logged in for an unreasonable amount of time before the time indicated for commencement of the medical screening examination.

§489.24 (e)(2)(A) and (B)
This is the second requirement of an appropriate transfer.

The transferring hospital must obtain permission from the receiving (recipient) hospital to transfer an individual. The transferring hospital should document its communication with the receiving (recipient) hospital, including the date and time of the transfer request and the name of the person accepting the transfer.

§489.24 (e)(2)(iii)
This is the third requirement of an appropriate transfer.

Necessary medical records must accompany individuals being transferred to another hospital. If a transfer is in an

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individual's best interest, it should not be delayed until records are retrieved or test results come back from the laboratory. Whatever medical records are available at the time the individual is transferred should be sent to the receiving (recipient) hospital with the patient. Test results that become available after the individual is transferred should be telephoned to the receiving (recipient) hospital, and then mailed or sent via electronic transmission consistent with HIPAA provisions on the transmission of electronic data.

Surveyor Probe
Documentation in the medical records should identify the services that were performed before transfer.

§489.24 (e)(2)(iv)
This is the fourth requirement of an appropriate transfer.

Emergency medical technicians may not always be "qualified personnel" for purposes of transferring an individual under these regulations. Depending on the individual's condition, there may be situations in which a physician's presence or some other specialist's presence might be necessary. The physician at the sending hospital (and not the receiving hospital) has the responsibility to determine the appropriate mode, equipment, and attendants for transfer.

While the sending hospital is ultimately responsible for ensuring that the transfer is effected appropriately, the hospital may meet its obligations as it sees fit. These regulations do not require that a hospital operate an emergency medical transportation service.

FED - C2410 - WHISTLEBLOWER PROTECTION

Title WHISTLEBLOWER PROTECTION

Type Standard

CFR 489.24(e)(3)

Regulation Definition

A participating hospital may not penalize or take adverse action against a physician or a qualified medical person described in paragraph (e)(1)(ii)(C) of this section because the physician or qualified medical person refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized, or against any hospital employee because the employee reports a violation of a requirement of

Interpretive Guideline

A "participating hospital" means a hospital that has entered into a provider agreement under §1866 of the Act.

Hospital employees reporting alleged EMTALA violations are also protected by this regulation.

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this section.

FED - C2411 - RECIPIENT HOSPITAL RESPONSIBILITIES

Title RECIPIENT HOSPITAL RESPONSIBILITIES

Type Standard

CFR 489.24(f)

Regulation Definition

A participating hospital that has specialized capabilities or facilities (including, but not limited to, facilities such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers, which, for purposes of this subpart, means hospitals meeting the requirements of referral centers found at §412.96 of this chapter) may not refuse to accept from a referring hospital within the boundaries of the United States an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual. This requirement applies to any participating hospital with specialized capabilities, regardless of whether the hospital has a dedicated emergency department.

Interpretive Guideline

A participating hospital that has specialized capabilities or facilities may not refuse to accept from a referring hospital an appropriate transfer of an individual who requires such specialized capabilities or facilities. This assumes that, in addition to its specialized capabilities the recipient hospital has the capacity to treat the individual, and that the transferring hospital lacks that capability or capacity. This requirement applies to any participating hospital with specialized capabilities, regardless of whether the hospital has a dedicated emergency department. See Tag A-2409/C-2409 for discussion of an appropriate transfer.

A hospital with specialized capabilities or facilities includes, but is not limited to, facilities such as burn units, shock-trauma units, or neonatal intensive care units. With respect to rural areas, this includes regional referral centers that meet the requirements of referral centers found at 42 CFR 412.96.

A hospital with specialized capabilities or facilities that has the necessary capacity to treat an individual with an emergency medical condition may not condition, or attempt to condition, its acceptance of an appropriate transfer of an individual on the use by the sending hospital of a particular transport services instead of the transport arrangements made by the attending physician at the sending hospital.

A hospital with specialized capabilities that delays the treatment of an individual who arrives as a transfer from another facility could be in violation of EMTALA, depending on the circumstances. Hospitals that deliberately delay moving an individual from an EMS stretcher do not thereby delay the point in time at which their EMTALA obligation begins. Furthermore, such a practice of "parking" patients arriving via EMS, refusing to release EMS equipment or personnel, jeopardizes patient health and adversely impacts the ability of the EMS personnel to provide emergency response services to the rest of the community. On the other hand, this does not mean that a hospital will necessarily have violated EMTALA and/or the hospital CoPs if it does not, in every instance, immediately assume from the EMS provider all responsibility for the individual, regardless of any other circumstances in the hospital.

Lateral transfers, that is, transfers between facilities of comparable resources, are not mandated by §489.24(e),

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because the benefits of such transfer would not be likely to outweigh the risks, except where the sending hospital has a serious capacity problem, a mechanical failure of equipment, or similar situations.

The number of patients that may be occupying a specialized unit, the number of staff on duty, or the amount of equipment on the hospital's premises do not in and of themselves reflect the capacity of the sending or recipient hospital to care for additional patients. If a hospital generally has accommodated additional patients by whatever means (e.g., moving patients to other units, calling in additional staff, borrowing equipment from other facilities), it has demonstrated the ability to provide services to patients in excess of its occupancy limit. For example, a hospital may be able to care for one or more severe burn patient without opening up a "burn unit." In this example, if the recipient hospital has the capacity, the hospital would have a duty to accept an appropriate transfer of an individual requiring the hospital's capabilities, providing the sending hospital lacked the specialized services to treat the individual. The provisions of this requirement are applicable only when the sending hospital is located within the boundaries of the United States. Medicare participating hospitals with specialized capabilities or facilities are not obligated to accept transfers from hospitals located outside of the boundaries of the United States.

When investigating an allegation that a hospital has violated the EMTALA recipient hospital responsibility requirements, it is usually necessary to also obtain a copy of the patient's medical record from the transferring facility.

Rural Regional Referral Centers
The criteria for classifying hospitals as rural regional referral centers are defined in 42 CFR §412.96 for the purpose of exemptions and adjustments of payment amounts under the Inpatient Prospective Payment System. The criteria in 42 CFR §412.96 are applicable to the nondiscrimination provisions of §489.24. Check with the appropriate CMS RO for information as to whether the hospital is designated as a rural regional referral center. A designated rural regional referral center is obligated to accept appropriate transfers of individuals who require the hospital's specialized capabilities if the hospital has the capacity to treat the individual.

FED - C9999 - FINAL OBSERVATIONS

Title FINAL OBSERVATIONS

Type Memo Tag

CFR

Regulation Definition

Interpretive Guideline