

CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 78

Date: December 22, 2011

SUBJECT: Revised Appendix A, Interpretive Guidelines for Hospitals, and Revised Appendix W, Interpretive Guidelines for Critical Access Hospitals (CAHs)

I. SUMMARY OF CHANGES: New guidance is provided to reflect regulatory changes concerning the provision of telemedicine services in Hospitals and CAHs.

NEW/REVISED MATERIAL - **EFFECTIVE DATE*:** December 22, 2011
IMPLEMENTATION DATE: December 22, 2011

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/§482.12(a) Standard: Medical Staff (TAG A-0045 and A-0052)
R	Appendix A/§482.22(a) Standard: Composition of the Medical Staff (TAG A-0339 and A-0342 through A-0343)
R	Appendix A/§482.22(c) Standard: Medical Staff Bylaws (TAG A-363)
R	Table of Contents/Appendix W
N	Appendix W/§485.616(c) Standard: Agreements for Credentialing and Privileging of Telemedicine Physicians and Practitioners (TAG C-0196 and C-0197)
R	Appendix W/§485.635(c) Standard: Services Provided through Agreements or Arrangements (TAG C-0285)
R	Appendix W/§485.641(b) Standard: Quality Assurance (TAG C-0340)

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2011 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

State Operations Manual

Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

A-0045

(Rev. 78, Issued: 12-22-11, Effective/Implementation: 12-22-11)

[The governing body must:]

§482.12(a)(1) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;

Interpretive Guidelines §482.12(a)(1)

The governing body must determine, in accordance with State law, which categories of practitioners are eligible for appointment to the medical staff.

The medical staff must, at a minimum, be composed of physicians who are doctors of medicine or doctors of osteopathy. In addition, the medical staff may include other *types of health care professionals* included in the definition *of a physician* in Section 1861(r) of the Social Security Act:

- Doctor of medicine or osteopathy;
- Doctor of dental surgery or of dental medicine;
- Doctor of podiatric medicine;
- Doctor of optometry; and
- a Chiropractor.

In all cases, the *healthcare professionals* included in the definition of a physician must be legally authorized to practice within the State where the hospital is located and providing services within their authorized scope of practice. In addition, in certain instances the Social Security Act and regulations attach further limitations as to the type of hospital services for which a *healthcare professional* may be considered to be a “physician.” See [42 CFR 482.12\(c\)\(1\)](#) for more detail on these limitations.

The governing body has the flexibility to determine whether *healthcare professionals* included in the definition of a physician *other than a doctor of medicine or osteopathy* are eligible for appointment to the medical staff.

Furthermore, the governing body has the authority, in accordance with State law, to appoint some types of non physician practitioners to the medical staff. *Practitioners are defined in Section 1842(b)(18)(C) of the Act as a:*

- *Physician assistant;*
- *Nurse practitioner;*
- *Clinical nurse specialist (Section 1861(aa)(5) of the Act);*
- *Certified registered nurse anesthetist (Section 1861(bb)(2) of the Act);*
- *Certified nurse-midwife (Section 1861(gg)(2) of the Act);*
- *Clinical social worker (Section 1861(hh)(1) of the Act);*
- *Clinical psychologist (42 CFR 410.71 for purposes of Section 1861(ii) of the Act); or*
- *Registered dietician or nutrition professional.*

Other types of licensed healthcare professionals have a more limited scope of practice and are generally not eligible for hospital medical staff privileges, unless their permitted scope of practice in their State makes them comparable to the above types of practitioners.

Physicians and non physicians may be granted *medical staff* privileges to practice at the hospital by the governing body for practice activities authorized within their State scope of practice without being appointed a member of the medical staff.

Survey Procedures §482.12(a)(1)

Review documentation and verify that the governing body has determined and stated the categories of *physicians and* practitioners that are eligible candidates for appointment to the medical staff *or medical staff privileges*.

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A-0052

(Rev.78, Issued: 12-22-11, Effective/Implementation: 12-22-11)

[The governing body must:]

§482.12(a)(8) Ensure that, when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the agreement is written and that it specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements in paragraphs (a)(1) through (a)(7) of this section with regard to the distant-site hospital's physicians and practitioners providing telemedicine services. The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with §482.22(a)(3) of this part, grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital.

§482.12(a)(9) Ensure that when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the written agreement specifies that the distant-site telemedicine entity is a contractor of services to the hospital and as such, in accordance with §482.12(e), furnishes the contracted services in a manner that permits the hospital to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in paragraphs (a)(1) through (a)(7) of this section with regard to the distant-site telemedicine entity's physicians and practitioners providing telemedicine services. The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with §482.22(a)(4) of this part, grant privileges to physicians and practitioners employed by the distant-site telemedicine entity based on such hospital's medical staff recommendations; such staff recommendations may rely on information provided by the distant-site telemedicine entity.

Interpretive Guidelines §482.12(a)(8)&(a)(9)

“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 hospital 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 physician or practitioner. “Non-simultaneously” means that, while the telemedicine physician or practitioner still provides clinical services to the patient upon a formal request from the patient's attending physician, 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 25551-25552, May 5, 2011)

A hospital may make arrangements through written agreements either with a distant-site Medicare-participating hospital or a distant-site telemedicine entity for the provision of telemedicine services to the hospital's patients by physicians or practitioners who have been granted privileges by the distant-site hospital or telemedicine entity. 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 hospital using its services to meet all applicable CoPs, particularly those requirements related to the credentialing and privileging of practitioners providing telemedicine services to the patients of a hospital. 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 hospital. (See 76 FR 25553, May 5, 2011)

If a hospital enters into an agreement for telemedicine services with a distant-site hospital or telemedicine entity, the agreement must be in writing. Furthermore, the written agreement must specify, in the case of a:

- Distant-site hospital, that it is the responsibility of the governing body of the distant-site hospital to satisfy the requirements of §§482.12(a)(1) through (a) (7) with respect to those physicians and practitioners at the distant-site hospital who furnish telemedicine services under the agreement. Since the distant-site hospital must also be a Medicare-participating hospital (see §482.22(a)(3)), it has an independent obligation to comply with these governing body requirements concerning medical staff membership and privileging. Nevertheless, the written agreement between the hospital and the distant-site hospital must explicitly include a provision addressing the distant-site hospital's obligation to comply with these provisions.*
- Distant-site telemedicine entity, that the written agreement specifies that they entity is a contractor providing telemedicine services to the hospital, and that, in accordance with the requirements governing services under arrangement at §482.12(e), the telemedicine entity furnishes the contracted telemedicine services in a manner that permits the hospital to comply with the Conditions of Participation, including, but not limited to, the governing body requirements of §§482.12(a)(1) through (a) (7) with respect to those physicians and practitioners at the distant-site telemedicine entity who furnish telemedicine services under the agreement.*

There are additional requirements for the content of the written agreement, specified at §482.22(a)(3) and §482.22(a)(4) under the medical staff Condition of Participation, which are discussed in the interpretive guidelines for those regulations.

The hospital's governing body must grant privileges to each telemedicine physician or practitioner providing services at the hospital under an agreement with a distant-site hospital or telemedicine entity before they may provide telemedicine services. The scope of the privileges in the hospital must reflect the provision of the services via a telecommunications system. For example, a surgeon at a distant-site hospital may provide telemedicine consultation services at a hospital under agreement, but obviously would not be able to perform surgery by this means and must not have surgical privileges in the hospital as part of his/her telemedicine services privileges. If the surgeon also periodically performed surgery on-site at the hospital, then he or she would have to have privileges to do so, granted in the traditional manner provided for at §482.12(a)(1) through §482.12(a)(7) and §482.22(a)(1) and §482.22(a)(2).

In granting privileges to telemedicine physicians and practitioners, the hospital's governing body has the option of considering hospital medical staff recommendations that rely, in accordance with §482.22(a)(3) and §482.22(a)(4), upon the credentialing and privileging decisions of the distant-site hospital or telemedicine entity. With respect to the decisions of a distant-site telemedicine entity, the regulation states that this streamlined privileging option is available to the hospital for physicians and practitioners "employed" by the distant-site telemedicine entity. We are interpreting "employed" in this context to mean "utilized by" the distant-site telemedicine entity to provide telemedicine services to the hospital under an agreement. Since it is common for telemedicine entities to contract with, rather than employ, the physicians and practitioners it utilizes to provide telemedicine services, it would not be reasonable or consistent with the regulatory intent to interpret "employed" to mean that the physicians or practitioners are employees of the distant-site telemedicine entity.

When the hospital's governing body exercises the option to grant privileges based on its medical staff recommendations that rely upon the privileging decisions of a distant-site telemedicine hospital or entity, it may, but is not required to, maintain a separate file on each telemedicine physician and practitioner, or may instead have a file on all telemedicine physicians and practitioners providing services at the hospital under each agreement with a distant-site hospital or telemedicine entity, indicating which telemedicine services privileges the hospital has granted to each physician and practitioner on the list.

Relying upon the credentialing and privileging decisions of the distant-site hospital or telemedicine entity is an option available to the hospital's governing body, not a requirement. A governing body may, if it so chooses, require its medical staff to independently review the credentials of and make privileging recommendations for each telemedicine physician and practitioner in accordance with §482.22(a)(1) and §482.22(a)(2), rather than permit its medical staff to rely upon the privileging decisions of the distant-site hospital or telemedicine entity. The agreement with the distant-site hospital or telemedicine entity may not require the hospital to rely upon the distant-site organization's privileging decisions.

Survey Procedures §482.12(a)(8)&(a)(9)

- *Ask the hospital'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) or telemedicine entity(ies). Does each agreement include the required elements concerning credentialing and privileging of the telemedicine physicians and practitioners?*
- *Does the hospital have documentation indicating that it granted privileges to each telemedicine physician and practitioner?*
- *Does the documentation indicate that for each telemedicine physician and practitioner there is a medical staff recommendation, including an indication of whether the medical staff conducted its own review or relied upon the decisions of the distant-site hospital or telemedicine entity?*

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A-0339

(Rev.78, Issued: 12-22-11, Effective/Implementation: 12-22-11)

§482.22(a) Standard: Composition of the Medical Staff

The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body.

Interpretive Guidelines §482.22(a):

The medical staff must at a minimum be composed of physicians who are doctors of medicine or doctors of osteopathy. In addition, the medical staff may include other *healthcare professionals* included in the definition in Section 1861(r) of the Social Security Act of a physician:

- Doctor of medicine or osteopathy;
- Doctor of dental surgery or of dental medicine;
- Doctor of podiatric medicine;
- Doctor of optometry; and a
- Chiropractor.

In all cases the *healthcare professional* included in the definition of a physician must be legally authorized to practice within the State where the hospital is located and providing services within their authorized scope of practice. In addition, in certain instances the Social Security Act and regulations attach further limitations as to the type of hospital services for which a *healthcare professional* may be considered to be a “physician.” See §482.12(c)(1) for more detail on these limitations.

The governing body has the flexibility to determine whether *healthcare professionals* included in the definition of a physician *other than a doctor of medical or osteopathy* are eligible for appointment to the medical staff.

Furthermore, the governing body has the authority, in accordance with State law, to appoint non-physician practitioners to the medical staff. *Practitioners are defined in Section 1842(b)(18)(C) of the Act as a:*

- *Physician assistant;*
- *Nurse practitioner;*
- *Clinical nurse specialist (Section 1861(aa)(5) of the Act);*
- *Certified registered nurse anesthetist (Section 1861(bb)(2) of the Act);*
- *Certified nurse-midwife (Section 1861(gg)(2) of the Act);*
- *Clinical social worker (Section 1861(hh)(1) of the Act);*
- *Clinical psychologist (42 CFR 410.71 for purposes of Section 1861(ii) of the Act); or*
- *Registered dietician or nutrition professional.*

Other types of licensed healthcare professionals have a more limited scope of practice and are generally not eligible for hospital medical staff privileges, unless their permitted scope of practice in their State makes them comparable to the above types of practitioners.

Physicians and non-physician *practitioners* may be granted *medical staff* privileges to practice at the hospital by the governing body for practice activities authorized within their State scope of practice without being appointed a member of the medical staff.

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A-0342

(Rev. 78, Issued: 12-22-11, Effective/Implementation: 12-22-11)

§482.22(a)(3) When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site hospital, that all of the following provisions are met:

(i) The distant-site hospital providing the 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 at the distant-site hospital.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital 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 hospital whose patients are receiving the telemedicine services, the hospital 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 performance information for use in the 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 hospital's patients and all complaints the hospital has received about the distant-site physician or practitioner.

Interpretive guidelines §482.22(a)(3)

The hospital's governing body has the option, when considering granting privileges to telemedicine physicians and practitioners, to have the hospital's medical staff rely upon the credentialing and privileging decisions of the distant-site hospital for these physicians and practitioners. This process would be in lieu of the traditional process required under §482.22(a)(1) and §482.22(a)(2), whereby the hospital's medical staff conducts its own review of each telemedicine physician's or practitioner's credentials and makes a recommendation based on that individualized review.

In order to exercise this alternative credentialing and privileging option, the hospital's governing body must ensure through its written agreement with the distant-site hospital that all of the following requirements are met:

- 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 hospital may no longer receive telemedicine services under the agreement;*
- The distant-site hospital provides to the hospital a list 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;*
- Each physician or practitioner who provides telemedicine services to the hospital's patients under the agreement holds a license issued or recognized by the State where the hospital (not the distant-site hospital) 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 hospital 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 hospital 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 under the agreement and on all complaints it has received about a telemedicine physician or practitioner covered by the agreement.*

Survey Procedures §482.22(a)(3)

- *If the hospital provides telemedicine services to its patients under an agreement with a distant-site hospital, ask whether the hospital's governing body has exercised the option to have the medical staff rely upon the credentialing and privileging decisions of the distant-site hospital in making privileging recommendations on telemedicine physicians and practitioners. If yes, ask to see:*
 - *The written agreement with the distant-site hospital. Does the agreement address the required elements concerning the distant-site hospital's Medicare participation, licensure of telemedicine physicians and practitioners, current list of telemedicine physicians and practitioners with privileges, and review by the hospital of the telemedicine physicians' and practitioners' services and provision of information based on its review to the distant-site hospital?*
 - *The list provided by the distant-site hospital of the telemedicine physicians and practitioners, including their current privileges and pertinent licensure information.*
 - *Evidence that the hospital reviews the services provided by the telemedicine physicians and practitioners, including any adverse events and complaints, and provides feedback to the distant-site hospital.*

A-0343

(Rev.78, Issued: 12-22-11, Effective/Implementation: 12-22-11)

§482.22(a)(4) When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine

entity furnishes services that, in accordance with §482.12(e), permit the hospital to comply with all applicable conditions of participation for the contracted services. The hospital's governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of 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 §482.12(a)(1) through (a)(7) and §482.22(a)(1) through (a)(2).

(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides the hospital with a current list 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 hospital whose patients are receiving such telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital 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 performance information for use in the 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 hospital's patients, and all complaints the hospital has received about the distant-site physician or practitioner.

Interpretive guidelines §482.22(a)(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 hospital using its services to meet all applicable Conditions of Participation, particularly those requirements related to the credentialing and privileging of practitioners providing telemedicine services to the patients of a hospital. 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 hospital. (See 76 FR 25553, May 5, 2011)

The hospital's governing body has the option, when considering granting privileges to telemedicine physicians and practitioners, to have the hospital's medical staff rely upon the credentialing and privileging decisions of the distant-site telemedicine entity for these physicians and practitioners. This process would be in lieu of the traditional process required under §482.22(a)(1) and §482.22(a)(2), whereby the medical staff conducts its own review of each telemedicine physician's or practitioner's credentials and makes a recommendation based on that individualized review.

In order to exercise this alternative credentialing and privileging option, the hospital's governing body must ensure that its written agreement with the distant-site hospital enables the hospital, as required under the regulation at §482.12(e) governing services provided under arrangement, to comply with all applicable hospital Conditions of Participation. In particular,

the written agreement between the hospital and the distant-site telemedicine entity must ensure that all of the following requirements are met:

- *The distant-site telemedicine entity utilizes a medical staff credentialing and privileging process and standards that at least meets the standards for the medical staff of a hospital established at §482.12(a)(1) through (a)(7) and §482.22(a)(1) through (a)(2);*
- *The distant-site telemedicine entity provides a list to the hospital of all 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 hospital's patients under the agreement holds a license issued or recognized by the State where the hospital 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 hospital has evidence that it reviews the telemedicine services provided to its patients and provides a written copy of this review to the distant-site telemedicine entity for the latter's use in its periodic appraisal of the physicians and practitioners providing telemedicine services under the agreement. At a minimum, the hospital must review and send information to the distant-site telemedicine entity on all adverse events that result from a physician or practitioner's provision of telemedicine services and on all complaints it has received about a telemedicine physician or practitioner.*

Survey Procedures 482.22(a)(4)

- *If the hospital provides telemedicine services to its patients under an agreement with a one or more distant-site telemedicine entities, ask whether the hospital's governing body has exercised the option to have the medical staff rely upon the credentialing and privileging decisions of the distant-site telemedicine entity in making privileging recommendations on telemedicine physicians and practitioners. If yes, ask to see:*
 - *The written agreement(s) with the distant-site telemedicine entity(ies). Does each agreement 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, appropriate licensure of telemedicine physicians and practitioners, current list of telemedicine physicians and practitioners specifying their privileges, and written review by the hospital of the telemedicine physicians' and practitioners' services and provision of information based on its review to the distant-site hospital?*

- *The list provided by the distant-site telemedicine entity of the telemedicine physicians and practitioners covered by the agreement, including their current privileges and pertinent licensure information.*
- *Evidence that the hospital 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 hospital how it verifies that the telemedicine entity employs a credentialing and privileging process that meets or exceeds what is required for hospitals under the Medicare CoPs? (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 whether the hospital takes steps to ensure that the distant-site telemedicine entity complies with the terms of the written agreement.)*

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A-0363

(Rev.78, Issued: 12-22-11, Effective/Implementation: 12-22-11)

[The bylaws must:]

§482.22(c)(6) - Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. *For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the hospital, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in §482.12(a)(8) and (a)(9), and §482.22(a)(3) and (a)(4).*

Interpretive Guidelines §482.22(c)(6)

All patient care is provided by or in accordance with the orders of a *physician or* practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted privileges in accordance with those criteria by the governing body, and who is working within the scope of those granted privileges.

Privileges are granted by the hospital's governing body to individual practitioners based on the medical staff's review of that individual practitioner's qualifications and the medical staff's recommendations for that individual practitioner to the governing body. *However, in the case of telemedicine physicians and practitioners providing telemedicine services under an agreement, the governing body has the option of having the medical staff rely upon the credentialing and privileging decisions of the distant-site hospital or telemedicine entity with which the hospital has entered into an agreement. When the governing body has exercised this option, the medical staff's bylaws must include a provision allowing the medical staff to rely upon the credentialing and privileging decisions of a distant-site hospital or telemedicine entity when that distant-site*

hospital or entity is required under the terms of its agreement with the hospital to employ a credentialing and privileging process that conforms to the provisions of §482.12(a)(8) and (a)(9), and §482.22(a)(3) and (a)(4).

Survey Procedures §482.22(c)(6)

- Verify that the medical staff bylaws contain criteria for granting, withdrawing, and modifying clinical privileges to individual *physicians and* practitioners of the medical staff and that a procedure exists for applying these criteria.
- *In the case of telemedicine physicians and practitioners providing telemedicine services under an agreement with the hospital where the hospital's governing body has opted to have the medical staff rely upon the credentialing and privileging decisions of the distant-site hospital or telemedicine entity, verify that the bylaws include a provision permitting such reliance.*
- Verify that *physicians and* practitioners who provide care to patients are working within the scope of the privileges granted by the governing body.

State Operations Manual
Appendix W – Survey Protocol, Regulations and
Interpretive Guidelines for Critical Access Hospitals (CAHs)
and
Swing-Beds in CAHs

(Rev. 78, 12-22-11)

Transmittals for Appendix W

§485.616(c) Standard: Agreements for credentialing and privileging of telemedicine physicians and practitioners.

C-0196

(Rev.78, Issued: 12-22-11, Effective/Implementation: 12-22-11)

§485.616(c) Standard: *Agreements for credentialing and privileging of telemedicine physicians and practitioners.*

(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 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.**

Interpretive Guidelines §485.616(c) §485.616(c)(1)&(2)

“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.*
- 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.*

C-0197

(Rev. 78, Issued: 12-22-11, Effective/Implementation: 12-22-11)

§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).

(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.

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:

- *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;*
 - *Approve 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?*
 - *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.)

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C-0285

(Rev.78, Issued: 12-22-11, Effective/Implementation: 12-22-11)

§485.635(c) Standard: Services Provided Through Agreements or Arrangements

(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 telemedicine entity, the distant-site telemedicine entity is not required to be a Medicare-participating provider or supplier.

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 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.*

* * *

C-0340

(Rev.78, Issued: 12-22-11, Effective/Implementation: 12-22-11)

§485.641(b)(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;**
- (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 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;*

Interpretive Guidelines §485.641(b)(4)

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.

Survey Procedures §485.641 (b)(4)

- 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?*
- 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?*
- 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?*
- 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?*