HMA

HEALTH MANAGEMENT ASSOCIATES

Credentialing Under Medicare and Accreditation Programs: Implications for Telehealth Practitioners

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I. Overview

The Center for Connected Health Policy (CCHP) has asked Health Management Associates (HMA) to examine recent changes to The Joint Commission's (TJC's) credentialing standards for telehealth providers to determine the impact on hospitals, rural health clinics (RHCs), federally-qualified health centers (FQHCs), and clinics operated by the Indian Health Service (IHS). In addition, CCHP asked HMA to examine whether any changes also govern telehealth care provided to Medi-Cal and private pay patients, as well as to identify the risks of noncompliance with Medicare Conditions of Participation (CoPs).

Medicare CoPs set forth the conditions for participating in (receiving reimbursement from) the Medicare program. Providers may choose to be eligible for Medicare participation by seeking deemed status designation through meeting accreditation standards established by an approved accrediting body.

Hospitals having deemed status through the TJC's accreditation program are concerned about changes to the TJC standards for credentialing professionals who are engaged in providing telehealth services. TJC was required to change its credentialing and privileging by proxy requirements to conform to hospital Medicare CoPs. The Center for Medicare and Medicaid Services (CMS) requires telehealth service providers to be credentialed by each hospital that uses telehealth services. Many believe this requirement to be cumbersome, time-consuming and outdated given today's use of telehealth for delivering healthcare services.

Achieving a sensible, nation-wide credentialing/privileging standard for telehealth practitioners requires a fundamental regulatory solution that is embraced by CMS and by all committed to promoting telehealth services, recognizes the importance of telehealth in today's health care delivery system, and develops uniform standards that do not overly-burden hospitals providers.

This paper was prepared using readily-available resources and does not constitute a legal opinion.

II. CMS Medicare Conditions of Participation, Accreditation and Deemed Status

Medicare Conditions of Participation

Medicare CoPs are the minimum health and safety requirements that providers must meet in order to participate in the Medicare program. Compliance with these CoPs are determined through either a survey conducted by the State Survey Agency (SSA) or through verification of compliance by an AO whose standards and processes have been formally approved by CMS as meeting or exceeding the minimum Medicare CoPs (deemed status). CoPs have specific standards related to each condition. CMS has provided interpretive guidelines and survey procedures to clarify these requirements for both providers and SSAs.

Accrediting Organizations

Accrediting organizations (AOs) offer providers an opportunity to have external quality assurance oversight of their governance and operations. Achieving accreditation status identifies providers as having met standards established by these AOs. Accreditation can be a condition of contracting with a managed care organization or other insurer, obtaining preferred status for liability insurance rate purposes, obtaining financial loans, or qualification for certain grants or other reimbursements. AOs may also apply to CMS to be designated as an AO for "deemed status" purposes.

Deemed Status Designation by CMS

Section 1865(b) of the Social Security Act permits providers and suppliers accredited by an approved national accrediting body to be "*deemed*" to meet Medicare CoPs. To receive approval, AOs must demonstrate to CMS that their requirements meet or exceed the Medicare CoPs. AOs seeking this designation must submit an application to CMS for approval. CMS conducts a review of the survey and accrediting process to determine if these requirements meet or exceed the Medicare CoPs.

Section 1865 (a)(3)(A) of the Social Security Act requires that CMS's review of deeming applications is completed within 210 calendar days after the date of receipt of the application. Within 60 days of receiving the application, CMS must publish a notice in the Federal Register that identifies the accrediting body, and the nature of the request, and provides at least 30 days for public comment about the application. At the end of the 210-day period, CMS must publish an approval or a denial of the application in the Federal Register with the effective and expiration dates of the approval.

Accreditation by an AO is voluntary on the part of the provider or supplier, and it is not required for participation in the Medicare program. A provider may opt for routine surveys by

an SSA to determine if it meets Medicare requirements in lieu of requesting deemed status through the accreditation process.[1]

Federal regulations permit participation via deemed status for certain categories of providers and suppliers.[2] To date, AOs have applied for and been approved by CMS for hospitals, critical access hospitals, ambulatory surgical centers, home health agencies and hospices. There are three AOs that are approved for hospitals: The Joint Commission, American Osteopathic Association's Health Facilities Accreditation Program (AOA/HFAP), and Det Norske Veritas Healthcare's National Integrated Accreditation for Healthcare Organizations (DNV/NIAHO).

There are no AOs that have applied for or are currently recognized by CMS for purposes of certifying compliance with Medicare CoPs for RHCs, FQHCs or clinics operated by the IHS. These providers and suppliers may choose to be accredited for quality assurance purposes, but they currently cannot be "deemed" to meet the Medicare CoPs by meeting the standards of an AO.

Process for Obtaining Deemed Status through Accreditation

If a provider seeks to obtain deemed status recognition from CMS, accreditation alone will not provide that recognition. A provider can be accredited by an AO, but not deemed. Providers seeking deemed status recognition for their accreditation must document that they are accredited under the AOs CMS-recognized deemed status accreditation program, and the AO must recommend to CMS that certification be granted via deemed status.

Providers must first apply to the Medicare Fiscal Intermediary (FI) or Medicare Administrative Contractor (MAC) for Medicare certification. The AO may not conduct the initial accreditation survey until the FI/MAC has completed its initial review of the provider's application for certification (CMS Form 855A) and has made a recommendation to CMS for approval. A copy of the CMS 855A is also sent to the SSA. The AO may proceed with the accreditation survey once the FI/MAC has recommended approval. Once the AO has conducted the accreditation survey and has determined compliance, the AO is required to notify CMS (both the Central Office and the Regional Office) and also provides a copy of this notification to the provider. The provider must provide a copy of this notice of compliance with the accreditation standards to the SSA. The SSA then sends the certification package, with documentation of approval by the

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[1] Thomas Hamilton, Director, Centers for Medicare and Medicaid Services (CMS) Survey and Certification Group, *S&C-09-02: Approval of Deeming Authority of Det Norske Veritas Healthcare, Inc. for Hospitals,* October 3, 2008.

[2] 42 CFR §§ 488.5 and 488.6: Ambulatory surgical centers; comprehensive outpatient rehabilitation facilities; critical access hospitals; home health agencies; hospices; hospitals; clinics, rehabilitation agencies or public health agencies providing outpatient physical therapy, occupational therapy or speech pathology services; psychiatric hospitals; religious non-medical health care institutions; rural health clinics; screening mammography services; skilled nursing facilities; and transplant centers, except for kidney transplant center.

FI/MAC, along with the AO notice of compliance and other documentation, to the CMS Regional Office for review and approval for Medicare certification via deemed status. The CMS Regional Office makes the final determination for deemed status approval.

III. Importance of Credentialing

> "Credentialing is the process of obtaining, verifying and analyzing information to assess the qualifications of a healthcare practitioner to provide patient care services in or for a healthcare entity. Credentialing involves evaluating the provider's licensure, current competency, education, training and ability to determine the practitioner's qualifications to perform the clinical activities he or she desires."[3]

Each hospital's governing body is responsible for the credentialing process and delegates certain responsibilities to the hospital medical staff for implementation. Verifying qualifications to provide care and treatment to hospital patients includes but is not limited to: confirmation of current professional license and board specialty certifications, checking with the National Practitioner Data Bank (NPDB), the Healthcare Integrity Protection Data Bank (HIPDB), DEA Active Controlled Substances Act (CSA) Registration Database and other similar databases, confirmation of schooling and degrees, and confirmation of membership in professional associations.

Hospital credentialing criteria can vary from hospital to hospital, but there are core criteria for medical staff selection imposed by CMS as a condition of participating in Medicare, and by standards established by AO. Hospital credentialing practices may exceed these core requirements. These criteria are individual character, competence, training, experience, and judgment.[4]

Credentialing is considered to be a patient protection measure to allow only those providers who meet particular high standards to treat patients. Credentialing is also a risk management activity.

> "If a patient suffers an adverse outcome at a hospital and the physician is at fault, the patient or patient's family can hold the hospital liable. If an investigation reveals that the hospital did not meet the industry standard for credentialing and privileging the provider, a court may find that the hospital was negligent in their credentialing practices."[5]

Credentialing is also used to comply with accreditation and regulatory entities. All three hospital AOs that have deemed status approval from CMS require hospitals to credential medical staff. CMS Medicare CoPs require hospital medical staff credentialing as a condition of participation in the Medicare program. Most states, including California, have some hospital credentialing requirements as a condition of licensure.

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[3] Kathy Matzke, COMSM, CPCS, Contributing Editor, *2010 Credentials Verification Desk Reference,* Credentialing Resource Center, HCPro, 2010.

[4] 42 CFR 482.12 (a)(6)

[5] Matzke, 2010.

In 2007, twenty-eight states' high courts upheld negligent credentialing claims where patients sued hospitals for allegedly granting privileges to doctors with questionable credentials. Two states' high courts rejected negligent credentialing claims.[6]

No instances of negligent credentialing involving telehealth providers were identified during the research for this paper. It is unknown if a hospital would be found liable, if the hospital holds telehealth providers to a lesser or different standard than medical staff providing service at the hospital, and if that different standard is identified as contributing to a patient's injury, illness or death.

[6] American Medical Association, American Medical News, *Hospital can be sued for credentialing doctor with questionable qualifications, Minnesota high court rules, 10/15/2007,* http://www.ama-assn.org/amednews/2007/10/15/prsa1015.htm State courts permitting claims: Alabama, Alaska, California, Colorado, Florida, Georgia, Hawaii, Illinois, Indiana, Michigan, Minnesota, Mississippi, New Mexico, New York, North Carolina, Oklahoma, Pennsylvania, Rhode Island, Tennessee, Texas, & Vermont. State courts rejecting claims: Delaware & Kansas.

IV. Medicare Conditions of Participation vs. Accreditation: Standards, Oversight and Risks of Noncompliance

This section summarizes the credentialing standards established by CMS Medicare Conditions of Participation, AOs, and California licensure for hospitals and clinics, as well as the risks of noncompliance.

A: Hospitals: Acute Care Hospitals

Medicare Hospital Conditions of Participation and Verification of Compliance:

Medicare hospital CoPs are established in regulations as authorized by federal statute.[7] These CoPs include requirements for the governing body, which is responsible for the overall operations and governance and medical staff. The governing body delegates some credentialing and privileging functions to the medical staff but retains responsibility for:

- Appointing the members of the medical staff based on medical staff recommendations;
- Approving medical staff bylaws and requirements;
- Ensuring that the medical staff is accountable to the governing body for providing quality patient care; and
- Ensuring that the selection criteria used for medical staff membership are based on character, competency, experience, training, and judgment.[8]

The CoPs require that the hospital medical staff is responsible for:

- Periodically conducting appraisals of medical staff members;
- Examining credentials of candidates for medical staff membership and make recommendations to the governing body for medical staff appointment;
- Enforcing medical staff bylaws and establish the duties and privileges for each category of medical staff (active, courtesy, etc.);
- Describing qualifications of medical staff; and
- Establishing criteria for privileges granted to individual practitioners.

CMS publishes State Operations Manuals (SOMs) for each provider or supplier category for which Medicare benefits are provided. These SOMs provide the text of the regulations, and also

[7] 42 CFR 482.
[8] 42 CFR 482.12.

provide Interpretive Guidelines (IGs) for both providers and SSAs to know how CMS is interpreting the regulatory requirements. In addition, CMS provides Survey Procedures to instruct SSAs on what to look for to verify compliance with regulations and the interpretation of the regulations during the course of conducting a survey.

The Interpretive Guidelines and Survey Procedures for both the Condition of Governing Body (42 CFR 482.12) and Medical Staff (42 CFR 482.22) contain information on CMS's interpretation and survey procedures used to determine compliance with federal Medicare hospital regulations (CoPs).

Relevant portions of the SOM that factor into the conflict between a credentialing/privileging by proxy process for medical staff and the CMS Medicare CoPs are included in Appendix A. While the excerpts in Appendix A are central to the subject of this paper, the entire CoPs for governing body and medical staff provide valuable context on this issue. Of particular note are the interpretive guidelines that state: there must be a single medical staff that is responsible to the governing body of the hospital for providing quality care to patients; and any criteria for credentialing or privileging must be equally-applied to all practitioners. CMS Medicare hospital CoPs do not have unique conditions or standards for the credentialing of telehealth practitioners.

Consequences of noncompliance for non-accredited hospitals:

Hospitals that are not accredited are under the jurisdiction of the SSA for purposes of verifying compliance with Medicare CoPs. CMS has established a system of prioritizing workload that the SSA performs on behalf of CMS. The highest priority workload is "Tier 1" and the lowest priority workload is "Tier 4". SSAs are expected to be able to complete all of higher priority workload in any given year, and are not to work on lower priority workload unless completion of higher priority workload is assured. CMS considers the receipt of a complaint with a high potential for immediate jeopardy to patient to be a Tier 1 workload. CMS requires the SSA to survey non-accredited hospitals no less than once every 5 years (Tier 2 workload), or no less than once every 4-5 years (Tier 3 workload), or no less than once every 3 years (Tier 4 workload) if all other higher priority workload has been accomplished.

Should the SSA find that a condition of participation is not met, it recommends to the CMS RO that the Medicare agreement be terminated. The hospital has an opportunity to correct the deficient practice and have compliance verified by a revisit from the SSA. The timeframe within which the hospital must take the corrective action depends on the severity of the deficient practice. Immediate jeopardy situations permit only 23 days, but most situations provide six months for corrective action. Actual decertification of a hospital is rare. Should a hospital's Medicare agreement be terminated, the hospital's Medi-Cal agreement is also terminated. (See Section V, page 20 for more detail on the relationship between Medicare and Medi-Cal standards.)

Hospital Accreditation and Deemed Status:

Deemed status through accreditation for hospitals is approved by CMS for three accreditation organizations: The Joint Commission (TJC), American Osteopathic Association's Health Facilities Accreditation Program (AOA/HFAP), and most recently, Det Norske Veritas Healthcare's National Integrated Accreditation for Healthcare Organizations (DNV/NIAHO). The number of California hospitals that are accredited and non-accredited is summarized in the following chart:

ACCREDITATION TYPE/STATUS	NUMBER OF CALIFORNIA HOSPITALS (Excluding Critical Access Hospitals)
The Joint Commission	370
American Osteopathic Association	21
Det Norske Veritas Healthcare	0
Non-accredited	20
Total	**411**

Information from the California Department of Public Health, Licensing and Certification, and accreditation organization websites. (3/10)

The Joint Commission

In 1965, federal law granted approval for the Joint Commission hospital accreditation program to have deemed status. The vast majority of California's hospitals are accredited by The Joint Commission. In the past, CMS did not have oversight of TJC's standards because of TJC's statutory authority to have its accreditation program be approved for deemed status designation. Other AOs were, and are, required to submit an application to CMS for deemed status approval for their accreditation programs.

In 2001, TJC released new standards by which a Joint Commission-accredited hospital with deemed status could accept a "privileging by proxy" process with another Joint Commission-accredited hospital. This was viewed by many as a step toward recognizing the changing health care delivery system's use of telehealth, while preserving patient health and safety through using a standardized credentialing process.

The Medicare Improvements for Patients and Providers Act (MIPPA) enacted July 15, 2008, removed the statutory status of the Joint Commission's hospital accreditation program effective July 15, 2010. CMS now has the authority to review TJC's accreditation program and confirm that it meets or exceeds Medicare CoPs.

The Joint Commission was required to submit an application for approval to CMS to determine if TJC standards meets or exceeds federal Medicare hospital Conditions of Participation. As a part of this application process, CMS notified the TJC that the credentialing and privileging requirement by proxy did not meet the minimum Medicare hospice Conditions of Participation standard for medical staff credentialing. TJC was required to conform its accreditation standards to meet or exceed the CMS Medicare hospital Conditions of Participation, for those

hospitals seeking deemed status through accreditation. TJC was granted deemed status approval for its hospital accreditation program effective November 27, 2009, through July 15, 2014.[9]

The Joint Commission released a statement in October 2009 that, although TJC continues to engage CMS and members of Congress regarding the issue of credentialing and privileging by proxy as it related to telemedicine providers and users, TJC must survey to the current Medicare requirements and has changed the requirements for hospitals seeking deemed status through accreditation. These changes will be effective July 15, 2010.[10] These "Revised Hospital Requirements for Telemedicine" for hospitals seeking deemed status through accreditation include:

> LD.04.03.09, EP 4: Leaders monitor contracted services by establishing expectations for the performance of the contracted services. Note 2: For hospitals that use Joint Commission accreditation for deemed status purposes: The leaders who monitor the contracted services are the governing body. All licensed independent practitioners who are responsible for the patient's care, treatment, and services via a telemedicine link are credentialed and privileged to do so at the originating site. (See also MS.13.01.01, EP 1; LD.04.03.09, EP 9)
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> LD.04.03.09, EP9: Note: For hospitals that use Joint Commission accreditation for deemed status purposes: All licensed independent practitioners who are responsible for the patient's care, treatment, and services via a telemedicine link are credentialed and privileged to do so at the originating site. (See also MS.13.01.01, EP 1 and LD.04.03.09, EP 4)
>
> MS.13.01.01, EP 1:—For hospitals that use Joint Commission accreditation for deemed status purposes: All licensed independent practitioners who are responsible for the patient's care, treatment, and services via a telemedicine link are credentialed and privileged to do so at the originating site, according to standards MS.06.01.03 through MS.06.01.13. Note: If the distant site is a Medicare-participating hospital, the originating site's medical staff may use a copy of the distant site's credentialing packet for privileging purposes. This packet includes a list of all privileges granted to the licensed independent practitioner by the distant site and an attestation signed by the distant site indicating that the packet is complete, accurate, and up to date.

Hospitals not seeking accreditation for deemed status purposes are not required to comply with these sections. TJC has alternative requirements for telemedicine for accreditation-only

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[9] The Joint Commission press release, *The Joint Commission's Hospital Accreditation Recognized by CMS,* November 30, 2009.

[10] The Joint Commission Perspectives, *Credentialing and Privileging by Proxy and Telemedicine,* October 2009

providers. However, if a hospital chooses not to apply for deemed status designation by CMS, the SSA has jurisdiction for routine, periodic surveys of the hospital to determine compliance with Medicare CoPs.

American Osteopathic Association/Health Facilities Accreditation Program

Hospitals accredited by the AOA/HFAP are not permitted to accept the credentialing and privileging decision of another organization (credentialing/privileging by proxy). This standard is regardless of whether the hospital seeks a deemed status by accreditation. The hospital must:

- Use the same credentialing process as required for all other providers
- Complete specified qualifications review
- Ensure that each telemedicine provider is approved using the medical staff credentialing process.[11]

Det Norske Veritas Healthcare National Integrated Accreditation for Healthcare Organizations (DNV)

There are no California hospitals currently accredited by DNV. Unlike the AOA/HFAP and TJC, DNV does not have separate standards for telemedicine credentialing and privileging. However, DNV's credentialing standards are consistent with federal Medicare hospital CoPs.

Consequences of Non-compliance for Accredited Hospitals: Accredited hospitals with deemed status, are not under the jurisdiction of the SSA for routine Medicare certification surveys. The AO conducts the routine survey. However, the SSA retains the authority to investigate complaints. Should a complaint investigation reveal such serious problems that the SSA believes that Medicare CoPs may not be met, the SSA will request CMS for permission to do a "complaint validation survey" to determine whether or not the hospital meets the CoPs.

Hospitals with deemed status may also be surveyed by the SSA under other circumstances. CMS has instructed the SSA to conduct "sample validation surveys" by selecting 10% of all accredited hospitals each year to validate whether these hospitals continue to meet the Medicare CoPs.

A finding that CoPs are not met will result in the same recommendation that the Medicare agreement be terminated, with the hospital having a specific timeframe within which they must take corrective action to come back into compliance. In addition, the hospital may lose it's deemed status while undertaking corrective action, which puts the hospital under the authority of the SSA. Deemed status may be restored by CMS after corrective action has been verified.

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[11] NCPro, *2010 Credentials Verification Desk Reference,* p. 51.

Accreditation and deemed status does not mean that a hospital no longer needs to comply with Medical hospital CoPs. Deemed status only means that the SSA does not conduct the routine verification of compliance with federal CoPs.

California State Licensing Requirements for General Acute Care Hospitals: California hospital licensing regulations for medical staff credentialing and privileging are somewhat general, and would not necessarily conflict with either the more stringent CMS Medicare medical staff credentialing standards, or the more flexible credentialing and privileging by proxy requirements established by TJC for hospitals that are not seeking accreditation for deemed status purposes.

> Title 22, § 70203. Medical Service General Requirements.
>
> (a) A committee of the medical staff shall be assigned responsibility for:
>
> (1) Recommending to the governing body the delineation of medical privileges.
>
> (2) Developing, maintaining and implementing written policies and procedures in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate….
>
> (d) Periodically, an appropriate committee of the medical staff shall evaluate the services provided and make appropriate recommendations to the executive committee of the medical staff and administration.

California State licensing requirements indicate a hospital must comply with its own policies and procedures. These include the hospital bylaws and other policies and procedures that govern the hospital credentialing and privileging processes.

The California SSA conducts periodic state licensing surveys once every three years as a part of a consolidated licensing survey with TJC. Joining the SSA are physician surveyors from the California Medical Associations Institute for Medical Quality (CMA/IMQ) to review medical staff, peer review processes and medical staff minutes. It is rare for the SSA to revoke a hospital license. However, there have been occasions where a temporary suspension order is issued to immediately suspend (and close operations of) a hospital.

As is the case with enforcement of federal certification standards, hospitals are provided an opportunity to correct deficient practices. It is more likely that, upon identification of a state licensing requirement with serious implications for patient health and safety, that the SSA will request of CMS approval to use federal authority to require corrective action. The threat of losing Medicare and Medicaid funding is a more immediate threat to a hospital's "bottom line" than the process for revoking a licensing, which can take 12 months or more. Regardless of

whether the deficient practice is identified under state or federal law, hospital are very sensitive to any deficient findings and quickly take corrective action in the vast majority of cases.

B. Critical Access Hospitals

Critical Access Hospital (CAH) designation applies to small hospitals which have met certain criteria, thereby qualifying for a higher level of Medicare reimbursement (cost plus 1%). A facility that meets the following criteria may be designated by CMS as a CAH:

- Is located in a State that has established with CMS a Medicare rural hospital flexibility program; *and*
- Has been designated by the State as a CAH; *and*
- Is currently participating in Medicare as a rural public, non-profit or for-profit hospital; or was a participating hospital that ceased operation during the 10-year period from November 29, 1989 to November 29, 1999; or is a health clinic or health center that was downsized from a hospital; *and*
- Is located in a rural area or is treated as rural; *and*
- Is located more than a 35-mile drive from any other hospital or CAH (in mountainous terrain or in areas with only secondary roads available, the mileage criterion is 15 miles); *and*
- Maintains no more than 25 inpatient beds; *and*
- Maintains an annual average length of stay of 96 hours per patient for acute inpatient care; *and*
- Complies with all CAH Conditions of Participation, including the requirement to make available 24-hour emergency care services 7 days per week.[12]

Medicare Critical Access Hospital Conditions of Participation:

Medical critical access hospital (CAH) CoPs have a similar structure to that of acute care hospitals in that the governing body is responsible for appointing practitioners to the medical staff, must approve of the medical staff bylaws that establish the criteria for medical staff appointment, and must review the periodic evaluations of medical staff. However, since CAHs are very small and rural, a responsible individual can serve in the role of the hospital governing body. In addition, CAHs may have a single physician on staff, but does not need to be on site at all times. A mid-level practitioner may also be the medical staff of a CAH.

The medical staff membership of a CAH has similar responsibilities to screen candidates for appointment to the medical staff. An interesting difference in the CAH interpretive guidelines when compared to the acute care hospital guidelines is that there is no mention of the medical

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[12] Centers for Medicare and Medicaid Services, *Certification and Compliance: Critical Access Hospitals,* http://www.cms.hhs.gov/CertificationandComplianc/04_CAHs.asp

staff criteria to be applied equally. It is not known if this is an intentional oversight or is an indication of CMS willing to grant more flexibility for CAHs. Consultation with CMS would be required to determine the significance of this difference.

Critical Access Hospital Accreditation and Deemed Status:

ACCREDITATION TYPE/STATUS	NUMBER OF CALIFORNIA CRITICAL ACCESS HOSPITALS
The Joint Commission	12
American Osteopathic Association	1
Det Norske Veritas Healthcare	0
Non-accredited	15
Total	**28**

Information from the California Department of Public Health, Licensing and Certification, Office of Statewide Health Planning and Development, and accreditation organization websites. (3/10)

Fifty-three percent (53%) of all critical access hospitals in California are not accredited.

The Joint Commission

TJC was granted deemed status approval for its critical access hospital accreditation program effective July 2009, through November 21, 2011.[13] TJC has stated that, "… all Medicare CoPs for CAHs are encompassed by Joint Commission standards…" [14]

American Osteopathic Association/Health Facilities Accreditation Program

The AOA/HFAP has been deemed to meet or exceed Medicare CoPs. The AOA/HFAP also incorporates the Medicare CoPs in its standards.

Consequences of Non-compliance for Accredited and Non-accredited Hospitals: The consequences and enforcement of CAH non-compliance is the same as for acute care hospitals. Hospitals are provided an opportunity to correct the non-compliance. The timeframe within which the CAH is required to complete correction depends on the severity of the violation and how it affects the health and safety of patients. CAHs with deemed status may have their deemed status revoked by CMS until the hospital is confirmed to be back in compliance with CoPs.

California State Licensing Requirements for Critical Access Hospitals:

CAH designation is a federal designation. CAHs are licensed as general acute care hospitals (GACHs) in California, and must comply with the same state requirements for medical staff credentialing for GACHs. There are also special state regulatory requirements for "small and

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[13] The Joint Commission press release, *CMS Recognizes The Joint Commission's Critical Access Hospital Accreditation*, July 8, 2009.

[14] The Joint Commission website: *Facts about Critical Access Hospital Accreditation*, http://www.jointcommission.org/AccreditationPrograms/CriticalAccessHospitals/cah_facts.htm

rural hospitals" that provides some flexibility from GACH requirements[15]. However, the requirements for medical staff are the same for GACHs as for "small and rural" hospitals.

[15] Title 22, Sections 70901 through 70923.

C. Clinics

The potential for conflict between credentialing requirements for Medicare participation and AO does not exist at this point in time for any category of clinic. No AO has applied, nor has CMS approved any accreditation program for "deemed status" designation for rural health clinics (RHCs), federally-qualified health centers (FQHCs), FQHC look-alikes, Indian health clinics, or other categories of primary care clinics.

Rural Health Clinics (RHCs):

Rural Health Clinics (RHCs) can be owned and operated by a physician, non-profit or for-profit organization, hospital, skilled nursing facility, or home health agency and the clinic must be located in a an area that is designated as a shortage area. Hospital-based RHCs must meet hospital medical staff credentialing requirements. Otherwise, the RHC must confirm that physician's who own, are employed by or under contract to provide services in the clinic are licensed in the state where the center is located. The RHC must also ensure that there are arrangements or agreements with providers for inpatient and other services.[16] Credentialing or privileging by proxy would not be prohibited under Medicare CoPs in an RHC unless the RHC is hospital provider-based.

Oversight of compliance with federal Medicare CoPs rests with the SSA. CMS would consider as high priority (Tier 1 workload), a complaint that presents the potential for immediate jeopardy to patients. In addition, CMS has set a SSA goal of conducting at least 5% of RHCs of providers more at risk of quality problems (Tier 2 workload) Otherwise, CMS has assigned to the SSA a survey interval of 7.0 years (Tier 3 workload), or 6.0 years (Tier 4 workload), if higher priority workload for other provider categories has first been completed.

Federally-Qualified Health Centers (FQHCs) and FQHC look-alikes:

FQHCs must meet the same conditions of participation as RHCs. FQHC primary care providers must be licensed to practice in the State where the center is located. The FQHC's physicians, "… should obtain admitting privileges at their referral hospital(s) so health center patients can be followed as inpatients by health center clinicians in order to ensure continuity of care. When this is not possible, the applicant must have firmly established arrangements for patient hospitalization, discharge planning and patient tracking".[17] These are the only requirements related to credentialing or privileging, therefore privileging by proxy arrangements would not be prohibited by CMS for FQHCs.

However, unlike RHCs, oversight for FQHC compliance does not rest with the SSA. An FQHC that wishes to become a Medicare-certified supplier is subject to a filing procedure instead of certification through the SSA. The FQHC must attest that it is in compliance with Medicare

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[16] 42 CFR 491.9(d).

[17] United States Health Resources and Service Administration (HRSA), *Policy Information Notice 2003-21:Federally Qualified Look-Alike Guidelines and Application*, http://bphc.hrsa.gov/policy/pin0321.htm

regulations. The SSA does not conduct a survey to confirm compliance with Medicare requirements.

Any complaints about the FQHC are the jurisdiction of the CMS Regional Office. The RO reviews the complaint and refers the complaint to the United States Health Resources and Services administration (HRSA) or to the Indian Health Service (HIS), as applicable. If the complaint alleges non-compliance with the federal Medicare Conditions of Participation, the RO will request that the SSA conduct the complaint investigation. The RO will conduct the complaint investigation if the FQHC is located on reservation property.

The CMS RO may terminate the Medicare agreement with an FQHC if it finds that the FQHC no longer meets the Medicare eligibility standards and/or is not in substantial compliance with other Medicare requirements for FQHCs. [18]

FQHC's seeking enrollment as a Medi-Cal provider do go through the SSA application process.

Indian Health Service Clinics:

Medicare certification for any facility owned or operated by the IHS is the jurisdiction of the CMS Regional Office because it involves intergovernmental jurisdiction. The state is responsible for determining whether the facility meets state Medicaid certification requirements. The state may accept Medicare certification as evidence of meeting Medicaid requirements, or the state may conduct a survey. Indian health tribal facilities may or may not be under Federal jurisdiction, therefore the CMS RO determines whether the RO or the state has jurisdiction.[19]

V. Medi-Cal requirements

California requires Medicare certification as a condition for provider enrollment in the Medi-Cal program.

> Title 22, § 51200(d) states that, "All applicants applying for enrollment, or providers applying for continued enrollment, in the Medi-Cal program shall be certified for participation in the Medicare program of the Federal Social Security Act (Title XVIII), if they provide services that are included in the Medicare scope of benefits and if they provide those services to persons who are eligible beneficiaries of the Medicare program".

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[18] Centers for Medicare and Medicaid Services, *CMS Manual System: Publication 100-07 State Operations Provider Certification*

[19] Centers for Medicare and Medicaid Services, *State Operations Manual: Chapter 1Program Background and Responsibilities, Section 1018,* http://www.cms.hhs.gov/manuals/downloads/som107c01.pdf

In addition, the California State Plan[20] establishes the relationship between the state Medicaid agency (Department of Health Care Services) and the SSA (California Department of Public Health or CDPH), for purposes of establishing standards for public or private institutions that provide services to Medicaid beneficiaries. CDPH determines if institutions and agencies meet the requirements for participation in the Medicaid program. This arrangement complies with 42 CFR 610.610 which requires this relationship be established. CDPH uses Medicare CoPs for provider categories that are included in the Medicare scope of benefits. For primary care clinics that provide services that are not included in the Medicare scope of benefits, the SSA uses state licensing requirements as the standard for enrollment in the Medi-Cal program.

[20] California State Plan, Section 4.11, http://www.dhcs.ca.gov/formsandpubs/laws/Pages/CaliforniStatePlan.aspx

VI. Impact of Credentialing Standards on Private Pay Patients:

Medicare Conditions of participation are requirements for each hospital that wishes to bill Medicare and/or Medi-Cal. Medicare requires a single medical staff with the criteria for medical staff credentialing and privileging to be applied equally to all practitioners, thereby not permitting a different medical staff credentialing process for private pay patients than is required for Medicare or Medi-Cal beneficiaries. Indeed, even if a different process were permitted, hospitals may find a dual-credentialing and privileging process to be extraordinarily cumbersome, and expose the hospital to unnecessary liability.

VII. Summary and Conclusions

At this time, CMS will not permit credentialing or privileging by proxy for telehealth practitioners. The federal Medicare hospital CoPs clearly require each hospital's governing body to have the authority and responsibility to appoint each practitioner to the hospital's medical staff or to grant hospital privileges. The appointment or granting of privileges is to be approved only after the hospital medical staffs have satisfied themselves that the candidate meets or exceeds the criteria established by the medical staff and approved by the governing body. CMS requires that this criterion be applied equally to all hospital practitioners.

It is important that all stakeholders involved in promoting the use of telehealth services engage CMS to determine the extent to which hospital credentialing and privileging processes can continue to protect the health and safety of hospital patients and not present such a significant barrier to using telehealth services. CMS would most likely insist that hospitals have the same credentialing/privileging requirements whether they are accredited, accredited with deemed status or non-accredited. CMS would also most likely insist that all AOs have largely the same types of requirements.

Achieving a sensible, nation-wide credentialing/privileging standard for telehealth practitioners cannot be done by the AOs alone. Necessary change requires a fundamental regulatory solution that is embraced by CMS, recognizes the importance of telehealth in today's health care delivery system, and develops uniform standards that do not overly-burden hospitals providers.

Appendix A: 42 CFR 482

(Medicare Hospital Conditions of Participation)

Governing Body
***Regulations: 42 CFR 482.12*(a)(5) Standard: "Ensure that the medical Staff is accountable to the governing body for the quality of care provided to patients."**
Interpretive Guidelines: "…All hospital patients must be under the care of a practitioner … who has been granted medical staff privileges, or under the care of a practitioner who is directly 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 who has been granted privileges in accordance with the criteria established by the governing body, and who is working within the scope of those granted privileges."
Survey Procedure: "Verify that any individual providing patient care services is a member of the medical staff or is accountable to a member of the medical staff qualified to evaluate the quality of services provided, and in turn, is responsible to the governing body for the quality of services provided"[21]

Governing Body
***Regulations 42 CFR 482.12(a)(6) Standard:* "Ensure the criteria for selection are individual character, competence, training, experience, and judgment."**
Interpretive Guidelines: "The governing body must ensure that the hospital's bylaws governing medical staff membership or the granting of privileges apply equally to all practitioners [emphasis added] in each professional category of practitioners."
Survey Procedures: No guidance on the specific interpretation related to "privileges applying equally".

[21] State Operations Manual, *Appendix A: Survey Protocol, Regulations and Interpretive Guidelines for Hospitals*.

Medical Staff
Regulations 42 CFR 482.22 Condition: **"The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to its patients by the hospital."**
Interpretive Guidelines: "The hospital may have only one medical staff for the entire hospital (including all campuses, provider-based locations, satellites, remote locations, etc.). The medical staff must be organized and integrated as one body that operates under one set of bylaws approved by the governing body. These medical staff bylaws must apply equally to all practitioners [emphasis added] within each category of practitioners at all locations of the hospital and to the care provided at all locations of the hospital. The single medical staff is responsible for the quality of medical care provided to patients by the hospital."
Survey procedures: There are no survey procedures for this condition-level requirement.

Medical Staff
Regulations 42 CFR 482.22(a)(2) Standard: the medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.
Interpretive Guidelines: There must be a mechanism established to examine credentials of individual prospective members (new appointments or reappointments) by the medical staff. … The medical staff makes recommendations to the governing body for each candidate for medical staff membership/privileges that are specific to type of appointment and extent of the individual practitioner's specific clinical privilege, and then the governing body takes final appointment action. A separate credentials file must be maintained for each individual medical staff member of applicant. The hospitals must ensure that the practitioner and appropriate hospital patient care areas/departments are informed of the privileges granted to the practitioner.
Survey Procedures: Determine whether the medical staff bylaws identify the process and criteria to be used for the evaluation of candidates for medical staff membership/privilege. Determine whether the criteria used for evaluation comply with the requirements of this section, State law, and hospital bylaws, rules and regulations. Determine whether the medical staff has a system to ensure that practitioners seek approval to expand their privileges for tasks/activities/procedures that go beyond the specified list of privileges for their category of practitioner.

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Regulations 42 CFR 482.22(a)(2) Standard: the medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.
Interpretive Guidelines: There must be a mechanism established to examine credentials of individual prospective members (new appointments or reappointments) by the medical staff. … The medical staff makes recommendations to the governing body for each candidate for medical staff membership/privileges that are specific to type of appointment and extent of the individual practitioner's specific clinical privilege, and then the governing body takes final appointment action. A separate credentials file must be maintained for each individual medical staff member of applicant. The hospitals must ensure that the practitioner and appropriate hospital patient care areas/departments are informed of the privileges granted to the practitioner.
Survey Procedures: Determine whether the medical staff bylaws identify the process and criteria to be used for the evaluation of candidates for medical staff membership/privilege. Determine whether the criteria used for evaluation comply with the requirements of this section, State law, and hospital bylaws, rules and regulations. Determine whether the medical staff has a system to ensure that practitioners seek approval to expand their privileges for tasks/activities/procedures that go beyond the specified list of privileges for their category of practitioner.

Medical Staff
Regulations 42 CFR 482.22(c)(4) Standard: "Describe the qualification to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body."
Interpretive Guidelines: "…The bylaws must apply equally [emphasis added] to all practitioners in each professional category of practitioner. The medical staff then recommends individual candidates that meet those requirements to the governing body for appointment to the medical staff."
Survey Procedures: "Verify that there are written criteria for appointments to the medical staff and granting of medical staff privileges. Verify that granting of medical staff membership or privileges, is based upon an individual practitioner's meeting the medical staff's membership/privileging criteria. Verify that at minimum, criteria for appointment to the medical staff/granting of medical staff privileges are individual character, competence, training, experience, and judgment. …"

Medical Staff
Regulations 42 CFR 482.22(c)(6 Standard): "Include criteria for determining the privileges to be granted to individual practitioners and a procedure for apply the criteria to individuals requesting privileges."
Interpretive Guidelines: "All patient care is provided by or in accordance with the orders of a practitioner show 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 practitioner's qualifications and the medical staff's recommendations for that individual practitioner to the governing body."
Survey Procedures: "Verify that the medical staff bylaws contain criteria for granting, withdrawing, and modifying clinical privileges to individual practitioners of the medical staff and that a procedure exists for applying those criteria. Verify that practitioners who provide care to patients are working with in the scope of the privileges granted by the governing body."

Appendix B: 42 CFR 485

(Medicare Critical Access Hospital Conditions of Participation)

Governing Body
Regulation 42 CFR 485.627(a) Standard: "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 Guidelines: "…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 … the governing body (or responsible individual) decide whether or not to appoint new medical staff members or continue current members of the medical staff. … 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. … 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: "… 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 or State laws and regulations. … Verify that any individual providing patient care services is a member of the medical staff or is accountable to a member of the medical 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. 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 minimum, criteria for selection to the medical staff are individual character, competence, training, experience and judgment.