

TELEMEDICINE

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On July 5, 2011, the new Centers for Medicare and Medicaid (CMS) Rules for Hospital and Critical Access Hospital Conditions of Participation (COP): Telemedicine Credentialing and Privileging went into effect. These rules superceded the prior Joint Commission (TJC) recommendations and revised the former COPs, ostensibly in an effort to relieve what was perceived to be undue hardship in obtaining credentialing and privileging for each distant site physician and practitioner providing services to an originating site. While the new rules do, in fact, ease the originating site's credentialing burden by allowing it to rely upon the credentialing and privileging decisions made by the distant-site hospital or telemedicine entity, these new rules are, nonetheless, fraught with peril for any originating Hospital's Risk Manager or Governing Board.

WHAT IS TELEMEDICINE?

CMS defines telemedicine as the provision of clinical services to patients from a distance via electronic communications. Telemedicine is the ability to provide interactive healthcare utilizing modern technology and telecommunications. Basically, Telemedicine allows patients to visit with physicians live over video for immediate care or capture video/still images and patient data are stored and sent to physicians for diagnosis and follow-up treatment at a later time. The distant site telemedicine physician or practitioner (the consultant) provides clinical services to a hospital or critical access hospital (CAH) either simultaneously - i.e., in real-time, similar to an in-person consultation - or non-simultaneously, as an after-the-fact interpretation of diagnostic tests in order to provide an assessment of the patient's condition, such as a radiologist who interprets a patient's studies and reports their findings back to the patient's attending physician.

It is important to note, however, that CMS specifically excludes informal consultation among practitioners or the provision of professional consultation services (the informal request for specialist consultation or opinion) from one attending to another from its new rules. CMS does not seek to stifle the informal exchanges that occur on a daily basis between physicians in the hallway, via email, or telephone as they promote safe, effective care for patients.

THE OLD RULES

Under the prior COPs, the governing body of the hospital was required to make all privileging decisions based upon the recommendations of its medical staff after the medical staff had thoroughly examined and verified the credentials of each and every practitioner applying for privileges, and after the staff had applied specific criteria to determine whether an individual practitioner should be privileged at the hospital, regardless of whether services would be provided in person and onsite or remotely through telecommunications.

This resulted in the formation of "affiliative staffs" of outside physicians who were technically members of a hospital's medical staff without any specific clinical privileges. The new rules now allow for "telemedicine staff," which would permit privileges in telemedicine to be granted without inclusion on the medical staff.

Under its previous statutory deeming authority, TJC permitted "privileging by proxy," which had allowed TJC-accredited hospital to privilege "distant-site" physicians and practitioners by allowing one TJC-accredited facility to accept the privileging decisions of another TJC-accredited facility utilizing a streamlined independent determination process, rather than making an individualized decision based on the practitioner's credentials and record. CMS felt this method often did not meet with CMS credentialing requirements, and now requires TJC to conform its accreditation program to the Medicare requirements (which it has done by standards generated on 7/18/11), including the provisions governing credentialing and privileging, and enforce them at all their accredited hospitals.

So, under the old rule the governing body of the Hospital or CAH was required to make all privileging decisions based upon the recommendations of its medical staff after a thorough independent examination of each and every applicants request for privileges whether providing services in person or remotely, without the right to rely on the credentialing already undertaken by the practitioner's outside or prior facility. This resulted in duplicative credentialing, burdensome efforts and conflicts with TJC's "privileging by proxy" provisions which allowed a TJC-accredited facility to accept the decisions of another.

THE NEW RULES

The new rules permit a governing body of a hospital or CAH to rely on credentialing and privileging decisions made by distant-site hospitals or telemedicine entities when privileging practitioners for telemedicine services, as long as certain conditions are met. Distant-site Hospitals are Medicare-participating hospitals providing the consulting practitioner. Distant-Site Telemedicine Entities can include non-Medicare participating hospitals or entities established specifically for the provision of telemedicine services to hospitals and CAHs.

To rely on a distant-site hospital's credentialing and privileging decisions, the hospital or CAH **must have a written agreement** that establishes the following:

- 1) The distant-site hospital is a Medicare- participating entity;
- 2) The distant-site practitioner is privileged at the distant-site hospital as evidenced by a current list of the practitioner's privileges provided by the distant-site hospital;
- 3) The distant-site practitioner holds a license issued or recognized by the State in which the hospital or CAH whose patients are receiving telemedicine services is located; and,
- 4) The hospital that credentials and privileges the distant-site practitioner shares the practitioner's performance review information (adverse events, complaints, internal reviews).

In contracting with a distant-site telemedicine entity, as opposed to a distant-site hospital, the originating hospital also has the obligation of establishing that the entity's credentialing process meets CMS standards; that the distant-site practitioner has the experience and expertise represented

by the entity; that the practitioner holds a license in the State in which the hospital or CAH is located and that the hospital or CAH obtains the practitioner's thorough performance review.

On the issue of informed consent, CMS relies upon existing medical staff procedures and applicable State and Federal Law to proscribe the manner in which informed consent will be obtained and required in telemedicine. In other words, so long as the distant-site practitioner is providing services, there is no difference between distant-site or in-house requirements. If they provide treatment that, under medical staff policy or State law, requires informed consent, then consent must be obtained, whether the treatment is furnished through telemedicine or not. If consent is not customarily required on-site, then it would not be required when the telemedicine practitioner performs the same services.

WHAT IT ALL MEANS

While attempting to streamline the process and relive the credentialing burden from the originating site's medical staff, the new CMS rules carry with them the potential for myriad policy, performance, privilege and liability issues for the originating site hospital and distant site entity.

Whereas the governing board of a hospital customarily relies upon the recommendations of its medical staff in hiring and credentialing physicians, in the telemedicine arena they will be relying upon the due diligence of an outside entity and their knowledge of that practitioner. This shift in credentialing responsibility brings with it a series of new responsibilities and concerns. Rather than review the candidate, the credentials committee will now review his or her application and the distant site facility's disclosure prior to approval. Whether reliance upon the distant site entity's due diligence will protect the originating site from liability for the distant site practitioner's alleged malpractice or misconduct or whether it will expose the originating site hospital to a negligent hiring, retention and/or supervision claim remains to be seen. Consideration must be given to building indemnification or hold harmless clauses into telemedicine agreements but the question remains as to whether they will be deemed legally valid. These are all questions that can only be answered in time, but which must be discussed by the originating site's Governing Board and its counsel prior to engaging in any telemedicine agreements under the new rules. The appropriate liability and privilege protections will have to be built into any agreement.

Likewise, there will, by law, have to be a level of disclosure and communication shared between originating and distant site facilities as it pertains to the distant site practitioner's performance reviews. How that information can be shared without violating hospital and State quality assurance or privilege laws will have to be discussed and included in the telemedicine bylaws and the site to site arrangements. Who owns the privilege under these circumstances and who has a duty to protect it will have to be managed on a case by case basis.

There is no question that any participating facility will need to address changes in its Medical Staff bylaws as they pertain to Telemedicine, particularly whether there will be a new standard for Telemedicine, or whether it will fit into existing categories on a case by case basis (Radiology, Dermatology, etc). Any staff policy that requires the "physical presence" of a physician may have to be altered to consider telecommunication and evaluation, and issues regarding reimbursement, HIPAA compliance, billing and insurance coverage issues (Directors and Officers, General Liability and malpractice) will have to be addressed.

Eventually, there may be a National licensing standard applicable to all 50 states as it pertains to telemedicine (New York has a bill under consideration), but at present there are widely disparate regulations from state to state. What regional standard of care eventually applies to telemedicine treatment will also have to be addressed, as by its very nature the typical "community standard" no longer applies when the community no longer has geographical boundaries.

For now, we would suggest that any written agreements for telemedicine services should outline the specific responsibilities of the telemedicine provider's governing body or other responsible decision-makers in terms of internal review and credentialing of practitioners and the provision of services, along with all of the aforementioned provisions of the new COPs. Whether the originating hospital will still be "responsible" for the care remains to be seen, but there should be direct inquiry by the "home" hospital as to whether the distant site is a Medicare provider; whether a list is maintained of credentialed providers for telemedicine services, and that the distant site regularly reviews the services provided by those providers for quality and safety.

The originating site should review these agreements with counsel to ensure they contain adequate warranties of representation when a distant site subcontracts; proof of liability insurance on both ends of the agreement; indemnification and risk-sharing provisions; and a right to review agreements that might be made between the distant site entity and any subcontractors it enters into arrangements with to ensure the same level of scrutiny is being applied by the subcontractors to the quality and service of their providers. The originating site hospital should set up provisions to monitor the distant site practitioners and perform internal reviews of the distant site practitioner's performance and privileges regularly. Updates and appraisals should be shared with the distant site and should include all known or reported adverse events and any and all complaints the hospital has received regarding the practitioner.

Myriad other issues for the originating site's medical staff and governing body are certain to arise – the sharing and protection of confidential information and who should have access to it; whether a telemedicine entity will be considered a recognized peer review body such that the applicable state or federal privileges will attach to shared information with such an entity; what types of hearing rights if any a practitioner will possess under medical staff bylaws or state law for telemedicine care; whether hospitals will want to set up entire telemedicine departments for the collection, monitoring and storage of telemedicine treatment and practitioner review data or for the establishment and administration of that care.

For those hospitals currently embarking upon this endeavor, however, it is enough to digest the new COPs and to ensure, at minimum, that any originating or distant site hospital is complying with them before entering into any covenants for the provision of telemedicine care. As with any new or developing area of medicine, all of the ancillary issues will develop over time, perhaps through trial and error and perhaps through litigation, but for now any hospital Board that intends to pursue telemedical care must give consideration to all of the existing and potential ancillary issues and not only address them, but plan for them by drafting adequate protections of their own interests and those of their patients.

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