Risk Managing the Telemedicine Final Rule

“Upon reflection, we came to the conclusion that our present requirement is a duplicative and burdensome process for physicians, practitioners, and the hospitals involved in this process, particularly small hospitals and CAHs, which often lack adequate resources to fully carry out the traditional credentialing and privileging process for all of the physicians and practitioners that may be available to provide telemedicine services.”

Almost a year after issuing a proposed rule, the Centers for Medicare and Medicaid Services (CMS) has issued the final regulation on telemedicine, credentialing and privileging. Set to take effect on July 5, 2011, the rule makes important changes to the Conditions of Participation for hospitals and critical access hospitals.

The changes create two tracks for telemedicine services. One involves hospital or critical access hospitals (CAH) relying upon the credentialing and privileging decisions of a distant-site hospital. The second track involves reliance on the credentialing and privileging decisions of a distant-site telemedicine entity. In both instances there is supposed to be a written agreement in place between the hospital or CAH and the distant-site hospital or telemedicine entity.

The new regulatory process is supposed to “enable patients to receive medically necessary interventions in a more timely manner” than under the existing regulatory framework. However, there are some major risk issues that emerge from the new system, including liability exposures and abrogation of evidentiary privilege. One of the greatest liability risk exposures may be enterprise liability for the very hospitals and CAH facilities in line to avail themselves of the new regulatory framework. Additionally, there are practical considerations, including how the smaller CAH facility can keep track of staffing changes among
An Overview of the New Regulatory Requirements.

For hospitals, CMS added two new provisions to the Condition of Participation for the Medical Staff. The first provision involves a hospital-to-hospital process. In this instance the medical staff of the local facility may rely upon the distant-site hospital’s credentialing and privileging determinations for individual distant-site physicians and other practitioners providing telemedicine services when making “recommendations on privileges”\(^6\) for them.

A similar approach is taken with respect to the use of a distant-site telemedicine entity. The governing body of the local facility may decide to have its medical staff rely on the credentialing and privileging determinations of the distant-site telemedicine entity when “making recommendations on privileges for the individual distant-site physicians and practitioners providing such services...”\(^7\)

Whether the arrangement is one between two hospitals or between a hospital and a distant-site telemedicine entity, there must be in place a written agreement. The contracts must contain four core elements, as seen in the following chart:

<table>
<thead>
<tr>
<th>Hospital and Distant-Site Hospital Contract</th>
<th>Hospital and Distant-Site Telemedicine Entity Contract</th>
</tr>
</thead>
<tbody>
<tr>
<td>The distant-site hospital providing the telemedicine services is a Medicare-participating hospital.</td>
<td>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).</td>
</tr>
<tr>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>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.</td>
<td>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.</td>
</tr>
</tbody>
</table>
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.

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 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.

In the first criterion for distant-site telemedicine entities, reference is made to a number of regulatory requirements: §482.12(a)(1) through (a)(7) and § 482.22(a)(1) through (a)(2). The first provision refers to the Medical Staff Standard in the Condition of Participation for the Governing Body. The second regulatory reference, §482.22(a)(1) through (a)(2) – is the Standard for Composition of the Medical Staff found in the Condition of Participation for the Medical Staff.

The regulatory change includes a revision to an existing paragraph found in the Condition of Participation for the Medical Staff. This change deals with the determination of privileges. As modified, the Condition of Participation will now read:

“(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).”

As part of the new regulatory framework, CMS added §482.12(a)(8) and (a)(9). The first new component addresses the requirement for a written agreement with the distant-site hospital and the ability of the hospital medical staff to rely upon information provided by the distant-site hospital to make recommendations for the grant of privileges. The second component specifically addresses a written
agreement between the hospital and the distant-site telemedicine entity as a contractor of services. The hospital medical staff, using information from the distant-site telemedicine provider may make recommendations to the governing body on the grant of privileges.\(^\text{15}\)

For CAH facilities, there were **three regulatory amendments** made to accommodate telemedicine credentialing and privileging. The changes include:

- A new standard for agreements on credentialing and privileging of telemedicine physicians and providers;\(^\text{16}\)
- A new paragraph under the Condition of Participation for the Provision of Services that deals with telemedicine services;\(^\text{17}\) and,
- A revision to the current Condition of Participation for periodic evaluation and quality assurance review.\(^\text{18}\)

**The Risk Exposures with the New Regulatory Requirements.**

Although the regulatory Preamble suggests that the revisions are intended to remove “unnecessary barriers to the use of telemedicine,”\(^\text{19}\) the new framework may increase liability risks. Coupled with concerns about state law requirements, evidentiary protection, credentialing and regulatory compliance, and insurance coverage, hospitals and CAH facilities might want to consider carefully whether the benefits of the new rules are worth the potential exposures.

Consider the following risk exposures:

**Liability Risks.** The hospital that is utilizing the distant-site for telemedicine services may think it can shift liability risk via contract to the latter hospital. Language in the new regulation with respect to credentialing criteria seems to galvanize this thinking:

“….the agreement is written and…specifies that it is the responsibility of the distant-site hospital to meet the requirements….”\(^\text{20}\)

But can the hospital exculpate itself from liability for negligent credentialing because it relied on the written agreement enabling “proxy” credentialing?

A guiding principle in law is the *Restatement of Contracts.* In the Second Edition of the *Restatement of Contracts* there is a provision that addresses the issue of a non-delegable duty of care:
“§318 Delegation of Performance of Duty

(1) An obligor can properly delegate the performance of his duty to another unless the delegation is contrary to public policy or the terms of his promise.

(2) Unless otherwise agreed, a promise requires performance by a particular person only to the extent that the obligee has a substantial interest in having that person perform or control the acts promised.

(3) Unless the obligee agrees otherwise, neither delegation of performance nor a contract to assume the duty made with the obligor by the person delegated discharges any duty or liability of the delegating obligor.”[Emphasis added]

More than a matter of legal theory, the Restatement of Contracts, Second Edition section has been cited by courts in cases dealing with a non-delegable duty of care. Indeed, as a Florida court suggested in discussing this section, it drew a distinction between tort liability and contractual duty on the part of a hospital:

“Under the law of tort, the hiring of an independent contractor, unless done negligently, precludes liability because the hiring party has no duty to an injured third party to procure non-negligent performance of the independent contractor. However, delegation of a contractual duty to an independent contractor does not eliminate the duty.”

So what does this mean in the context of a hospital executing a written agreement with a distant-site hospital or a distant-site telemedicine entity? If a hospital has a contractual obligation with a patient in the delivery of services, it cannot delegate away its obligations under that contract. The general admission form between a patient and a hospital may serve as such a contractual obligation. Further, if a hospital knew or ought to have known, that the distant-site hospital or distant-site telemedicine entity acted negligently in meeting the standards for credentialing and privileging, then the hospital would be liable under tort law to patients injured as a result of such negligent care. In other words, the hospital availing itself of the new federal regulatory scheme could face both contractual and tort liability risk exposures under state law.

Consent Risks. In the Preamble to the new rule changes, CMS rejected the idea that the modification should include terms requiring hospitals and CAH to

“inform the patient about the use of telemedicine services for diagnostic care,
so that the patient (or the patient’s representative as allowed under State law) may make an informed decision about whether to accept or decline care provided in this way.\(^{23}\)

It was noted that under the Federal Code of Regulations it is the medical staff that usually delineates those procedures and treatments that require an informed consent process under pertinent Federal and State law. However CMS made a rather interesting observation:

“As long as the telemedicine practitioner is performing his or her duties within the privileges granted by the hospital or CAH, there is no difference between distant-site practitioners and in-house or on-site practitioners in this regard.”\(^{24}\) [Emphasis added]

With due respect to CMS, there is a difference between on-site and distant-site telemedicine services. Personal health information is being transmitted electronically beyond the confines of a healthcare facility. The patient does not know how the information is sent (encrypted or unencrypted), the quality of transmission, and, in the case of imaging, the patient is not aware that the distant-site may not have the same type of device or software to visualize the content as does the local facility (for example, 64 versus 32 bit slice). That the distant-site hospital or telemedicine entity may not be able to detect nuances due to this disparity is a significant or material risk, one that demonstrates that there is a difference between on-site and distant-site telemedicine services.

To be sure, several states have laws that require informed consent and telemedicine services.\(^{25}\) To be sure, the statutes often create an exception for emergency situations and “… when the patient is not directly involved in the telemedicine interaction, for example when one health care practitioner consults with another health care practitioner,\(^{26}\) or “to the transmission of diagnostic images to a health care provider serving as a consultant or the reporting of diagnostic test results by that consultant.”\(^{27}\) But even with such state laws, there still may be a requirement for informed consent, not for the consultation or transmission of telemedicine information, but rather for the telemedicine provider to perform a professional service: to interpret a diagnostic image. It is one matter to be a consultant to another provider; it is quite different when the telemedicine provider is doing the actual medical service.

Telemedicine is a furtive ground for litigation on a variety of topics, including consent. Depending upon the nuances and interpretations of state law, consent
and telemedicine may be the subject of interpretation by trial and appellate courts. Rather than becoming a test case for such litigation, a prudent approach may be to consider a revision to current consent practices. As discussed later in risk management strategies for telemedicine credentialing and privileging, such an approach deals generally with effective expectation setting with telemedicine patients.

**Evidentiary Protection.** In the telemedicine final regulatory framework, CMS obliges the hospital to send to the distant-site hospital and the distant-site telemedicine entity what is termed “performance information” that can be used in “periodic appraisal” of the physician or practitioner. The data for this purpose must include adverse event and complaint information involving telemedicine services. A similar regulatory process is in place for CAH facilities.

By sending such quality data to a third party, is there not a risk that a hospital will abrogate any evidentiary protection available under applicable state law? If the hospital shares this information with a third party, what does it do to the distant-site telemedicine physician or provider who is now the subject of peer review at the local healthcare facility?

Some might suggest that such risks can be mitigated by making the distant-site hospital or distant-site telemedicine facility “ad hoc” members of the quality assurance and peer review committees. State law must be reviewed to make certain that it is possible to have such “ad hoc” members. But are they really fulfilling a role as “active” members, or are they just a repository of information that is then used, in turn, for their own performance review work?

These are good questions to contemplate as both hospitals and CAH facilities develop contracts conducive to meet their needs for proxy credentialing in telemedicine.

**Credentialing and Regulatory Compliance.** Both state and federal law speak to credentialing. Under the federal Conditions of Participation Standard for the Medical Staff, the governing body of the hospital must,

> “Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff,”

State law speaks to a threshold issue for credentialing, licensure, with some jurisdictions having statutory requirements for a telemedicine license. For
example, in Montana, to qualify for a telemedicine license, a physician must establish under oath that he or she:

“(1) has a full, active, unrestricted certificate or license to practice medicine or osteopathic medicine in another state or territory of the United States or the District of Columbia;
(2) is board-certified or meets the current requirements to take the examination to become board-certified in a medical specialty pursuant to the standards of, and approved by, the American board of medical specialties or the American osteopathic association bureau of osteopathic specialists;
(3) has no history of disciplinary action or limitation of any kind imposed by a state or federal agency in a jurisdiction where the physician is or has ever been licensed to practice medicine;
(4) is not the subject of a pending investigation by a state medical board or another state or federal agency;
(5) has no history of conviction of a crime related to the physician's practice of medicine;
(6) has submitted proof of current malpractice or professional negligence insurance coverage in the amount to be set by the rules of the board;
(7) has not paid, or had paid on the physician's behalf, on more than three claims of professional malpractice or negligence within the 5 years preceding the physician’s application for a telemedicine license;
(8) has identified an agent for service of process in Montana who is registered with the secretary of state and the board and who may be a physician licensed to practice medicine in this state;
(9) has paid an application fee in an amount set by the rules of the board; and
(10) has submitted as a part of the application form a sworn statement attesting that the physician has read, understands, and agrees to abide by Title 37, chapters 1 and 3, and the administrative rules governing the practice of medicine in Montana.”

Hospitals participating in Medicare and Medicaid have in place compliance plans. The goal is to put policies, procedures, and processes in place to prevent and address regulatory non-compliance.

In its 2005 update to the original 1998 guidance on a model hospital compliance program, the Office of the Inspector General (OIG) made clear that:
“In reviewing the quality of care provided, hospitals must not limit their review to the quality of their nursing and other ancillary services. Hospitals must monitor the quality of medical services provided at the hospital by appropriately overseeing the credentialing and peer review of their medical staffs.”[Emphasis added]

Going further, on the issue of enforcement of disciplinary standards, the OIG’s 2005 model guidance for hospital included seven areas for review in a compliance program, including at least annually a review for employees, contractors and members of the medical staff against:

“…government sanctions lists, including the OIG’s List of Excluded Individuals/Entities (LEIE) and the General Services Administration’s Excluded Parties Listing System.”

Why is this important in the context of telemedicine credentialing and privileging? The hospital must have a written agreement with the distant-site hospital or distant-site telemedicine entity. Hospitals, as compliance program-based entities, need the data necessary to properly monitor quality care, complete credentialing, and take appropriate disciplinary action for non-adherent behaviors. A listing of a telemedicine physician or practitioner on the LEIE list would be significant in this regard. So too, would be data with which to evaluate quality of care. In using the new proxy credentialing process, the hospital is relying upon the actions of the distant-site hospital and distant-site telemedicine entity to meet obligations set forth in the written agreement. Hopefully, the content will incorporate language that goes to these core issues for purposes of credentialing and also regulatory compliance.

It is noteworthy, however, that the new regulatory requirement only states that the distant-site hospital or distant-site telemedicine entity provides a “current list” of the privileged telemedicine physicians. It is silent on how frequently this list must be refreshed. Moreover, it is silent on an obligation to notify the hospital if the privileged telemedicine provider is the subject of licensure action or regulatory compliance sanctions, including debarment.

Understandably, the hospital can check the LEIE list. But if it is relying on the distant-site hospital of distant-site telemedicine entity for such information, it may be prudent to think twice about such reliance. The importance of this issue should not be minimized, particularly in light of significant requirements found in the Patient Protection and Affordable Care Act (PPACA) that reinforce the
importance of reporting and checking important regulatory action.

As part of this major health reform, Congress moved to eliminate duplication between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank.\(^3\) In essence, HIPDB is being blended into the National Practitioner Data Bank, opening up a greater depth of information that was previously not accessible by hospitals. Among the types of information now accessible will be adverse actions by state law and fraud enforcement, including civil judgments against a practitioner in a state court based on delivery of a health care service, criminal convictions involving delivery of a health care service, and exclusion from a state health care program.\(^3\)

Credentialing will be a key piece of telemedicine under Medicare. So too, the terms of the contract with the distant-site hospital or distant-site telemedicine entity. Credentialing is not restricted to issues of quality of care; it will impact adherence to hospital compliance programs, the new Patient Protection Act requirements, and also existing federal laws and regulations that deal with fraud and abuse.

The credentialing data “net” must be broad, capturing timely, salient information. Contracts with distant-site hospitals and distant-site telemedicine providers must capture necessary information. Hospitals must then analyze the information and take appropriate action. The failure to do so – including the failure of distant-site hospitals or distant-site telemedicine entities to do so – will not exculpate the hospital from such a responsibility.

**Insurance Coverages.** Should hospitals and CAH facilities decide to avail themselves of the new credentialing and privileging regulatory framework for telemedicine services, careful consideration should be given to insurance coverages. For example:

- Will existing health professional liability (HPL) coverage address errors and omissions on the part of distant-site physicians and practitioners? Are there any jurisdictional limits? What if the physician “licensed” in Nevada works in New Zealand or Israel? Will (HPL) coverage extend to such services?

- What types of insurance coverage is in place for negligent credentialing, where claims are based on reliance on credentialing and privileging information submitted by a distant-site hospital or distant-site
telemedicine entity?

- Does the hospital have appropriate coverage for business disruption (the third party vendor stops offering the service) or cyber risk (confidentiality of data is breached in the transmission of patient level identifiable data, or the data integrity or availability is harmed)?

- What types of insurance coverages and limits will be required by contract of the distant-site hospital and distant-site telemedicine entities?

- Will the contract preclude shared coverage among the “listed” care providers and the distant-site hospital or distant-site telemedicine entity?

- Will the insurance coverage include indemnification coverage for cost of defense up to the point of disposition of a regulatory investigation based on the telemedicine services furnished by the distant-site hospital or distant-site telemedicine entity?

Insurance coverages warrant careful review. Such review should extend to the various layers of an insurance program – excess carriers – and also to specialty programs such as RRGs, insurance trusts and captive insurance plans.

**Risk Management Telemedicine Goes Beyond Credentialing and Privileging.**

Although the new Federal requirements focus on credentialing and privileging for telemedicine, the topic matter is much broader. As such it is conducive to an enterprise risk management (ERM) approach. Strategies for this purpose include the following:

1. **Identify State Law Requirements for Telemedicine.**
   Work with legal counsel to determine relevant telemedicine laws and regulations. Look at such issues as a requirement for state licensure or a telemedicine certificate for healthcare providers; credentialing, consent, and scope of practice laws. Utilize this information in developing the contract with a distant-site hospital or distant-site telemedicine entity.
2. **Review Consent Requirements.**
   Ask legal counsel to carefully review the current general admission consent requirements to see if the language contains not only an acknowledgement but an acceptance of the hospital or CAH using distant-site telemedicine services in the delivery of clinical services. Determine if state law requires a patient or surrogate’s authorization for telemedicine services. Make certain such authorizations are obtained when required by law for more than a consultation.

3. **Set Patient Expectations.**
   Think about providing in patient brochures and on the website of the hospital or CAH facility information about the use of telemedicine services. Make clear how care providers are selected who participate in the delivery of such services. Provide patients and surrogates with a process to discuss any questions that they may have about telemedicine services. Make certain that there is a process to document responses to such inquiries.

4. **Develop a Contract for Telemedicine Services.**
   Use a team approach to develop an appropriate telemedicine service contract. Involve IT, legal, clinical, credentialing and compliance content experts, asking them for what they see as risks and how best to resolve such matters. Work with legal counsel to write the terms of the agreement and get input from insurance agents, brokers, or consultants on necessary insurance coverage provisions for the agreement. Minimally, consider the following subjects:
   - Terms
   - Conditions
   - Definitions
   - Credentialing requirements
   - Re-credentialing requirements
   - Expiration date on list of credentialed telemedicine physician and providers
   - Updating of list of credentialed telemedicine physician and providers
   - Inclusion on quality or performance improvement committees (when allowed by applicable law)
   - Staffing requirements including delineated privileges

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Inclusion on peer review committees (when allowed by applicable law)
- Use of adverse event and complaint data
- Access to data for defense of claims
- Access to data for billing and coding
- Access to data to respond to regulatory investigations and audits
- Insurance coverages and limits
- Right to substitute or to use another telemedicine provider
- Equipment specifications for interpreting results of teleradiology, telepathology and teledermatology
- Timeframe for completion of and reports on telemedicine services
- Style and content of telemedicine service reports
- Notification requirements by the distant-site hospital or distant-site telemedicine entity for downtime, termination of a telemedicine physician or provider, data breach, etc.
- Overreads
- Quality data that must be accessible from the distant-site hospital and the distant-site telemedicine entity by the hospital or the CAH for credentialing and recredentialing telemedicine providers
- Right of first refusal on sale or assignment of the contract to another distant-site hospital or distant-site telemedicine provider.
- Effect of loss of accreditation or certification by the distant-site hospital or distant-site telemedicine entity
- Restriction on the use of moonlighting residents or researchers to serve as telemedicine physicians or providers
- Restriction on use of locum tenens or agency personnel serving as telemedicine physicians or providers
- List of “notifiable events”
- Right to correct deficiencies
- Termination of the contract


Ask IT experts to develop a workable plan to maintain data security in the encryption, transmission, storage and receipt of information from the distant-site telemedicine hospital and distant-site telemedicine.
entity. Ensure that the security plan includes provisions for the
detection of not just violations of data confidentiality but events that
impact its integrity and validity, and its availability at all times to
authorized users. Incorporate relevant requirements in the
telemedicine contract. Recognize that the protocol should also
address record retention and e-Discovery requirements and the need
for long-term archiving. This should include planning as to how data
will be protected, identified, segregated and kept available and
readable when the format of the data, or the software used to create it,
is no longer in regular use.

Develop clinical protocols for scope of practice for radiology techs,
radiology PAs, and radiology nurses who will be responsible for direct
patient services in the course of teleradiology services. Do the same
for other care providers involved in telemedicine services. Consider:

- Individual licensure requirements
- Competencies
- The need for supervision
- The use of contrast dyes
- The ability to “rescue” a patient who experiences an adverse
  reaction or event at the local hospital or CAH facility
- Chain of command

Have a process in place to respond to notifiable events delineated in
the contract including but not limited to:

- Downtime or system shut down at the distant-site telemedicine
  hospital or distant-site telemedicine entity.
- Critical test results warranting prompt or immediate action.
- Termination of a credentialed telemedicine physician or
  provider
- Loss of licensure by a credentialed telemedicine physician or
  provider
- Data security breaches and uncorrected vulnerabilities
  involving telemedicine patient identifiable data (including
  events impacting confidentiality, integrity, and availability of
  data or interpretation services)
- Misreads
- Missed reads
A need to re-do a test or procedure
- Federal or state regulatory audits, investigations or adverse actions involving the distant-site telemedicine hospital, the distant-site telemedicine entity or telemedicine physician provider

8. **Develop A Contingency Plan for Down Times.**
Be prepared for down times and exigencies such as denial of service attacks that block or dramatically slow the transmission of telemedicine data. Have a back-up plan in place for situations in which the distant-site telemedicine service is not available.

9. **Review Insurance Coverages for Telemedicine Services.**
Work with insurance agents, providers, and consultants to design the right insurance coverage program for telemedicine services.

10. **Review and Update Bylaws.**
Recognize that the bylaws of the hospital, the CAH and of the medical staff may need to be modified or updated to accommodate the credentialing process found in the federal rule changes. Take a collaborative approach, to make certain that there is a coordinated approach for the healthcare entity and the medical staff.

**Conclusion.**
Some may ask: given all the risks, why bother using the new regulatory framework developed by CMS for telemedicine credentialing and privileging? After all, it is voluntary to follow this alternate approach to credentialing and privileging. Others may see beyond the hurdles and derive solutions to overcome regulatory and legal concerns.

Telemedicine is part of contemporary healthcare. It is only apt to grow to become a larger part of the healthcare field. There is much work to be done. For example, hospitals and CAH entities will need to map out the scope of services, define the process for the “delineation of privileges” in telemedicine, a process that is different than credentialing, and dealing with practical issues such as who will be involved in the disclosure of an adverse or unanticipated outcome involving telemedicine services.
To be certain that it matures into a patient safe, quality component of healthcare delivery, an aggressive enterprise risk management approach is needed now to identify and manage risk exposures. Telemedicine credentialing and privileging is only a part of a much larger framework for the use of distant-site hospitals and distant-site entities. The process need not become the basis for litigation. Instead, strong input and guidance from an enterprise risk management approach could galvanize the process into a workable system for the benefit of Medicare recipients.

**If you would like assistance with developing an enterprise risk management program for telemedicine services, please contact us at (860) 242-1302.**


3 Id at 25563

4 Id.

5 Id. at 25550.

6 Id. at 25563.

7 Id.

8 Id.

9 Id.

10 Id. 42§482.12(a)(1) through (a)(7) provides:

(a) **Standard: Medical staff.** The governing body must:

1. Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;
2. Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;
3. Assure that the medical staff has bylaws;
4. Approve medical staff bylaws and other medical staff rules and regulations;
5. Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;
6. Ensure the criteria for selection are individual character, competence, training, experience, and judgment; and
7. 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.

11 Medicare and Medicaid Programs: Changes Affecting Hospital and Critical Access Hospital Conditions of Participation: Telemedicine Credentialing and Privileging,” Final Rule, Federal Register 76 (87): 25550-25565, 25563, May 5, 2011, referring to 42 CFR §482.22(a)(1) through (a)(2) as follows:

(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.

1. The medical staff must periodically conduct appraisals of its members.
2. 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.

12 Id. at 22563 referring to 42 CFR§482.22(c)(6).

13 Id. at 22563.

14 The new (a)(8) provides as follows:

“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."


The new (a)(9) provides as follows:

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.

5. Section 485.616 is amended by adding a new paragraph (c) to read as follows:

§ 485.616 Condition of participation: Agreements.

(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.
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 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.

(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.

(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 paragraphs (c)(1)(i) through (c)(1)(vii) of this section.

(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 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 CAH’s patients and all complaints the CAH has received about the distant-site physician or practitioner.”
This publication is not intended to be and should not be used as a substitute for specific legal or risk management advice. Readers should obtain specific legal or risk management advice in addressing issues discussed in this newsletter.
33 Id. at 4876.
34 See references 8 and 9, supra.
35 Patient Protection and Affordable Care Act”. 124 STAT. 776, PUBLIC LAW 111–148—MAR. 23, 2010,
36 Id. at Section 6403.
37 Id.