

have concluded this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction. The rule involves establishing a safety zone. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, and Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

- 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05-1(g), 6.04-1, 6.04-6, and 160.5; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

- 2. Add § 165.1184 to read as follows:

§ 165-1184 Safety Zone; Coast Guard Use of Force Training Exercises, San Pablo Bay, CA

(a) *Location.* This safety zone will apply to the navigable waters in the San Pablo Bay, and will encompass an area beginning at position 38°01'44" N, 122°27'06" W; 38°04'36" N, 122°22'06" W; 38°00'35" N, 122°26'07" W; 38°03'00" N, 122°20'20" W (NAD 83) and back to the starting point.

(b) *Enforcement.* The Coast Guard will notify the public via a Broadcast Notice to Mariners prior to the activation of this safety zone. The safety zone will be activated on average two times per month, but could be activated up to six times per month. It will be in effect for approximately three hours from 9 a.m. to 11:59 p.m. If the exercises conclude prior to the scheduled termination time, the Coast Guard will cease enforcement of this safety zone and will announce that fact via Broadcast Notice to Mariners. Persons and vessels may also contact the Coast Guard to determine the status of the safety zone on VHF-16 or the 24-hour Command Center via telephone at (415) 399-3547.

(c) *Definitions.* As used in this section, designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a

Federal, State, and local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

(d) *Regulations.* (1) Under the general regulations in § 165.23, entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the COTP or the COTP's designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or the COTP's designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or the COTP's representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or the COTP's designated representative. Persons and vessels may request permission to enter the safety zone on VHF-16 or the 24-hour Command Center via telephone at (415) 399-3547.

Dated: March 31, 2011.

Cynthia L. Stowe,

Captain, U.S. Coast Guard, Captain of the Port San Francisco.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482 and 485

[CMS-3227-F]

RIN 0938-AQ05

Medicare and Medicaid Programs: Changes Affecting Hospital and Critical Access Hospital Conditions of Participation: Telemedicine Credentialing and Privileging

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will revise the conditions of participation (CoPs) for both hospitals and critical access hospitals (CAHs). The final rule will implement a new credentialing and privileging process for physicians and practitioners providing telemedicine services. Currently, a hospital or CAH receiving telemedicine services must go through a burdensome credentialing and privileging process for each physician and practitioner who will be providing telemedicine services to its patients.

This final rule will remove this undue hardship and financial burden.

DATES: *Effective Date:* These regulations are effective on July 5, 2011.

FOR FURTHER INFORMATION CONTACT: CDR Scott Cooper, USPHS, (410) 786-9465. Jeannie Miller, (410) 786-3164.

SUPPLEMENTARY INFORMATION:

I. Background

This final rule reflects the Centers for Medicare and Medicaid Services' commitment to the general principles of the President's Executive Order released January 18, 2011, entitled "Improving Regulation and Regulatory Review." The rule revises the conditions of participation (CoPs) for both hospitals and critical access hospitals (CAHs) to: (1) Make current Federal requirements more flexible for rural and/or small hospitals and for CAHs; and (2) encourage innovative approaches to patient-service delivery.

CMS regulations currently require a hospital to have a credentialing and privileging process for all physicians and practitioners providing services to its patients. The regulations require a hospital's governing body to appoint all practitioners to its hospital medical staff and to grant privileges using the recommendations of its medical staff. In turn, the hospital medical staff must use a credentialing and privileging process, provided for in CMS regulations, to make its recommendations. CMS requirements do not take into account those practitioners providing only telemedicine services to patients. Consequently, hospitals apply the credentialing and privileging requirements as if all practitioners were onsite. This traditional and limited approach fails to embrace new methods and technologies for service delivery that may improve patient access to high quality care.

This final rule will permit hospitals and CAHs to implement a new credentialing and privileging process for physicians and practitioners providing telemedicine services. The removal of unnecessary barriers to the use of telemedicine may enable patients to receive medically necessary interventions in a more timely manner. It may enhance patient follow-up in the management of chronic disease conditions. These revisions will provide more flexibility to small hospitals and CAHs in rural areas and regions with a limited supply of primary care and specialized providers. In certain instances, telemedicine may be a cost-effective alternative to traditional service delivery approaches and, most

importantly, may improve patient outcomes and satisfaction.

As noted above, the current Medicare Hospital conditions of participation (CoPs) for credentialing and privileging of medical staff at 42 CFR § 482.12(a)(2) and § 482.22(a)(2) require the governing body of the hospital to make all privileging decisions based upon the recommendations of its medical staff after the medical staff has thoroughly examined and verified the credentials of practitioners applying for privileges, and after the staff has applied specific criteria to determine whether an individual practitioner should be privileged at the hospital. The current critical access hospital (CAH) CoPs at 42 CFR 485.616(b) similarly require every CAH that is a member of a rural health network to have an agreement for review of physicians and practitioners seeking privileges at the CAH. The agreement must be with a hospital that is a member of the network, a Medicare Quality Improvement Organization (QIO), or another qualified entity identified in the State's rural health plan. In addition, the services provided by each doctor of medicine or osteopathy at the CAH must be evaluated by one of these same three types of outside parties. These requirements apply to all physicians and practitioners seeking privileges at the hospital or CAH, respectively, regardless of whether services will be provided in person and onsite at the hospital or CAH, or remotely through a telecommunications system.

While hospitals may use third-party credentialing verification organizations to compile and verify the credentials of practitioners applying for privileges, the hospital's governing body is still legally responsible for all privileging decisions. Similarly, each CAH is required to have its privileging decisions made by either its governing body or the person responsible for the CAH.

In the past, hospitals that were accredited by The Joint Commission (TJC) were deemed to have met the Medicare CoPs, including the credentialing and privileging requirements, under TJC's statutory deeming authority. Section 125 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275, July 15, 2008) (MIPPA), terminated the statutory recognition of TJC's hospital accreditation program, effective July 15, 2010. The law now requires TJC to secure CMS approval of its standards in order to confer Medicare deemed status on hospitals.

Under its previous statutory deeming authority, TJC has permitted "privileging by proxy," which had

allowed TJC-accredited hospitals to privilege "distant-site" (as that term is defined at section 1834(m)(4)(A) of the Social Security Act (the Act)) physicians and practitioners. TJC privileging by proxy standards allowed for 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. Even though they were TJC-accredited, hospitals that have used this method to privilege distant-site medical staff technically did not meet the CMS requirements that applied to other hospitals. When we learned of specific instances of such noncompliance through on-site validation surveys by State survey agencies, the hospital was required to change its policies to come into compliance. However, the majority of Joint Commission-accredited hospitals were not routinely subjected to validation surveys of their privileging practices, and it appears that many of them were employing the practices permitted by The Joint Commission.

With the loss of statutory status for its hospital accreditation program, The Joint Commission is now required to conform its accreditation program to the Medicare requirements, including the provisions governing credentialing and privileging, and enforce it accordingly in all of its accredited hospitals.

TJC-accredited hospitals, therefore, have been concerned that they may be unable to meet the long-standing CMS privileging requirements while sustaining their current telemedicine agreements. Small hospital medical staffs, in particular, are concerned about the burden of privileging hundreds of specialty physicians and practitioners that large academic medical centers make available to them. Because of the complexity of the issues, and to minimize disruption to accredited hospitals and CAHs, we decided to allow additional time for The Joint Commission to ensure conformity to the Medicare Conditions of Participation (CoPs). Accordingly, we notified TJC that we would expect implementation of its new accreditation standards no later than the effective date of this 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. In addition to the costs involved, small hospitals and CAHs often do not have in-house medical staff with the clinical expertise to adequately evaluate and privilege the wide range of specialty physicians that larger hospitals can provide through telemedicine services. The public comments we received on the proposed rule, which we discuss in this final rule, overwhelmingly reinforced this perception.

II. Provisions of Proposed Rule and Response to Comments

We published a proposed rule in the **Federal Register** on May 26, 2010 (75 FR 29479). In that rule, we proposed to revise both the hospital and CAH credentialing and privileging requirements to eliminate regulatory impediments and to allow for the advancement of telemedicine nationwide.

While telemedicine is included under the broader scope of telehealth, we consider telemedicine, as the term is used in the proposed rule and as we use it here in this final rule, to be the provision of clinical services to patients by practitioners from a distance via electronic communications. The distant-site telemedicine physician or practitioner provides clinical services to the hospital or CAH patient either simultaneously, as is often the case with teleICU services, for example, or non-simultaneously, as may be the case with many teleradiology services. "Simultaneously" would mean that the clinical services (for example, assessment of the patient with a clinical plan for treatment, including any medical orders needed) are provided to the patient in "real time" by the telemedicine practitioner, similar to the actions of an on-site practitioner when called in by a patient's attending physician to see the patient. Generally, payment for telehealth services under section 1834(m) of the Act, distinguished from "telemedicine services" as discussed here, requires that services be provided to a patient in real time while the patient is physically present at the originating site. "Non-simultaneously" means that while the telemedicine practitioner still provides clinical services to the patient upon a formal request from the patient's attending physician, such services may involve after-the-fact interpretation of diagnostic tests in order to provide an assessment of the patient's condition and do not necessarily require the telemedicine practitioner to directly assess the patient in "real time." This would be similar to the services

provided by an on-site radiologist who interprets a patient's x-ray or CT scan and then communicates his or her assessment to the patient's attending physician who then bases his or her diagnosis and treatment plan on these findings. In fact, the actual location (distant-site versus on-site) of the radiologist performing the readings is often the major distinguishing factor between in-house radiologists and teleradiologists. These services are not payable as "telehealth services" under section 1834(m) of the Act because in addition to not meeting the "real time" requirements, these services do not meet the telehealth patient location requirements also contained under this section of the Act and upon which the CMS telehealth payment requirements are based.

We also indicated that the proposed revisions would preserve and strengthen the core values of the credentialing and privileging process for all hospitals, provide accountability to all patients, and assure that medical staff are privileged to provide services in the hospital based on evaluation of the practitioner's medical competency.

We provided a 60-day public comment period in which we received a total of 113 timely comments from hospitals, CAHs, physicians, professional organizations, providers of teleradiology interpretation services, other specialty practitioners providing telemedicine services, and hospital systems. Overall, the majority of commenters were supportive of the proposed changes, but many also raised several separate issues. The most common comment expressed was that the proposed regulation did not go far enough in restructuring privileging and credentialing requirements for telemedicine providers. Summaries of the major issues and our responses are set forth below.

Hospital CoPs (§ 482.12 and § 482.22)

The proposed revisions to the hospital CoPs for the credentialing and privileging of telemedicine physicians and practitioners are contained within two separate CoPs: § 482.12, "Governing body," and § 482.22, "Medical staff."

For the Governing body CoP, we proposed to add a new paragraph, § 482.12(a)(8), which would require the hospital's governing body to ensure that, when telemedicine services are furnished to the hospital's patients through an agreement with a Medicare-participating hospital (the "distant-site" hospital as defined at section 1834(m)(4)(A) of the Act), the agreement must specify that it is the responsibility of the governing body of the distant-site

hospital providing the telemedicine services to meet the existing requirements in § 482.12(a)(1) through (a)(7) with regard to its physicians and practitioners who are providing telemedicine services. These existing provisions cover the distant-site hospital's governing body responsibilities for its medical staff that all Medicare-participating hospitals must meet.

We proposed at § 482.12(a)(8) to allow the governing body of the hospital whose patients are receiving the telemedicine services to grant privileges based on its medical staff recommendations, which would rely on information provided by the distant-site hospital, as a more efficient means of privileging the individual distant-site physicians and practitioners providing the services.

This provision would be accompanied by the proposed requirement in the "Medical staff" CoP at § 482.22(a)(3), which would provide the basis on which the hospital's governing body, through its agreement as noted above, could choose to have its medical staff rely upon information furnished by the distant-site hospital when making recommendations on privileges for the individual physicians and practitioners providing such services. We specified that this option would allow the hospital's medical staff to rely upon the credentialing and privileging decisions of the distant-site hospital in lieu of the current requirements at § 482.22(a)(1) and (a)(2), which require the hospital's medical staff to conduct individual appraisals of its members and examine the credentials of each candidate in order to make a privileging recommendation to the governing body. In the proposed rule, we stated that this option would not prohibit a hospital's medical staff from continuing to perform its own periodic appraisals of telemedicine members of its staff, nor would it bar them from continuing to use the traditional credentialing and privileging process required under the current regulations. Our intent of this proposed requirement was to relieve burden for smaller hospitals by providing for a less duplicative and more efficient privileging scheme with regard to physicians and practitioners providing telemedicine services.

However, in an effort to ensure accountability to the process, we proposed within this same provision (§ 482.22(a)(3)) that the hospital, in order to choose this less burdensome option for privileging, would have to ensure that—(1) The distant-site hospital providing the telemedicine services was another Medicare-

participating hospital; (2) the individual distant-site physician or practitioner was privileged at the distant-site hospital providing telemedicine services, and that this distant-site hospital provides a current list of the physician's or practitioner's privileges; (3) the individual distant-site physician or practitioner held a license issued or recognized by the State in which the hospital whose patients are receiving the telemedicine services is located; and (4) with respect to a distant-site physician or practitioner granted privileges by the hospital, the originating-site hospital had evidence of an internal review of the distant-site physician's or practitioner's performance under these telemedicine privileges and sent the distant-site hospital this information for use in its periodic appraisal of the individual distant-site physician or practitioner. We also proposed that the information sent for use in the periodic appraisal would, at a minimum, have to include all adverse events that did result or could have resulted from telemedicine services provided by the distant-site physician or practitioner to the originating hospital's patients, and all complaints the originating site hospital had received about the distant-site physician or practitioner.

Within the revisions to the hospital CoPs, we also proposed that additional language be added to the current requirement at § 482.22(c)(6), which requires that the hospital's medical staff bylaws include criteria for determining privileges and a procedure for applying the criteria to individuals requesting privileges. We proposed to add language to stipulate that in cases where distant-site physicians and practitioners were requesting privileges to furnish telemedicine services through an agreement between hospitals, the criteria for determining those privileges and the procedure for applying the criteria would be subject to the proposed requirements at § 482.12(a)(8) and § 482.22(a)(3).

Comment: We received several comments that are outside the scope of this rule. Specifically, several commenters requested that we consider establishing a central credentialing bank that would provide overall clearance for telemedicine services, possibly through regional compacts or reciprocity agreements. A number of commenters recommended that all TJC-accredited facilities (including hospitals) be able to share credentialing. A few commenters suggested that we establish a national licensing process for physicians and other practitioners in order to ease the

burden associated with credentialing and privileging.

Response: We thank all commenters for their comments, but are not responding to these comments here because they are outside the scope of this rulemaking.

Comment: The majority of commenters supported the changes proposed. However, most of these commenters felt that the revisions to the CoPs did not go far enough in addressing the burdens borne by those small hospitals and CAHs that, through agreements and/or contracts, use the telemedicine services of practitioners who are not part of the medical staff of a Medicare-participating hospital. The commenters pointed out that, under the proposed requirements, small hospitals and CAHs would still be required to perform the duplicative and burdensome process of credentialing and privileging practitioners that provide telemedicine services through a distant-site telemedicine entity that is not a hospital.

Several commenters provided examples of simultaneous and non-simultaneous telemedicine services, such as teleradiology, teleICU, teleneurology, and telepathology, where distant-site physicians and practitioners provide radiology, ICU/critical care medicine, neurology, and pathology services to hospital and CAH patients under the auspices of a non-hospital entity that is nationally accredited as having met a national accreditation organization's (AO) standards for credentialing and privileging of medical staff (in addition to other standards established by the national AO). Many commenters specifically mentioned the TJC's Ambulatory Care accreditation program, which surveys and accredits nearly 2,000 ambulatory care entities (of which these non-hospital telemedicine entities, along with ambulatory surgery centers, imaging centers, and dentist offices, are included) out of approximately 30,500 ambulatory care entities nationwide. Commenters suggested that CMS include these telemedicine entities in the requirements so that small hospitals and CAHs would be able to enter into agreements with them.

Many commenters stated that including the medical staff of these distant-site telemedicine entities as part of an optional and streamlined credentialing and privileging process, as we have already proposed for distant-site Medicare-participating hospitals, would increase the overall effectiveness of this rule. They posited that if the goals of this rule were to greatly improve patient care by increasing

patient access to specialty services and reduce the burdens and costs for hospitals and CAHs by removing the impediment of the traditional credentialing and privileging process, then excluding distant-site telemedicine entities would severely limit such goals. In addition, commenters stated that telemedicine practitioners are part of a growing national network that is supported by both hospitals and non-hospital telemedicine entities.

Response: We appreciate the comments supporting the rule as well as the suggestions for improving the rule. When drafting the proposed rule, we gave much thought and consideration to ideas that were similar to those that commenters have expressed regarding the inclusion of non-hospital telemedicine entities as part of these requirements. After careful consideration of the comments and the options available to us for revising the proposed rule, we have concluded that it is important that the medical staff of a distant-site telemedicine entity, which is not a Medicare-participating hospital, be included in an optional and streamlined credentialing and privileging process for those hospitals and CAHs electing to enter into agreements for telemedicine services with such entities. We believe that this inclusion would draw us significantly closer to accomplishing the stated goals of this rule, which are—(1) Increasing patient access to specialty services; and (2) reducing burden on small hospitals and CAHs.

However, this decision presented significant challenges to us as we sought to balance our desire to achieve the worthy goals noted above with the equally important mission of ensuring, through our regulatory authority and responsibility, the health and safety of all patients. As we contemplated revisions to the proposed rule that would broaden its application, the most significant challenge that we faced was reconciling inclusion of distant-site telemedicine entities into this new streamlined process without CMS having any regulatory or oversight authority over these entities. We also note that we do not have any oversight or approval process for accreditation programs (such as that of TJC) for these entities. This situation differs greatly from our proposed inclusion of other Medicare-participating hospitals, where we are assured through the State survey or Medicare-approved accreditation processes that distant-site hospitals providing telemedicine services are in compliance with our CoPs, particularly those pertaining to credentialing and privileging of medical staff.

In addition, we note that there is no statutory definition for a telemedicine entity contained in the Act. Therefore, for the purposes of this rule, we are defining a distant-site telemedicine entity as one that—(1) Provides telemedicine services; (2) is not a Medicare-participating hospital (therefore, a non-Medicare-participating hospital that provides telemedicine services would be considered a distant-site telemedicine entity also); and (3) provides contracted services in a manner that enables a hospital or CAH using its services to meet all applicable CoPs, particularly those requirements related to the credentialing and privileging of practitioners providing telemedicine services to the patients of a hospital or CAH.

Taking all of these factors into consideration, we came to the conclusion that any revisions to the regulatory language finalized here would need to hold distant-site telemedicine entities accountable to the originating-site hospital for meeting CMS practitioner credentialing and privileging standards. Likewise, hospitals and CAHs using telemedicine services will need to provide, upon request when surveyed, the most current telemedicine services agreement showing that the distant-site entities providing the services are required to comply with the CMS standards (even though CMS has no direct authority over those entities) in order for the hospital or CAH to make use of the more streamlined process when credentialing and privileging practitioners from these distant-site telemedicine entities. Similar to our regulations proposed for hospitals and CAHs using the telemedicine services of distant-site Medicare-participating hospitals, the written agreement between the hospital or CAH and the distant-site telemedicine entity will be the foundation for ensuring accountability on both sides. However, due to the differences already discussed between Medicare-participating distant-site hospitals providing telemedicine services and distant-site telemedicine entities providing similar services, there must also be differences in the way the regulations are written.

Therefore, in addition to the proposed requirements, we are also finalizing new provisions that will apply to the credentialing and privileging process and the agreements between hospitals or CAHs and distant-site telemedicine entities (§ 482.12(a)(9) and § 482.22(a)(4) for hospitals; § 485.616(c)(3) and (c)(4) for CAHs). These new provisions will require the governing body of the hospital (or the CAH's governing body

or responsible individual), through its written agreement with the distant-site telemedicine entity, to ensure that the distant-site telemedicine entity, acting as a contractor of services, furnishes its services in a manner that enables the hospital (or CAH) to comply with all applicable conditions of participation and standards. For the contracted services, the applicable CoPs and standards include, but are not limited to, the credentialing and privileging requirements for distant-site physicians and practitioners providing telemedicine services.

For hospitals, we have directly linked this new requirement to an existing requirement at § 482.12(e), which requires the hospital's governing body to ensure that a contractor of services to the hospital (in this case, the distant-site telemedicine entity) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for contracted services. The applicable conditions of participation and standards would include the credentialing and privileging requirements as currently found at § 482.12(a)(1) through (a)(7) of this section and would apply (in accordance with the hospital's policy) to the telemedicine entity's physicians and practitioners that provide telemedicine services to the hospital's patients.

For CAHs, we also linked these new requirements to an existing requirement (at § 485.635(c)(4)) that, like § 482.12(e) for hospitals, pertains to contractors of services and the CAH governing body's (or responsible individual's) obligation to ensure that contracted services are furnished in a manner that enables the CAH to meet all applicable conditions of participation and standards. The standard also contains a provision, at § 485.635(c)(1), that requires the CAH to have agreements or arrangements with one or more *Medicare-participating* providers or suppliers in order to furnish other services to its patients. We see the "Medicare-participating" modifying provision as an impediment to the type of agreements that CAHs may now have with distant-site telemedicine entities under this final rule. Since these entities are not considered Medicare-participating providers or suppliers by CMS, we needed to make an exception to the requirement at § 485.635(c)(1). Therefore, in this final rule, we are adding a new paragraph at § 485.635(c)(5) to provide an exception to this "Medicare-participating" requirement for telemedicine entities in cases where a written agreement exists between a CAH and such entity.

We believe that the combination of the new requirements, as finalized here, and the existing requirements cited above and in the final requirements, which place responsibility on hospitals and CAHs to ensure that contracted services fully enable them to meet the CoPs, will allow hospitals and CAHs to make full use of the telemedicine services offered by non-hospital telemedicine entities without duplicating the credentialing and privileging process. This final rule will now allow hospitals and CAHs to take advantage of these streamlined credentialing and privileging options when using the telemedicine services of other Medicare-participating hospitals, non-Medicare-participating telemedicine entities, or a combination of both types of service providers. And with these new requirements dually aimed at increasing patient access to care and reducing the regulatory burden on hospitals and CAHs, CMS believes that the potential of telemedicine can be more fully realized while still maintaining essential health and safety protections.

Comment: A number of commenters stated that practitioner-to-practitioner "tele-emergency" video communications should not require credentialing and privileging of the distant-site practitioner. Another commenter requested that CMS consider that full credentialing and privileging should not be required when telemedicine services are only consultative in nature. However, the commenter did not clarify what he or she meant by "consultative" services.

Response: Any time services are provided to a patient in a hospital or CAH, the requirements regarding the credentialing and privileging of the practitioners providing the services would apply, whether such practitioners were onsite or available to the patient through telemedicine services.

Regarding "consultative" services as mentioned by the commenter, it is important to distinguish between informal consultation among practitioners (traditionally known as a "curbside consult"), and the furnishing of professional consultation services, which would include providing medical diagnosis and treatment recommendations to patients after a formal request for such services by the practitioner responsible for patient's care. The CMS privileging requirements do not apply in instances where, for example, the attending physician of record seeks informal advice from another physician(s) by whatever communications media the physicians

choose to use. The physician whose advice is being sought is not providing clinical services to the patient, but is merely rendering an informal opinion on the patients' condition to the patient's attending physician, who may or may not make use of the opinion when treating the patient. Such discussions between medical professionals occur on a routine basis in hospitals across the nation and do not require that the practitioners involved be privileged at the same hospital in order for this exchange of medical opinions to take place; in fact, we believe such communications may promote safer, more effective care for patients. Only the attending physician, who is providing clinical services to the patient, would need to be privileged by the hospital or CAH to provide such services. However, a formal consult provided by a specialty or other type of practitioner, where the hospital or CAH patient receives clinical services from the specialty practitioner after the patient's attending physician requests such services be provided (either simultaneously as is often the case with teleICU services, or non-simultaneously as may be the case with many teleradiology services), would require that the practitioner is privileged to do so at the hospital or CAH where the patient is located.

Comment: One commenter stated that to further reduce burden, we should consider a "contract" approach to credentialing and privileging for telemedicine services, particularly for consultations requested by referring providers. Some commenters stated that such agreements or contracts, which essentially allow for credentialing and privileging by proxy, leave hospitals vulnerable to legal liabilities and risks and, therefore, should be prohibited under this rule. Another commenter suggested that, with regard to legal risks and liabilities, mandatory language addressing these issues should be required within the written agreements between distant-site hospitals and the hospital or CAH where the patient receives the services.

Response: The requirements, as proposed, are aimed at reducing the telemedicine credentialing and privileging burden for small hospitals and CAHs by specifically allowing for contracts or, as we refer to them, "agreements," between a distant-site hospital or telemedicine entity providing the telemedicine services and a hospital or CAH that uses these services for the benefit of its patients. In these agreements, it is the responsibility of the hospital or CAH using the services to ensure that the specifics of

the proposed requirements in this rule are explicitly laid out before entering into such an arrangement. Along these lines, we have corrected an oversight in the proposed rule and have revised the requirements in this final rule to clarify that these agreements must be "written." It has always been the intent of this rule to allow for hospitals and CAHs to have the option of credentialing and privileging the distant-site telemedicine practitioners using the traditional process. Hospitals and CAHs electing to use the traditional credentialing and privileging process must not be compelled by a distant-site telemedicine hospital (or distant-site telemedicine entity) to enter into an agreement that requires the use of the more streamlined approach as outlined here.

Regarding the legal risks and liabilities of such agreements, the governing body of each individual hospital and CAH must weigh the risks and benefits of opting for this more streamlined process of credentialing and privileging telemedicine practitioners. We understand that there are many complex legal issues, including issues of liability, inherent to contracts and agreements between institutions. However, we believe that these issues are beyond the scope of this rule, and that any relevant legal issues must be worked out between the parties entering into the agreements in accordance with other laws and regulations governing such contracts or agreements.

Comment: One commenter cited § 482.12(b), under the "Exercise of rights" standard in the Patients Rights CoP, to state that the rule must contain language that requires the hospital or 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. The commenter believes that the patient's informed consent must be obtained by the hospital or CAH before it makes use of the telemedicine services.

Response: We respectfully disagree with the commenter. In accordance with 42 CFR 482.24(c)(2)(v), the medical staff generally specifies procedures and treatments, in addition to those required by applicable Federal or State law, that require informed consent. 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. If they provide treatment that, under medical staff policy, requires informed consent,

then this consent must be obtained, regardless of whether the treatment is furnished using telemedicine or not. Likewise, if, as is typical, hospital medical staff or CAH professional staff policies do not require the patient's informed consent in order for an on-site radiologist to interpret an x-ray or CT scan that had been performed on the patient, then consent also would not be required when a distant-site telemedicine radiologist, who is privileged by the hospital or CAH to interpret such diagnostic radiological tests, performs the same services.

Comment: One commenter expressed concern that there is no incentive for a distant-site hospital to provide these services for independent physician groups without corporate affiliation, even if they happen to be on the distant-site hospital medical staff.

Response: While it is not clear to whom this comment is referring ("* * * independent physician groups without corporate affiliation, even if 'they' happen to be on the distant-site hospital medical staff * * *"), the intent of this rule is not to provide business incentives for the provision of telemedicine services (as we believe they exist already), but to provide a more streamlined process for credentialing and privileging telemedicine practitioners that would be more efficient and less burdensome for all of the hospitals, CAHs, and distant-site hospitals involved in this process. We believe that by allowing for such an optional process, the incentives for distant-site hospitals to provide telemedicine services and for hospitals and CAHs to make use of these services will not diminish, but will greatly increase. Ultimately, we believe this will lead to even greater patient access to timely care that might not otherwise be available.

Comment: A commenter questioned the long-run sustainability of increased workload associated with telemedicine (both at the patient-site and at the distant-site facility), which, in the commenter's opinion, seems inevitable. The commenter also questioned whether our revisions would meet quality of care objectives within the commenter's facility.

Response: The goal of this proposed rule is to ensure that all patients have access to quality care in their communities. We believe that this rule provides the framework for such care. We also believe that providers and practitioners will continue to schedule patient visits and appropriately refer patients in such a manner as to not overwhelm either facility or its practitioners. We believe that this rule

will increase patient access to specialty services and reduce burden on facilities and providers.

Comment: One commenter believes that CMS should assess the impact of the final rulemaking on practitioners. A few commenters stated that these requirements will increase burden on practitioners, because they will experience significant downstream reporting requirements for purposes of medical licensure renewal.

Response: It is not clear from the comments as to whom the commenters are referring with the term, "practitioners." Assuming that the commenters means those physicians and practitioners who are providing telemedicine services, we do not believe that this rule will increase the burden of reporting requirements for license renewal any more than the traditional credentialing and privileging processes presently do.

Comment: Two commenters expressed support for the proposed regulation and requested that it be expanded to include small hospitals under 100 beds, as opposed to just rural hospitals that are participating in a State-approved telemedicine program. One commenter expressed concern that community-based facilities, which are neither hospitals nor CAHs (such as rural health clinics and federally qualified health centers), are not included in this rule as patient-site facilities. Another commenter requested that we expand the scope of the rule to all facilities regulated by Medicare.

Response: We would like to thank the commenters for their support of the proposed rule. However, we would like to clarify that this rule applies to all Medicare-participating hospitals, regardless of facility size, as well as to all Medicare-participating CAHs. Rural health clinics and federally qualified health centers are subject to separate Medicare Conditions for Coverage that do not require credentialing and privileging of their physicians and practitioners, and thus there is no basis for extending this rule to those types of facilities. However, it should be noted that many insurers, including Medicare, may place limits or restrictions on their payment for telehealth services, depending on the location of the patient who receives those services.

Comment: Two commenters stated their opposition to the proposed rule because they felt that it allowed privileging by proxy to which they are opposed. One commenter stated that the changes only invite misuse by hospital and CAH governing bodies seeking to sidestep medical staff decisions regarding credentialing and privileging

and to place direct economic pressure on hospital-based practitioners (with the threat of replacing them with distant-site practitioners). The commenter further stated that the changes will effectively remove the local medical staff from any obligation that they may have in determining the qualifications of each individual applying for privileges.

Response: We respectfully disagree with the commenter. As we have stated previously, the requirements being finalized here are an option for hospitals and CAHs as they approach the credentialing and privileging process for telemedicine practitioners. Though we cannot estimate the numbers, we fully expect some hospitals and CAHs to continue credentialing and privileging telemedicine practitioners through the traditional process. Such decisions will have to be determined and agreed upon by each hospital and CAH, after the risks and benefits of each process are fully analyzed. Furthermore, since the practice of privileging by proxy has been common for TJC-accredited hospitals for several years now, there has been ample time for problems, such as the ones the commenter mentions, to come to light. We are not aware of any evidence that indicates these problems have arisen from this process.

Comment: A few commenters expressed belief that some language we used throughout the proposed rule is ambiguous and confusing and suggested that the terms “distant-site hospital” and “patient-site facility” be used consistently. Another commenter requested that we use the terms “distant site” and “originating site” to ensure consistency among CMS publications and avoid confusion. Another commenter requested that we clarify the nomenclature within the regulation so the responsibilities of each facility are explicit.

Response: In drafting the proposed rule, we gave much thought to the terms that we would use to describe, and distinguish between, the hospital that provides the telemedicine services and the hospital or CAH that receives the telemedicine services on behalf of its patients. We came to the conclusion that it would only be more confusing (for a number of reasons) to use the terms “distant site” and “originating site,” as they are contained in both the Act and the payment rules. First among these reasons is the fact that, under the Act, there are sites (for example, rural health clinics, federally qualified health centers, and physician and practitioner offices) that are defined as “originating,” but which do not apply in the context of the hospital and CAH CoPs.

Additionally, the Act applies restrictions to these originating sites for specific Medicare payment purposes, which have no bearing on the hospital and CAH CoPs.

We also considered other terms, such as “patient-site facility,” but found them too vague and inappropriate as well. Upon final analysis and consideration, we decided that distant-site hospital was an appropriate term to describe those larger hospitals that provide telemedicine services to patients of smaller hospitals and CAHs.

In considering which term to use for a hospital or CAH whose patients receive telemedicine services, it became readily apparent to us that the clarity of the language in the proposed requirements was best served if we continued to use the terms used throughout the current hospital and CAH CoPs to describe the facility to which the CoPs applied and to which a survey (through either the State agencies or the national accreditation organizations) for compliance with the CoPs would be performed. Put simply, the hospital would be referred to as the “hospital” and the CAH as the “CAH.” Any qualifying language preceding these terms might change the meaning and confuse which facility these CoPs applied. In some areas, we found it necessary to use qualifying phrases such as “the distant-site hospital providing the telemedicine services” and “the hospital (or CAH) whose patients are receiving the telemedicine services.” Therefore, we are finalizing these terms as proposed.

Comment: One commenter requested that we define and distinguish the differences between telemedicine and telehealth.

Response: In drafting this rule, we reviewed a variety of existing definitions of telemedicine and telehealth. The American Telemedicine Association states that “videoconferencing, transmission of still images, e-health including patient portals, remote monitoring of vital signs, continuing medical education, and nursing call centers are all considered part of telemedicine and telehealth.” Other organizations describe telemedicine as one part of a larger category of telehealth. The Institute of Medicine of the National Academy of Science defines telemedicine as “the use of electronic information and communication technologies to provide and support health care when distance separates the participants.” According to the California Telemedicine and eHealth Center, “telehealth refers to a broader scope of services that includes telemedicine, but it also includes other

services that can be provided remotely using communication technologies.” And the federal Office for the Advancement of Telehealth, describes telehealth as “including telemedicine and a variety of other services.” In addition, Section 1834(m) of the Social Security Act (the Act) addresses Medicare payment for “telehealth services.” In accordance with those statutory provisions, telehealth services are certain services provided by practitioners via a telecommunications system to patients of certain types of healthcare facilities (including hospitals and CAHs) and physician or practitioner offices that are located in rural areas.

The consensus in the telemedicine/telehealth community appears to be that telemedicine refers to the provision of clinical services to patients by practitioners from a distance via electronic communications and that it is included under the broader scope of telehealth, while the statutory Medicare telehealth payment provisions are considerably narrower. At § 1834(m) of the Act, telehealth services are defined as professional consultations, office visits, and office psychiatry services, and any additional service specified by the Secretary. Most significantly, the statute allows payment for services that are provided to patients in a variety of settings (otherwise known as “originating sites” and which include physician or practitioner offices, CAHs, rural health clinics, and hospitals), but requires that all of these originating sites must be located in one of three areas: (1) An area that is designated as a rural health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)); (2) in a county that is not included in a Metropolitan Statistical Area; or (3) from an entity that participates in a Federal telemedicine demonstration.

However, for the purposes of this rule, we see telemedicine as encompassing the overall delivery of healthcare to the patient through the practice of patient assessment, diagnosis, treatment, consultation, transfer and interpretation of medical data, and patient education all via a telemedicine link (for example, audio, video, and data telecommunications as may be utilized by distant-site physicians and practitioners), and which is not restricted to only patients in rural areas of the nation. Therefore, in order to make clear that the credentialing and privileging provisions finalized here apply to all Medicare-participating hospitals and CAHs and not to the narrower subset of services and sites eligible for Medicare telehealth payment, we chose to use the term,

“telemedicine,” throughout this rule instead of “telehealth.”

Comment: Two commenters stated that they do not support using the phrase “hospital’s patients.” They stated that often individuals who are not registered patients make use of a rural hospital’s telemedicine facilities without being registered patients. Two other commenters encouraged us to recognize and apply the proposed credentialing and privileging model to “all types of patients.” One commenter requested clarification of the word “patient” and suggests we further define that any reference to patient applies solely to inpatient services.

Response: We are aware that individuals that are not patients sometimes make use of a rural hospital’s or CAH’s facilities and telemedicine equipment in order to effect what are essentially office visits with distant-site telemedicine practitioners. Since these individuals are not patients of the hospital or CAH, and the distant-site telemedicine practitioners are not seeing them as patients of the hospital or CAH, the CoPs would not apply in these situations. This speaks directly to the other comments above requesting that these requirements be applied to all types of patients and, conversely, that we clarify that these requirements apply only to inpatients. Simply stated, the hospital and CAH CoPs are intended to ensure the health and safety of those patients, inpatients as well as outpatients, who are hospital and CAH patients.

Comment: A commenter expressed concern that patient-site hospitals may not have staff with appropriate expertise that would allow them to evaluate credentialing and privileging information for specialists.

Response: The proposed and final rules address the commenter’s concern. Small hospitals and CAHs that believe they lack the expertise to perform credentialing and privileging for the telemedicine services of specialized practitioners already privileged at a distant-site hospital or telemedicine entity would have the option of relying upon the distant site’s privileging process instead.

Comment: A commenter questioned whether it is sufficient for a distant-site hospital to provide the information in an agreement with the partnering patient-site institution. The commenter asked if the distant-site hospital is expected to provide the patient-site hospital with detailed information that may be contained in the physician’s credentialing file at the distant-site hospital.

Response: We would expect the parties engaged in the agreement to determine, within the written details of the agreement or contract, how much information would need to be included and sent for each practitioner providing telemedicine services to the hospital or CAH. At the very least, as part of its agreement with the distant-site hospital, we would expect a hospital or CAH to have access to the complete credentialing and privileging file upon request for each practitioner who is covered by the agreement.

Comment: We received a number of comments concerning the issue of State licensure and telemedicine practitioners. A few commenters stated that a telemedicine practitioner must be licensed in the State in which he or she is located as well as in any State(s) that he or she provides telemedicine services to patients. Other commenters asked for clarification on the term “recognized” as used in the proposed rule and asked if it was equivalent to the “privilege to practice” authority provided for by Nurse Licensure Compact States. A few commenters also stated that the licensure language was not clear and further stated that if it was intended that the requirements would allow for reciprocity agreements, endorsements, other compact arrangements, or situations where a State does not require local licensure, then the requirements should be amended to reflect this.

Response: We appreciate the suggestions offered by commenters. However, we believe that the proposed licensure language provides enough flexibility to hospitals and CAHs so that they may address these issues in their required agreements with distant-site telemedicine hospitals and entities. In fact, our intention was that they should address such licensure issues in accordance with their respective State laws and regulations. We neither endorse nor prohibit licensure arrangements among States, which are mentioned above. Practitioners providing telemedicine services, as well as the distant-site hospitals and entities under whose auspices they provide these services, must be aware of the licensure laws in the States where they are located in addition to the laws, compacts, and arrangements of those States in which they look to provide their services to patients.

CMS recognizes that practitioner licensure laws and regulations have traditionally been, and continue to be, the provenance of individual States, and we are not seeking to pre-empt State authority in this matter. We believe that the proposed requirements regarding State licensure leave room for the laws

that exist today as well as any changes to these laws that may occur in the future, including any increase in the number of States that decide to engage in compacts, privilege to practice or reciprocity agreements, endorsements, and other arrangements regarding practitioner licensure. Therefore, we are finalizing this aspect of the requirements as proposed.

Critical Access Hospital (CAH) CoPs (§ 485.616 and § 485.641)

We proposed to make revisions to the CAH CoPs at § 485.616, “Agreements,” and § 485.641, “Periodic evaluation and quality assurance review.” We specified in the proposed rule that the majority of the proposed revisions, particularly those which mirror the proposed hospital revisions, are found in the “Agreements” CoP, specifically § 485.616(c). At § 485.616(c), we proposed a new standard entitled, “Agreements for credentialing and privileging of telemedicine physicians and practitioners.”

The proposed telemedicine credentialing and privileging requirements for CAHs are modeled after the hospital requirements, with almost no differences in the regulatory language. Since the only existing requirements in the CAH CoPs specific to the responsibility of the governing body to grant medical staff privileges concerns surgical privileges for practitioners, we proposed to add language that follows the language in the hospital requirements at § 482.12(a). This language delineates the responsibilities of the governing body for the professional staff privileging process.

At § 485.641(b)(4)(iv), which does not have an equivalent provision in the hospital CoPs, we proposed to make a minor change to the CAH CoPs here. We proposed to add a new provision that would allow the distant-site hospital to evaluate the quality and appropriateness of the diagnosis and treatment furnished by its own staff when providing telemedicine services to the CAH. This proposed change would add distant-site hospitals to the three other entities already allowed to perform this function under the existing regulations.

Comment: One commenter noted that we use slightly different language in the requirements for CAHs than we do for the hospital requirements, and stated that we do not discuss the reasons for the differences in the preamble to the proposed rule. The commenter noted that we state at § 485.616(c)(2) that 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.”

Response: We thank the commenters for pointing out the discrepancy between the regulatory language for hospitals and that for CAHs in this instance. We have revised the hospital language to be consistent with that for CAHs.

III. Provisions of the Final Rule

Based on public comment and our own internal discussions, we are adding new provisions to this final rule that will apply to the credentialing and privileging process and the agreements between hospitals and CAHs and non-hospital, distant-site telemedicine entities that provide telemedicine services (§ 482.12(a)(9) and § 482.22(a)(4) for hospitals; § 485.616(c)(3) and § 485.616(c)(4) for CAHs). These new provisions will require the governing body of the hospital (or the CAH's governing body or responsible individual), through its written agreement with the distant-site telemedicine entity, to ensure that the distant-site telemedicine entity, acting as a contractor of services, furnishes its services in a manner that enables the hospital (or CAH) to comply with all applicable conditions of participation and standards for the contracted services, including, but not limited to, the credentialing and privileging requirements regarding its physicians and practitioners providing telemedicine services.

Essentially, the new provisions will allow for the governing body of the hospital (or the CAH's governing body or responsible individual) to rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making its own decisions on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body (or the CAH's governing body or responsible individual) ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity's medical staff credentialing and privileging processes and standards meet or exceed the standards at § 482.12(a)(1) through § 482.12(a)(7) and § 482.22(a)(1) through § 482.22(a)(2) for hospitals, and at § 485.616(c)(1)(i) through § 485.616(c)(1)(vii) for CAHs.

Additionally, the hospital's governing body (or the CAH's governing body or responsible individual) must ensure that the distant-site telemedicine entity, through a written agreement, meets

three other provisions finalized here (and similar to those proposed and finalized here for agreements between hospitals/CAHs and distant-site hospitals providing telemedicine services).

Accordingly, we have made revisions to § 482.22(c)(6) and § 485.641(b)(4) to reference these new provisions pertaining to distant-site telemedicine entities as finalized in this rule.

Additionally, we have made a revision to § 485.635(c). This standard currently requires a CAH to have agreements or arrangements with one or more *Medicare-participating* providers or suppliers in order to furnish other services to its patients. We saw that as an impediment to the agreements that CAHs may have with distant-site telemedicine entities under this final rule. Since these entities do not participate in Medicare, we needed to make an exception to the requirement at § 485.635(c)(1). We have added a new paragraph at § 485.635(c)(5) to provide an exception to this requirement in cases where a written agreement exists between a CAH and a distant-site telemedicine entity for the entity's distant-site physicians and practitioners to provide telemedicine services to the CAH's patients.

In this final rule, we have made two significant clarifying revisions to the language of the proposed rule.

In the requirements for both hospitals and CAHs pertaining to the agreement with a distant-site hospital providing telemedicine services, we have corrected an oversight in the proposed rule and have revised the requirements in this final rule to clarify that these agreements or contracts must be written.

We have also revised the hospital language to be more consistent with that for CAHs, where we now state that the hospital's governing body may choose to have its medical staff “rely upon the credentialing and privileging decisions made by the governing body of the distant-site hospital regarding individual distant-site physicians or practitioners.”

Finally, we have made a few minor clarifying revisions to the proposed rule in those places where we found inconsistencies in regulatory language and/or instances where we believe the language was not as clear as it should have originally been.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is

submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding Condition of Participation: Governing Body (§ 482.12)

Section 482.12(a)(8) requires the governing body of a hospital to 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 specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements in paragraphs (1) through (7) of this section with regard to its physicians and practitioners providing telemedicine services. The burden associated with this requirement is the time and effort necessary for a hospital's governing body to develop, review, and update as necessary the agreement with a distant-site hospital. We estimate that 4,860 hospitals (not including 1,314 CAHs) must develop the aforementioned written agreement. We also estimate that the initial development of the agreement will take 1,440 minutes at an estimated cost of \$1,996. Assuming at most an annual update, the review will take 360 minutes at an estimated cost of \$516. The total cost associated with this requirement is \$2,512.

Section 482.12(a)(9) requires the governing body of a hospital to ensure that, when telemedicine services are furnished to the hospital'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 hospital and as such, in accordance with § 482.12(e), furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services,

including, but not limited to, the requirements in paragraphs (a)(1) through (a)(7) of this section with regard to its physicians and practitioners providing telemedicine services. The burden associated with this requirement is the time and effort necessary for a hospital's governing body to develop, review, and update as necessary the agreement with a distant-site telemedicine entity. While this requirement is subject to the PRA, the associated burden is accounted for in our discussion of § 482.12(a)(8).

B. ICRs Regarding Condition of Participation: Medical Staff (§ 482.22)

Section 482.22(a)(3) states that when telemedicine services are furnished to a hospital's patients through an agreement with a distant-site hospital, the governing body of the hospital whose patients are receiving the telemedicine services may choose to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual physicians and practitioners providing such services. To do this, a hospital's governing body must ensure that all of the provisions listed at § 482.22(a)(3)(i) through (iv) are met. Specifically, § 482.22(a)(3)(iv) contains a third-party disclosure requirement. Section 482.22(a)(3)(iv) requires that 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 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.

The burden associated with this third-party disclosure requirement is the time and effort necessary for a hospital to send evidence of a distant-site physician's or practitioner's performance review to the distant-site hospital with which it has an agreement for providing telemedicine services. We estimate 4,860 hospitals (not including 1,314 CAHs) must comply with this requirement. We estimate that each disclosure will take 60 minutes and that there will be approximately 32 annual disclosures. The estimated cost

associated with this requirement is \$1,088.

Section 482.22(a)(4) states that when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with § 482.12(e), permit the hospital to comply with all applicable conditions of participation and standards for the contracted services. To do this, a hospital's governing body must ensure that all of the provisions listed at § 482.22(a)(4)(i) through (iv) are met. Specifically, § 482.22(a)(4)(iv) contains a third-party disclosure requirement. Section 482.22(a)(4)(iv) states that 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 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 to the hospital's patients by the distant-site physician or practitioner and all complaints the hospital has received about the distant-site physician or practitioner. While this requirement is subject to the PRA, the associated burden is accounted for in our discussion of § 482.22(a)(3).

C. ICRs Regarding Condition of Participation: Agreements (§ 485.616)

Section 485.616(c)(1) states that 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 requirements listed at § 485.616(c)(1)(i) through (vii) and § 485.616(c)(2). The burden associated with this requirement is the time and

effort necessary for a CAH's governing body to develop, review, and update as necessary the agreement with a distant-site hospital. We estimate that 1,314 CAHs must develop and review the aforementioned written agreement. We also estimate that development of the agreement will take 1,440 minutes initially and, assuming at most an annual update, the review will take 360 minutes annually. The total cost associated with this requirement is \$2,512.

Section 485.616(c)(2) states that 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 for individual distant-site physicians or practitioners, if the CAH's governing body or responsible individual ensures that all of the provisions listed at § 485.616(c)(2)(i) through (iv) are met. The burden associated with this third-party disclosure requirement at § 485.616(c)(2)(iv) is the time and effort necessary for a CAH to send evidence of a distant-site physician's or practitioner's performance review to the distant-site hospital with which it has an agreement for providing telemedicine services. We estimate 1,314 CAHs must comply with this requirement. We estimate that each disclosure will take 60 minutes and that there will be approximately 32 annual disclosures. The estimated cost associated with this requirement is \$1,088.

Section 485.616(c)(3) states that 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 services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services, including, but not limited to, the requirements in this section with regard to its physicians and practitioners providing telemedicine services.

The burden associated with this requirement is the time and effort necessary for a CAH's governing body to develop, review, and update as necessary the agreement with a distant-site telemedicine entity. We estimate that 1,314 CAHs must develop and review the aforementioned written

agreement. We also estimate that development of the agreement will take 1,440 minutes (that is, 24 hours) initially and, assuming at most an annual update, the review will take 360 minutes (six hours) annually. The total cost associated with this requirement is \$2,512.

Section 485.616(c)(4) states that 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 all of the provisions listed at § 485.616(c)(4)(i) through (iv) are met. The burden

associated with this third-party disclosure requirement at § 485.616(c)(4)(iv) is the time and effort necessary for a CAH to send evidence of a distant-site physician's or practitioner's performance review to the distant-site telemedicine entity with which it has an agreement for providing telemedicine services. While this requirement is subject to the PRA, the associated burden is accounted for in our discussion of § 485.616(c)(2).

TABLE 1—ANNUAL REPORTING, RECORDKEEPING AND DISCLOSURE BURDEN

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total labor cost of reporting (\$)	Total capital/maintenance costs (\$)	Total cost (\$)
§ 482.12(a)(8) and (9).	0938—New	4,860	4,860	24	116,640	**	9,700,560	0	9,700,560
	4,860	4,860	6	29,160	**	2,507,760	0	2,507,760
§ 482.22(a)(3) and (4).	0938—New	4,860	155,520	1	155,520	34	5,287,680	0	5,287,680
§ 485.616(c)(1) and (3).	0938—New	1,314	1,314	24	31,536	**	2,622,744	0	2,622,744
	1,314	1,314	6	7,884	**	678,024	0	678,024
§ 485.616(c)(2) and (4).	0938—New	1,314	42,048	1	42,048	34	1,429,632	1,429,632

Total	6,174	209,916	382,788	22,226,400

** Wage rates vary by level of staff involved in complying with the information collection request (ICR). The wage rates associated with the aforementioned information collection requirements are listed in Tables 2–7 in the regulatory impact analysis of this final rule.

V. Regulatory Impact Analysis

A. Statement of Need

Currently, a hospital or CAH receiving telemedicine services must go through a burdensome credentialing and privileging process for each physician and practitioner who will be providing telemedicine services to its patients. In the past, under the Joint Commission's (TJC) statutory deeming authority, hospitals that were accredited by TJC were deemed to have met the CMS credentialing and privileging requirements. TJC's "privileging by proxy" standards allowed for one Joint Commission-accredited facility to accept the privileging decisions of another Joint Commission-accredited facility. TJC has been statutorily required to meet or exceed our requirements regarding credentialing and privileging since July 15, 2010.

This final rule will revise the conditions of participation (CoPs) for both hospitals and critical access hospitals (CAHs) and will implement a new credentialing and privileging process for physicians and practitioners furnishing telemedicine services. Additionally, and perhaps more significantly, failure to publish this final rule will place undue hardship and

financial burden on those hospitals and CAHs who have been credentialing and privileging telemedicine practitioners under TJC's "privileging by proxy" model. These hospitals and CAHs will have to take on the burden of credentialing and privileging a significant number of telemedicine practitioners in a relatively short period of time or they will have to consider canceling their telemedicine services. Cancellation of telemedicine services by small hospitals and CAHs will drastically reduce access to needed specialty services for a great number of patients, many of whom are Medicare beneficiaries.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism

(August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule is not an economically significant rule and does not impose significant costs. The benefits of finalizing this rule greatly outweigh any costs imposed. Conversely, the negative impacts on overall patient health and safety as well as on the operating costs of individual hospitals and CAHs were this rule not to be finalized would be significant compared to the minimal cost imposed by finalizing it here. Accordingly, we have prepared a regulatory impact analysis, which to the best of our ability, presents the costs and benefits of the rulemaking.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100

million or more in any 1 year). The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that the great majority of hospitals, including CAHs, are small entities as that term is used in the RFA. Individuals and States are not included in the definition of a small entity. While we do not believe that this final rule will have a significant impact on small entities, we do believe that this rule will have a positive impact by providing immediate regulatory relief for these small entities and will negatively impact them if not finalized here. Therefore, we are voluntarily preparing a Regulatory Flexibility Analysis.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule will not have a significant impact on small rural hospitals as it is intended to relieve the burden on hospitals, particularly on small rural hospitals and CAHs, and to reduce or eliminate the impact of the current regulatory impediments to efficient operation and patient access to essential healthcare services. Therefore, the Secretary has determined that this final rule will not have a significant negative impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA)

also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately \$136 million. This rule does not contain mandates that will impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector, of \$136 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule will not have a substantial direct effect on State or local governments, preempt State laws, or otherwise have a Federalism implication.

C. Anticipated Effects

1. Effects on Hospitals and Critical Access Hospitals (CAHs)

We estimate the costs to hospitals and CAHs to implement this final rule with comment period to be minimal, particularly when weighed against the significant benefits that the rule would bring about by reducing the regulatory burden for hospitals and CAHs. The major costs are related to developing the agreement between the distant-site hospital or distant-site telemedicine entity and the hospital or CAH at which patients who receive the telemedicine services are located. Many hospitals and CAHs may already have such telemedicine service agreements in place and therefore would not incur the initial costs of developing such an agreement.

Our figures, as of March 31, 2010, indicate that there were 4,860 hospitals and 1,314 CAHs (for a total of 6,174) participating in Medicare in the United States. However, we have no way of determining an exact number on which of these hospitals provide telemedicine services and which of these hospitals and CAHs receive telemedicine services, nor can we determine how many hospitals and CAHs already have telemedicine agreements. We do not have any reliable figures on the number of non-hospital, distant-site telemedicine entities that provide telemedicine services to hospitals and CAHs. Accordingly, we have based our cost estimates on the higher costs that would be incurred if every hospital and CAH in the United States was required to develop an agreement and review and update it annually. We prepared the cost estimates for hospitals and CAHs separately. However, all sides of this equation will require the initial services of a hospital or CAH attorney at an average of \$86/hour; a hospital or CAH chief of the medical/professional staff (a physician) at an average of \$103/hour; and a hospital or CAH administrator at an average of \$69/hour. For the third-party disclosure requirements, we also prepared the cost estimates for hospitals and CAHs separately, though both will require the annual services of a medical staff credentialing manager or a medical staff coordinator at an average of \$34/hour. Our salary figures are the most recent wage estimates from the Bureau of Labor Statistics (<http://www.bls.gov/home.htm>) with 33% added to the hourly wage to account for benefits. Our estimates of time and cost for each aspect of the agreement (development and initial cost, and annual review), as well as for the third-party disclosure, is as follows:

TABLE 2—INFORMATION COLLECTION REQUIREMENTS FOR A HOSPITAL TO DEVELOP AN AGREEMENT FOR TELEMEDICINE SERVICES: INITIAL COST

Individual	Hourly wage	Number of hours	Cost per individual	Total cost
Attorney	\$86	12	\$1,032
Physician	103	4	412	\$1,996
Hospital Administrator	69	8	552

TABLE 3—INFORMATION COLLECTION REQUIREMENTS FOR A HOSPITAL TO REVIEW AND UPDATE AN AGREEMENT FOR TELEMEDICINE SERVICES: ANNUAL COST

Individual	Hourly wage	Number of hours	Cost per individual	Total cost
Attorney	\$86	2	\$172
Physician	103	2	206	\$516
Hospital Administrator	69	2	138

Therefore, we estimate the total initial annual cost to review agreements for all cost to develop the agreement for all hospitals is estimated at \$2.5 million. 4,860 hospitals to be \$9.7 million. The

TABLE 4—INFORMATION COLLECTION REQUIREMENTS FOR A CAH TO DEVELOP AN AGREEMENT FOR TELEMEDICINE SERVICES: INITIAL COST

Individual	Hourly wage	Number of hours	Cost per individual	Total cost
Attorney	\$86	12	\$1,032
Physician	103	4	412	\$1,996
CAH Administrator	69	8	552

TABLE 5—INFORMATION COLLECTION REQUIREMENTS FOR A CAH TO REVIEW AND UPDATE AN AGREEMENT FOR TELEMEDICINE SERVICES: ANNUAL COST

Individual	Hourly wage	Number of hours	Cost per individual	Total cost
Attorney	\$86	2	\$172
Physician	103	2	206	\$516
Hospital Administrator	69	2	138

Therefore, we estimate the total initial annual cost to review agreements for all cost to develop the agreement for all CAHs is estimated at \$678,024. 1,314 CAHs to be \$2.6 million. The

TABLE 6—INFORMATION COLLECTION REQUIREMENTS FOR A HOSPITAL TO PREPARE AND SEND INDIVIDUAL PERFORMANCE REVIEWS FOR TELEMEDICINE SERVICES (THIRD-PARTY DISCLOSURE): ANNUAL COST

Individual	Hourly wage	Number of hours	Total cost
Medical Staff Coordinator or Medical Staff Credentialing Manager	\$34	32	\$1,088

Therefore, we estimate the total individual performance reviews for disclosure) for all 4,860 hospitals to be annual cost to prepare and send telemedicine services (third-party \$5.3 million.

TABLE 7—INFORMATION COLLECTION REQUIREMENTS FOR A CAH TO PREPARE AND SEND INDIVIDUAL PERFORMANCE REVIEWS FOR TELEMEDICINE SERVICES (THIRD-PARTY DISCLOSURE): ANNUAL COST

Individual	Hourly wage	Number of hours	Total cost
Medical Staff Coordinator or Medical Staff Credentialing Manager	\$34	32	\$1,088

Therefore, we estimate the total annual cost to prepare and send individual performance reviews for telemedicine services (third-party disclosure) for all 1,314 CAHs to be \$1.4 million.

The total cost of the information collection requirements for both hospitals and CAHs is estimated to be \$22.2 million.

D. Conclusion

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 1. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

Subpart B—Administration

■ 2. Section 482.12 is amended by adding new paragraphs (a)(8) and (a)(9) to read as follows:

§ 482.12 Condition of participation: Governing body.

* * * * *

(a) * * *

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

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

* * * * *

Subpart C—Basic Hospital Functions

- 3. Section 482.22 is amended by—
- A. Adding new paragraphs (a)(3) and (a)(4).
- B. Revising paragraph (c)(6).

The addition and revision read as follows:

§ 482.22 Condition of participation: Medical staff.

* * * * *

(a) * * *

(3) When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the governing body of the hospital whose patients are receiving the telemedicine services may choose,

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

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

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

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

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

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

with § 482.12(e), permit the hospital to comply with all applicable conditions of participation for the contracted services. The hospital's governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met:

(i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at § 482.12(a)(1) through (a)(7) and § 482.22(a)(1) through (a)(2).

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

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

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

* * * * *

(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).

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 4. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

■ 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.
- (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.

■ 6. Section 485.635 is amended by adding a new paragraph (c)(5) to read as follows:

§ 485.635 Condition of participation: Provision of services.

* * * * *

(c) * * *

(5) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, the distant-site telemedicine entity is not required to be a Medicare-participating provider or supplier.

* * * * *

■ 7. Section 485.641 is amended by revising paragraph (b)(4) to read as follows:

§ 485.641 Condition of participation: Periodic evaluation and quality assurance review.

* * * * *

(b) * * *

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

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

(ii) One QIO or equivalent entity;

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

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

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

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare Supplementary Medical Insurance Program). (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: January 27, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: April 29, 2011.

Kathleen Sebelius,

Secretary.

[FR Doc. 2011-10875 Filed 5-2-11; 11:15 am]

BILLING CODE 4120-01-P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 211 and 237

RIN 0750-AG72

Defense Federal Acquisition Regulations Supplement; Guidance on Personal Services (DFARS Case 2009-028)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD has adopted as final, with changes, the interim rule that

amended the Defense Federal Acquisition Regulation Supplement (DFARS) to implement section 831 of the National Defense Authorization Act for Fiscal Year 2009, which required DoD to develop guidance on personal services contracts.

DATES: *Effective Date:* May 5, 2011.

FOR FURTHER INFORMATION CONTACT: Mr. Dustin Pitsch, 703-602-1014.

SUPPLEMENTARY INFORMATION:

I. Background

Section 831 required DoD to mitigate the risks associated with personal services by developing guidance enabling contracting officers to better distinguish between personal services and nonpersonal services. The interim rule amended DFARS parts 211 and 237 to (1) require that statements of work or performance work statements clearly distinguish between Government employees and contractor employees and (2) ensure that procedures are adopted to prevent contracts from being awarded or administered as unauthorized personal services contracts. The interim rule included an internal requirement for a program manager, or equivalent, certification that the service contract requirement does not include an unauthorized personal services arrangement. Because of the differing missions of DoD agencies, the interim rule required agencies to adopt their own procedures.

DoD published an interim rule at 75 FR 54524 on September 8, 2010, to implement section 831 of the National Defense Authorization Act for Fiscal Year 2009 (Pub. L. 110-417, enacted October 28, 2009). The period for public comment closed on November 8, 2010. Five respondents provided public comments on the interim rule.

II. Discussion and Analysis

A. Support for DoD Actions

Comment: A respondent noted the DFARS requirement for agency-level procedures to ensure that service contract requirements are vetted and approved in a manner that will prevent them from being awarded or administered as unauthorized personal services contracts. The respondent stated its support for Defense agencies taking internal action to ensure that no unauthorized personal services contracts are requested. Another respondent expressed support for the rule and stated that it “helps create a boundary separating contractor and government employees in all workplace environments.”

Response: The respondents' support is noted. No change to the DFARS in this area was requested or made.

B. Limit Applicability

Comment: Two respondents specified that the DFARS should highlight and limit applicability of this rule solely to personal services contracts, not the general service contract population.

Response: No change was made in the final rule in response to this comment. It is precisely because of the potential for a migration of a “general service contract” into what is effectively a “personal services contract” that the rule is necessary. DoD, with strong encouragement from the DoD Office of Inspector General, has determined that there is a need to review all services for the purpose of ensuring the services do not become personal services.

C. Add More Guidance

Comment: A respondent stated that DFARS 211.106 provides no actual guidance to the agencies as to what the distinction between Government employees and contractor employees is or how an agency is to make such a determination. At a minimum, the respondent states, it may be appropriate to include in DFARS 211.106 a cross reference to the characteristics and descriptive elements in FAR 37.104. The respondent thinks the rule does not provide any actionable direction to contractors on what behaviors would be acceptable for contractor employees based on the policies and practices of the location where the contractor employee is assigned.

Response: A cross reference to FAR 37.104 and the characteristics and descriptive elements therein has been added to DFARS 211.106. However, the DFARS cannot unnecessarily repeat, paraphrase, or otherwise restate material contained in the FAR (see FAR 1.304(b)), so the DFARS addition was limited to a reference. Further, the agency-level procedures are the appropriate location for the actionable, agency-specific direction to contractors on acceptable behaviors.

D. Add More Specific Contract Administration Procedures

Comment: A respondent noted the absence in the interim rule, in DFARS parts 237 or 242, of procedures, guidance, or information focusing on postaward contract administration to prevent actual administration of a contract as an unauthorized personal services contract. The respondent recommended (a) referencing FAR 37.104(d) in DFARS 237.503 and (b)