the distribution of power and responsibilities between the Federal Government and Indian tribes." This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 14, 2010.

Steven Bradbury,

Acting Director, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

§ 180.110 [Removed]

2. Section 180.110 is removed.

[FR Doc. 2010–12376 Filed 5–25–10; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 482 and 485

[CMS–3227–P]

RIN 0938–AQ05

Medicare and Medicaid Programs: Proposed Changes Affecting Hospital and Critical Access Hospital (CAH) Conditions of Participation (CoPs): Credentialing and Privileging of Telemedicine Physicians and Practitioners

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the conditions of participation (CoPs) for both hospitals and critical access hospitals (CAHs). These revisions would allow for a new credentialing and privileging process for physicians and practitioners providing telemedicine services.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 26, 2010.

ADDRESSES: In commenting, please refer to file code CMS–3227–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3227–P, P.O. Box 8010, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3227–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: CDR Scott Cooper, USPHS (410) 786–9465. Marcia Newton, (410) 786–5265. Jeannie Miller, (410) 786–3164.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, on Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

Electronic Access

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I. Background

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 also used 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) 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, regardless of whether services will be provided in-person and on-site at the hospital or CAH, or remotely through a telecommunications system. CMS regulations currently require hospitals and CAHs receiving telemedicine services to privilege each physician or practitioner providing services to its patients as if such practitioner were on-site.

While hospitals may use third party credentialing verification organizations to relieve the time-consuming burden of compiling and verifying the credentials of practitioners applying for privileges, the hospital's governing body is still 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 requires TJC to secure CMS approval of its standards in order to confer Medicare deemed status on hospitals after July 15, 2010. This means that we do not have the discretion under the law to accept TJC policies or standards that do not meet or exceed the Medicare CoPs. One TJC policy that has been in direct conflict with the CoPs has been TJC's practice of permitting "privileging by proxy," which has allowed TJC-accredited hospitals to utilize a different methodology 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. In short, TJC privileging by proxy standards allowed for one TJC-accredited facility to accept the privileging decisions of another TJC-accredited facility. Hospitals that have used this method to privilege distant-site medical staff technically did not meet CMS requirements that applied to other hospitals even though they were TJC-accredited. When CMS learned of specific instances of such noncompliance through on-site surveys by State Survey Agencies, the hospital was required to change its policies to come into compliance.

As of July 15, 2010, TJC will be statutorily required to enforce CMS requirements regarding privileging physicians and practitioners in the hospitals they accredit, both those providing and those receiving telemedicine services. TJC-accredited hospitals, therefore, are concerned that they may be unable to meet the long-standing CMS privileging requirements while sustaining their current telemedicine agreements. Small hospital and CAH 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.

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, 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 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.

CMS has become increasingly aware, through outreach efforts and communications with the various stakeholders in the telemedicine community (for example, large academic medical centers that provide telemedicine services; small hospitals that make effective use of these services for the benefit of their patients; representative professional organizations; and Congressional representatives whose various constituencies are made up of telemedicine practitioners as well as the patients receiving telemedicine services), of the urgent need to revise the CoPs in this area so that access to these vital services may continue in a manner that is both safe and beneficial for patients and is free of unnecessary and duplicative regulatory impediments.

II. Provisions of the Proposed Rule

The following provisions of this proposed rule would apply to all hospitals and CAHs participating in the Medicare and Medicaid programs. Section 1861(e)(1) through (9) of the Act: (1) Defines the term "hospital"; (2) lists the statutory requirements that a hospital must meet to be eligible for Medicare participation; and (3) specifies that a hospital must also meet other requirements as the Secretary finds necessary in the interest of the health and safety of the hospital's patients. Under this authority, the Secretary has established in the regulations 42 CFR part 482, the requirements that a hospital must meet to participate in the Medicare program. Section 1905(a) of the Act provides that Medicaid payments may be applied to hospital services. Regulations at 42 CFR 440.10(a)(3)(iii) require hospitals to meet the Medicare CoPs to qualify for participation in Medicaid.

We recognize the advantages and benefits that telemedicine provides for patients and are interested in reducing the burden and the duplicative efforts of the traditional credentialing and privileging process for Medicare-participating hospitals, both those which provide telemedicine services and those which use such services. Therefore, we are proposing to revise both the hospital and CAH credentialing and privileging requirements to eliminate these regulatory impediments and allow for the advancement of telemedicine nationwide while still protecting the health and safety of patients. We believe that these proposed revisions would preserve and strengthen the core values of the credentialing and privileging process for all hospitals: accountability to all patients, and assurance that medical staff are privileged to provide services in the

hospital based on evaluation of the practitioner's medical competency.

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 are proposing 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.

The proposed requirements at § 482.12(a)(8) would 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, can 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. 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. 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. The intent of this proposed requirement is 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 are proposing within this same provision (§ 482.22(a)(3)) that the hospital, in order to choose this less burdensome option for privileging, must ensure that—(1) The distant-site hospital providing the telemedicine services is a Medicare-participating hospital; (2) the individual distant-site physician or practitioner is 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 holds 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 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 this information for use in its periodic appraisal of the individual distant-site physician or practitioner. We are also proposing, at a minimum, the information sent for use in the periodic appraisal would have to include all adverse events that may result from telemedicine services provided by the distant-site physician or practitioner to the hospital's patients and all complaints the hospital has received about the distant-site physician or practitioner.

Within the revisions to the hospital CoPs, we are also proposing 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 are proposing to add language to stipulate that in cases where distant-site physicians and practitioners are 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).

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

The proposed revisions to the CAH CoPs are found at § 485.616, "Agreements," and § 485.641, "Periodic evaluation and quality assurance review." However, the majority of the proposed revisions, particularly those which mirror the proposed hospital revisions, are found in the "Agreements" CoP, specifically § 485.616(c). We are proposing to add a new standard at § 485.616(c) 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 are proposing 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 medical staff privileging process.

At § 485.641(b)(4)(iv), we would make a minor change to the CAH CoPs that do not have an equivalent provision in the hospital CoPs. We are proposing to add a new requirement 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 requirement would be in addition to the three other entities already allowed to perform this function under the existing regulations.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-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 are soliciting 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) would require 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 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 subsection with regard to its physicians and practitioners providing telemedicine services. The burden associated with this requirement would be the time and effort necessary for a hospital's governing body to develop, initially review, and annually review 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 development and review of the agreement would take 1,440 minutes initially and the review would take 360 minutes annually. The total cost associated with this proposed requirement is $2,346.

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 information furnished 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) states that with respect to a distant-site physician or practitioner granted privileges, the hospital whose patients are receiving the telemedicine services, 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 would 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 would be 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) would have to comply with this requirement. Similarly, we estimate that each disclosure would take 60 minutes and that there would be approximately 32 annual disclosures. The estimated cost associated with this proposed requirement is $1,248.

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

Section 485.616(c)(1) would state 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 specifies that it is the responsibility of the governing body of the distant-site hospital to meet the proposed requirements listed at § 485.616(c)(1)(i) through (vii) and § 485.616(c)(2). The burden associated with this proposed requirement would be the time and effort necessary for a CAH's governing body to develop, initially review, and annually review 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 and review of the agreement would take 1440 minutes initially and the review would take 360 minutes annually. The total cost associated with this proposed requirement is $2,346.

Section 485.616(c)(2) would state 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) would be 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 would have to comply with this proposed requirement. Similarly, we estimate that each disclosure would take 60 minutes and that there would be approximately 32 annual disclosures. The estimated cost associated with this proposed requirement is $1,248.

TABLE 1—ANNUAL REPORTING AND RECORDKEEPING 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)	0938–New	4,860	4,860	24	116,640	**	8,942,400	0	8,942,400
	.....	4,860	4,860	6	29,160	**	2,459,160	0	2,459,160
§ 482.22(a)(3)	0938–New	4,860	155,520	1	155,520	39	6,065,280	0	6,065,280
§ 485.616(c)(1)	0938–New	1,314	1,314	24	31,536	**	2,417,760	0	2,417,760
	.....	1,314	1,314	6	7,884	**	664,884	0	664,884
§ 485.616(c)(2)	0938–New	1,314	42,048	1	42,048	39	1,639,872	0	1,639,872
Total	.....	6,174	209,916	.....	382,788	.....	.....	.....	.....

** 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 2–9 in the regulatory impact analysis of this proposed rule.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS–3227–IFC.

Fax: (202) 395–6974; or

E-mail: *OIRA_submission@omb.eop.gov.*

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act (the Act), section 202 of the Unfunded Mandates Reform Act of 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 Order 12866 directs 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 proposed rule is not an economically significant rule and does not impose significant costs. The benefits of finalizing this proposed rule would 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 were this rule not to be finalized would be significant compared to the minimal cost imposed. Accordingly, we have prepared a regulatory impact analysis, which to the best of our ability, presents the costs and benefits of the rulemaking.

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 proposed rule would have a significant impact on small entities, we do believe, as we have stated previously, that this rule would have a positive impact by providing immediate regulatory relief for these small entities and would negatively impact them if not finalized. 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 would 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 proposed rule would 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 2010, that threshold is approximately $135 million. This rule does not contain mandates that would impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector, of $135 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 proposed rule would not have a substantial direct effect on State or local governments, preempt States, or otherwise have a Federalism implication.

B. Anticipated Effects

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

We estimate the costs to hospitals and CAHs to implement this proposed rule to be minimal. The major costs are related to the agreement between the distant-site hospital and the hospital or CAH at which patients who receive the telemedicine services are located. Many hospitals and CAHs already have such telemedicine service agreements in place and would not incur the initial costs of developing and reviewing 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) 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 services, nor can we determine how many hospitals and CAHs already have telemedicine agreements. Accordingly, we have based on our cost estimates on the higher costs that would be incurred if every hospital and CAH in the United States were required to develop the agreement, to review it initially, and to review it annually. We prepared the cost estimates for hospitals and CAHs separately. However, all sides of this equation would require the initial services of a hospital or CAH attorney at an average of $66/hour; a hospital or CAH chief of the medical staff (a physician) at an average of $112/hour; and a hospital or CAH administrator at an average of $75/hour. For the third-party disclosure requirements, we also prepared the cost estimates for hospitals and CAHs separately, though both would require the annual services of a medical staff credentialing manager or a medical staff coordinator at an average of $39/hour. Our salary figures are from *http://www.salary.com/*. Our estimates of time and cost for each aspect of the proposed agreement (development, initial review, 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	$66	8	$528	
Physician	112	2	224	$1052
Hospital Administrator	75	4	300	

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

Individual	Hourly wage	Number of hours	Cost per individual	Total Cost
Attorney	$66	4	$264	
Physician	112	2	224	$788
Hospital Administrator	75	4	300	

TABLE 4—INFORMATION COLLECTION REQUIREMENTS FOR A HOSPITAL TO REVIEW AN AGREEMENT FOR TELEMEDICINE SERVICES: ANNUAL COST

Individual	Hourly wage	Number of hours	Cost per individual	Total cost
Attorney	$66	2	$132	
Physician	112	2	224	$506
Hospital Administrator	75	2	150	

Therefore, we estimate the total initial cost to develop and review the agreement for all 4,860 hospitals to be $8.9 million. The annual cost to review agreements for all hospitals is estimated at $2.5 million.

TABLE 5—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	$66	8	$528	
Physician	112	2	224	$1052
CAH Administrator	75	4	300	

TABLE 6—INFORMATION COLLECTION REQUIREMENTS FOR A CAH TO REVIEW AN AGREEMENT FOR TELEMEDICINE SERVICES: INITIAL COST

Individual	Hourly wage	Number of hours	Cost per individual	Total cost
Attorney	$66	4	$264	
Physician	112	2	224	$788
CAH Administrator	75	4	300	

TABLE 7—INFORMATION COLLECTION REQUIREMENTS FOR A CAH TO REVIEW AN AGREEMENT FOR TELEMEDICINE SERVICES: ANNUAL COST

Individual	Hourly wage	Number of hours	Cost per individual	Total cost
Attorney	$66	2	$132	
Physician	112	2	224	$506
Hospital administrator	75	2	150	

Therefore, we estimate the total initial cost to develop and review the agreement for all 1,314 CAHs to be $2.4 million. The annual cost to review agreements for all CAHs is estimated at $664,884.

TABLE 8—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	Cost per individual	Total cost
Medical Staff Coordinator or Medical Staff Credentialing Manager	$39	32	$1,248	$1,248

Therefore, we estimate the total annual cost to prepare and send individual performance reviews for telemedicine services (third-party disclosure) for all 4,860 hospitals to be $6.1 million.

TABLE 9—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	Cost per individual	Total cost
Medical Staff Coordinator or Medical Staff Credentialing Manager	$39	32	$1248	$1248

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 $1.6 million.

The total cost of the information collection requirements for both hospitals and CAHs is estimated to be $22.1 million.

C. 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 proposes to amend 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 a new paragraph (a)(8) 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 (as defined in section 1834(m)(4)(A) of the Act) hospital, the agreement 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 its 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), grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital.

* * * * *

Subpart C—Basic Hospital Functions

3. Section 482.22 is amended by—

A. Adding a new paragraph (a)(3).

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 (as defined at section 1834(m)(4)(A) of the Act) 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 information furnished 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 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.

(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 granted privileges, the hospital, whose patients are receiving the telemedicine services, 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.

* * * * *

(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 § 482.22(a)(3).

* * * * *

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 (as defined at section 1834(m)(4)(A) of the Act) hospital, the agreement 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 (as defined at section 1834(m)(4)(A) of the Act) 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 that the following provisions are met:

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

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

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the CAH is located; and

(iv) With respect to a distant-site physician or practitioner granted privileges by the CAH, 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.

6. Section 485.641 is amended by—

A. Republishing paragraph (b)(4)(i).

B. Revising paragraphs (b)(4)(ii) and (iii).

C. Adding a new paragraph (b)(4)(iv).

The additions and revisions 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; or

(iv) In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under an agreement between the CAH and a distant-site (as defined at section 1834(m)(4)(A) of the Act) hospital, the distant-site hospital.

* * * * *

(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: May 20, 2010.

Marilyn Tavenner,

Acting Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.

Approved: May 21, 2010.

Kathleen Sebelius,

Secretary.

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 578

[Docket No. NHTSA–2010–0066]

Reports, Forms and Record Keeping Requirements, Agency Information Collection Activity Under OMB Review

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of proposed extension, without change, of a currently approved collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, the agency must receive approval from the Office of Management and Budget ("OMB"). Under procedures established by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections. In compliance with the Paperwork Reduction Act of 1995, this notice describes one collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be submitted on or before July 26, 2010.

ADDRESSES: You may submit comments to the docket number identified in the heading of this document by any of the following methods:

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the