Supporting Statement – Part A

Supporting Statement For Paperwork Reduction Act Submissions

A. Background

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.

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.

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 Sec. 482.22(a)(3)(i) through (iv) are met. Specifically, Sec. 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.

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 Sec. 485.616(c)(1)(i) through (vii) and Sec. 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 Sec. 485.616(c)(2)(i) through (iv) are met. The burden associated with this third-party disclosure requirement at Sec. 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.

B. Justification

1 . Need and Legal Basis

CMS recognizes the advantages and benefits that telemedicine provides for patients and is 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.

The 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 Social Security 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 at 42 CFR part 482, the requirements that a hospital must meet to participate in the Medicare program. This authority extends as well to the separate requirements that a CAH must also meet to participate in the Medicare program, established in the regulations at 42 CFR part 485. Additionally, §1820 of the Act sets forth the conditions for designating certain hospitals as CAHs. 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.

2. Information Users

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.

3. Use of Information Technology

This collection of information may involve the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, specifically permitting electronic collection and exchange of information regarding the performance of duties by telemedicine physicians and practitioners in order to provide a more efficient means of doing this for hospitals and CAHs. We believe that this may help to reduce burden further by eliminating excessive paperwork and reducing the time required to send and receive information. However, we have no means for determining how many hospitals and CAHs would take advantage of information technology and what the percentage would be for electronic completion of these tasks.

It should be noted here that the proposed requirements pertaining to information collection do not require submission of any information to CMS or the Department.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be

obtained from any other source. The purpose of this proposed rule is to eliminate the duplicative process of credentialing and privileging telemedicine physicians and practitioners as is currently required by the CoPs.

5. Small Businesses

While the collection of information does impact small businesses or other small entities (small hospitals and CAHs), the purpose of this proposed rule is to eliminate the duplicative process of credentialing and privileging telemedicine physicians and practitioners as is currently required by the CoPs and to minimize burden for small hospitals and CAHs.

6. Less Frequent Collection

Not applicable.

7. Special Circumstances

Not applicable.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published as part of the proposed rule that published on May 26, 2010 (75 FR 29479).

9. Payments/Gifts to Respondents

Not applicable.

10. Confidentiality

Not applicable.

11. Sensitive Questions

Not applicable.

12. Burden Estimates (Hours & Wages)

Table 1--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 2--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 3--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 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	$66	8	$528	....
Physician	112	2	224	$1052
CAH Administrator	75	4	300	....

Table 5--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 6--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 7--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	$39	32	$1,248	$1,248

Manager...

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 8--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.

13. Capital Costs

Not applicable.

14. Cost to Federal Government

Not applicable.

15. Changes to Burden

Not applicable.

16. Publication/Tabulation Dates

Not applicable.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

Not applicable.