A GUIDE TO TELEMEDICINE

DESIGNING A HOSPITAL-BASED PROGRAM

ILLINOIS HOSPITAL ASSOCIATION
SOUTHERN ILLINOIS SCHOOL OF MEDICINE
C & G CONSULTING PARTNERS

ACKNOWLEDGEMENTS

Southern Illinois University School of Medicine Office of External and Health Affairs and the Illinois Hospital Association express their gratitude to the IHA Telemedicine Work Group in the development of this telemedicine guide for hospitals. The work group has benefited from the dedicated and personal commitment of its individual members, who represent a broad cross-section of those interested in the expansion of telemedicine services in rural regions of Illinois, to help address the current and anticipated shortages of health care workforce personnel.

The work group represented rural hospital leaders who are currently delivering telemedicine services along with those who are interested in providing telemedicine services. The work group represented critical access hospitals and low-volume PPS hospitals that are currently developing innovative strategies to address workforce shortages in rural regions of Illinois. The work group hopes that this report will assist additional rural Illinois hospitals to begin delivering services through telemedicine technology.

The work group would like to acknowledge the research and report development provided through C & G Consulting Partners, LLC, from Springfield, Illinois, and appreciates the support provided by the IHA Policy, Legal, and Communications Department staff members. Finally, the work group acknowledges the work by the SIU School of Medicine, specifically, Robert Wesley, Executive Director, Regional Medical Programs, Office of External and Health Affairs, and Glenn Groesch, Director, SIU Telehealth Networks and Programs, in their ongoing pursuit of telemedicine in Illinois. Their dedication and commitment to the expansion of telemedicine services in rural Illinois have made this work group and report possible.

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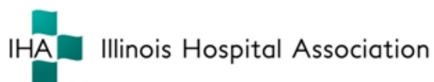
A Guide to Telemedicine: Designing a Hospital-Based Program was produced in 2012 by C & G Consulting Partners, LLC and the Illinois Hospital Association through a Rural Health Development Grant provided by the State of Illinois to the SIU School of Medicine, Office of External Affairs. All information included in this guide is for reference purposes only and should not be considered legal advice on regulatory, licensing, or billing procedures established under state and federal law. IHA is not responsible for actions taken by hospitals as a result of information included in the guide.



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INTRODUCTION

In Illinois, urban and rural providers are beginning to work together to improve efficiencies in the health care delivery system through telemedicine. Telemedicine is a rapidly growing method of care delivery that expands access to primary and specialty care in health professional shortage areas.[1] The concept originated in the 1950s when some facilities experimented with closed-circuit television to link physicians and patients. Since then, technology has dramatically improved and opened up a wide array of health care delivery possibilities by integrating new technologies into community-based primary care diagnosis and disease management. Pilot projects have demonstrated potential cost savings related to a reduction in unnecessary transports, emergency department usage and hospitalizations. This savings to the overall health care delivery system is beginning to motivate Illinois providers to use telemedicine to improve access to health care services in designated shortage areas (Appendix A).

Currently, telemedicine is being used by hospitals to:

- Improve access to primary and specialty care in underserved regions;
- Create efficiencies in the service delivery system; and
- Improve quality care and care coordination.

Telemedicine is able to meet these goals by:

- Increasing access to primary and specialty care providers;
- Reducing the cost of unnecessary transports to regional facilities;
- Reducing usage of the emergency department;
- Reducing inpatient hospitalizations;
- Improving communication between providers on the patient's care team; and
- Sharing of best practices and protocols among the care team.

Over the past 20 years, the State of Illinois has benefitted from several telehealth initiatives to promote the expansion of telemedicine with rural providers. The Illinois Department of Public Health Center for Rural Health (IDPH CFRH) has, in previous years, provided grant funds to critical access hospitals to encourage telehealth program participation. The U.S. Department of Agriculture Rural Development

[1] American Telemedicine Association definition.
[2] Appendix A includes workforce shortage areas of Illinois.

Agency (USDA RDA) has worked with rural leaders to provide technology to improve access to health care, education, and commerce. Southern Illinois University School of Medicine (SIU SOM) has used its rural development funds to help rural providers adopt telehealth through equipment grants, technical expertise and ongoing research of best practices. The Illinois Health Information Exchange (HIE) provides a forum for telehealth professionals to share challenges and best practices and to provide input on the integration of telehealth services as a component of the Illinois Statewide HIE.

In 2011, SIU SOM partnered with the Illinois Hospital Association (IHA) and the Illinois Critical Access Hospital Network (ICAHN) to distribute a survey to small, rural and critical access hospitals to identify those interested in developing a telehealth program and provide support to those hospitals to implement their programs.[2]

This guidebook provides small and rural hospitals with step-by-step instructions to develop a telemedicine program in their communities.

What is Telemedicine?

Telemedicine is the use of medical information exchanged from one site to another via electronic communications to improve patients' health status. Closely associated with telemedicine is the term "telehealth," which is often used to encompass a broader definition of remote healthcare that does not always involve clinical services. Videoconferencing, still-images transmission, 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.[4]

A telemedicine consultation service occurs when a provider cares for a patient, or advises another medical provider, when the patient and the provider are in different geographic locations. The provider communicates with patients and/or providers at a different location utilizing a variety of communication tools to exchange necessary medical information. A telemedicine definition list[5] is attached, but for the purposes of this guidebook, telemedicine includes an originating site and a distant site.

[3] Appendix B includes survey results.
[4] American Telemedicine Association definition.
[5] Appendix C includes telemedicine list of definitions.

Types of Sites

Originating Site

The originating site is the location where a patient accesses the telemedicine service. Medicare includes the following locations as "originating sites":

- A physician or practitioner office;
- Hospital;
- Rural Health Clinics (RHC);
- Federally Qualified Health Centers (FQHC);
- Hospital-based Renal Dialysis Centers (including satellite locations);
- Skilled Nursing Facilities; and
- Community Mental Health Centers.

The State of Illinois Medicaid program includes the following locations as "originating sites":

- Physicians' office;
- Podiatrists' office;
- Local health departments;
- Community mental health centers;
- Licensed hospital outpatient departments; and
- Substance abuse treatment centers licensed by the Department of Human Services – Division of Alcoholism and Substance Abuse.

Distant Site

The distant site is the location of the provider delivering consultation services from a remote location. Medicare allows reimbursement for the following practitioners at the distant site to provide telemedicine services:

- Physicians;
- Nurse practitioners;
- Physician Assistants;
- Nurse midwives;
- Clinical nurse specialists;
- Clinical psychologists;
- Clinical social workers; and
- Registered dietitians or nutritionists.

The State of Illinois Medicaid program reimburses the following provider types at the distant site for telemedicine services:

- Physicians;
- Podiatrist; and
- Advanced practice nurses (APN).

For telepsychiatry services, a physician must have completed an approved general or child and adolescent psychiatry residency program and have the corresponding certification form on file with the Illinois Department of Healthcare & Family Services (HFS).

According to the Federal Benefits Improvement and Protection Act[3], "telehealth service" is defined as professional consultations, office visits, and office psychiatry services (identified as HCPCS codes 99241- 99275, 99201-99215, 90804-90809, and 90862), and any additional service specified by the Secretary.

HFS defines telehealth as, "the use of a telecommunication system to provide medical services between places of lesser and greater medical capability and/or expertise, for the purpose of evaluation and treatment." Medical data exchanged can take the form of multiple formats: text, graphics, still images, audio and video. The information or data exchanged can occur in real time (synchronous) through interactive video or multimedia collaborative environments or in near real time (asynchronous) through "store-and-forward" applications.

The state previously limited telehealth services to medical evaluations between hospitals only. Effective January 29, 2010, the department expanded covered services and locations for telehealth to include telepsychiatry. This expansion was designed to improve participant access to specialists, while supporting the quality of care they receive.[4]

Telehealth communication tools include two fundamentally different care delivery platforms (Store-and-Forward vs. Live Interactive). Both platforms have strengths and weaknesses and the decision to use a specific platform will be based on the project being designed.

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[3] Federal Benefits Improvement and Protection Act, **www.federalregister.gov** (Appendix D)
[4] Medical Practice Act, State of Illinois, **http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1309&ChapterID=24** (Appendix E)

Types of Consultations

Live, Interactive Consultation
A live, interactive consultation involves two-way audio and video connection between the originating site and the distant site. Communication between the provider and the patient is usually facilitated through secure digital videoconferencing which allows two-way audio and video communication. It is important for the transmission to be HIPAA compliant and sufficiently fast enough for the provider and the patient to achieve anticipated consult outcomes. A discussion of telemedicine equipment is included on page 14 of this guide.

Store-and-Forward Consultation
A store-and-forward consultation allows the originating provider to collect medical information from a patient, store it in the electronic medical record, and forward it to the consulting provider for evaluation. It does not provide the necessary information for patients being evaluated for conditions that require the remote provider to evaluate a patient's movement or cognitive abilities. Radiology is the most common use of store-and-forward consultations. Most small and rural hospitals use teleradiology to share diagnostic information with radiologists and other specialists at a remote location. Teledermatology is also being used to capture digital pictures of a patient's rash or skin discoloration, upload those images to a secure server, and allow remote dermatologists and other specialists to review the images and provide consultation on the patient's care plan.

Hybrid Consultation
Some small and rural hospitals utilize a combination of these two technologies based upon the needs of the patient. A hybrid consultation involves using both components of the live, interactive consultation and the store-and-forward consultation. These are typically used in dermatology or cardiology specialties, where higher quality images are imperative for diagnosing the patient's condition. In the case of dermatology, the difference between a store-and-forward consultation and a hybrid consultation is that the specialist looks at the pictures on the server and reviews the notes of the primary care physicians to make a recommendation, versus the specialist that pulls up the image, and talks directly to the patient about the rash and then makes his/her recommendations.

Types of Telemedicine Services

Telemedicine allows providers to consult on initial diagnosis, referral determinations, disease management, care coordination, medication therapy management, treatment protocols, interpretive services, transitions from hospital to long-term care facilities, and patient education. Following are the types of health care services currently being offered through telemedicine:

Specialty/Subspecialty:

- Allergy/Immunology
- Anesthesia
- Behavioral Health
- Burn/Wound Care
- Cardiology
- Critical Care
- Dentistry
- Emergency Medicine
- Endocrinology
- Family/General Practice
- Gastroenterology
- Infectious Diseases
- Internal Medicine
- Maternal/Fetal Medicine
- Neurology
- Oncology/Hematology
- Ophthalmology/Optometry
- Orthopedics
- Otolaryngology (ENT)
- Pathology
- Pulmonology
- Radiology
- Rehabilitative Medicine
- Rheumatology
- Urology
- Palliative Care
- Others

In working with small and rural hospitals in Illinois, SIU SOM and IHA found that most hospitals interested in developing a telemedicine program are interested in providing one or more of the following telemedicine services.

Telepsychiatry services are growing in demand as a result of the sharp decrease of behavioral health services available in rural regions of Illinois. Due to diminishing state and federal resources, many behavioral health providers in Illinois have had to reduce services for those with mental illness and substance use disorders. Telepsychiatry has been effective in bringing behavioral health expertise to patients and primary care providers in rural regions of Illinois. Both Mason District Hospital and Sarah D. Culbertson Hospital in West Central Illinois are working with SIU SOM Department of Psychiatry to access a psychiatrist to provide consultation for primary care providers in the region. Live, interactive telepsychiatry services provides the best opportunity for the provider to assess the patient's condition both through

verbal and non-verbal communication, as well as allows the patient to see the physician and feel more comfortable in engaging in the consultation. Both hospitals have found the service to be helpful with medication management, patient education and engagement, and follow-up services.

Tele-endocrinology is growing quickly due to the prevalence and cost of diabetes in Illinois and across the nation. The American Diabetes Association estimates that 1 in 3 Americans will be diagnosed with Diabetes by 2050 and the cost of diabetes in Illinois alone is $7.2 trillion per year.[5] Tele-endocrinology allows providers to provide ongoing disease management services, education, patient engagement, and reduce travel costs in rural regions. Tele-endocrinology supports patient-provider interactions that can be live, interactive consultations or store-and-forward consultations.

Teledermatology provides much needed access to dermatology services in rural regions where a shortage of dermatologists exists. The best technique for teledermatology is through a hybrid consultation. The hybrid model makes it possible to get excellent digital stills of the affected skin, perform the assessment, and maintain an ongoing doctor-patient dialogue on progress with the treatment plan.

Teleneurology is being explored in many small and rural hospitals to improve the diagnosis and treatment of possible acute stroke patients due to a neurologist shortage in rural Illinois and in rural America.

On September 1, 2012, in rural, north-central Pennsylvania, Sesquahanna Health, a three-hospital system, announced a new telemedicine program to offer on-call, non-surgical, neurological services 24/7. The new program provides emergency department (ED) physicians and hospitalists with real-time, physician-to-physician consultation to quickly determine the best course of treatment for patients requiring emergency or advanced neurological care. When a potential stroke victim enters the ED, staff uses a mobile unit that can be placed at the patient's bedside to establish a videoconferencing link with an on-call expert neurologist. The consulting neurologist views and discusses diagnostic test results, including CT scan images performed at the local hospital. During the consult, physicians, patients and family

[5] American Diabetes Association estimates include excess medical costs of $4,782,000,000 attributed to diabetes, and lost productivity valued at $2,480,000,000 (ADA Website cost calculator).

members continue to have real-time discussions about diagnostic results, course of treatment and patient response.

A significant advantage to having an experienced critical stroke care neurologist involved is to assist in determining if the clot-busting drug Tissue Plasminogen Activator (TPA) should be part of the treatment. Recent research has demonstrated that TPA must be administered within 4.5 hours from the onset of the first stroke symptoms to be effective. TPA is a clot-busting (thrombolytic) drug that dissolves blood clots to restore blood flow to a blocked artery; it is made naturally in the body by cells in the blood vessel walls; and is the first-choice treatment for patients in the initial stage of blocked-vessel (ischemic) stroke. It is the only drug approved by the FDA for this use and is also used to treat heart attacks caused by clots.

This new level of physician expertise on-call will not only help to preserve brain function for many patients, but will also save lives. Support for emergency stroke care is just one component of Susquehanna Health's program, which also includes rapid access to consultation for patients with conditions including aneurysms, brain tumors, concussions, epilepsy and others affecting the head and spine.[6]

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[6] http://susquehannahealth.org/about-us/news/susquehanna-health-implements-teleneurology-program-for-critical-neurology-care-/page.aspx?id=4161

DESIGNING YOUR TELEMEDICINE PROGRAM

Step One: Convene Your Telemedicine Team

- To initiate a hospital telemedicine program, the first step is to convene a Telemedicine Team that should consist of the following hospital staff and community leaders:

- *Project Manager* –convenes the project team, provides education, initiates discussion items, facilitates the planning process, manages communications with CEO, trustees and hospital staff, and develops an evaluation process for the project.

- *Medical Staff Representative* –provides input into the design of the telemedicine program, manages communications with other hospital or community-based providers, and helps design the training curriculum for providers who will use the telemedicine program.

- *Information Technology Representative* –assists with identification of equipment, software and technology upgrades needed to implement the program. This person also provides input on how the telemedicine program will be integrated into the organization's overall health information technology plans, including flow of patient information into the electronic medical record (EMR), physician entry requirements, and the specific health information software being used at the hospital.

- *Financial Officer* –assists in the development of a cost/benefit ratio for review by the CEO and the necessary plans to integrate the telemedicine program into the hospital's budget process. The financial officer helps develop project start-up costs, patient use data, and reimbursement information to assist in the development of a project budget and estimated return on investment. Financial officers should have access to COMPdata from IHA or other data from reliable sources to assist them in projecting use and cost.

- *Human Resources Representative* –assists in the development of policies and procedures on the use of telemedicine by hospital or community-based providers and training curriculum for hospital staff and community providers, and

provides input into the credentialing and privileging process for telemedicine consultants providing service in the hospital.

- *Legal Representative* –provides input on HIPAA compliance issues, patient protections, provider liability reviews, and the development of contracts between the hospital, providers, and telemedicine consultants.

- *Quality Improvement Representative* –works with the team to ensure the telemedicine program follows hospital-specific protocols, quality indicators are collected, quality standards are documented, and that any specific telemedicine training needs related to quality improvement are integrated into the education programs offered at the hospital.

- *Consumer Advocate* –helps identify patient education programs and information materials, potential patient concerns and challenges, consumer and community outreach needed to promote the new program, and assists in the development of the program evaluation.

- *Other Community Health Leaders* –assists in identifying community health needs and promotion of telemedicine services to consumers and community-based organizations; and assist in the evaluation of telemedicine services. County health department staff, school districts, long-term care agencies, federally qualified health centers, behavioral health providers, and other community health professionals may be able to assist the team in the development of this new service delivery tool.

Step 2: Identify Community Needs

The Telemedicine Team will need to analyze existing community needs assessment information to identify gaps in health care services, as defined by the team, by using actual service area data, county-wide data, or multi-county data. In some cases, multiple hospitals may want to define the community as a region of the state.

The team can access a number of resources to identify services needed but not adequately available in the community. The team can analyze referral patterns through the IHA COMPdata program, review service use and admission data trends and pinpoint services accessed through the emergency room. The team should also review information in the county IPLAN (available through the local health

department). The Statewide Health Improvement Plan (SHIP) is another resource that can be used to identify priority health needs.

Many hospitals have developed a community needs assessment as required by the Internal Revenue Service (IRS) 990 form. However, if a hospital is looking to develop a community needs assessment, there are a couple of tools available for rural hospitals in Illinois. ICAHN and the Illinois Institute for Rural Affairs (IIRA) at Western Illinois University (WIU) both provide on-site technical assistance to rural hospitals in the development of a community needs assessment.

Once a list of health care services needed in the community is assembled, the team will need to analyze which of the needed clinical services can be provided through technology and consults with distant providers. For the purposes of this guide, the previously listed services requested by the small and rural hospitals in Illinois, have all successfully been demonstrated in rural communities in Illinois and in other states. The team will need to prioritize the clinical services based upon demand, cost and/or patient population data. For example, the team may decide to focus on telepsychiatry due to the cost of readmissions to the ED or inpatient hospitalizations versus the cost of regularly scheduled consults with patients to manage their medications. The team may decide to provide follow-up teleneurology consults to save patients from travel time, reduce costs, and provide care in an appropriate setting based on health status considerations.

Once the team has identified one or more services to be included in the telemedicine program, the team must identify the number of potential service users, average number of visits per person, average amount of time per consult, and the number of follow-up visits needed per consult. This information will help the team to frame the request for consulting services that will be sent to potential consultants during the implementation phase of the project.

Step 3: Assess Existing Community Resources

After the team has identified community needs, the telemedicine services to be provided, and the amount of consulting services needed to adequately meet community needs, the team will look at existing resources to deliver the telemedicine program including: facility, technology, staff, and financial resources.

Facility

First, the team must discuss the most appropriate place for the telemedicine services to be delivered. In most small and rural hospitals, telemedicine services are most likely to be delivered at the hospital where specialty care needs are most often identified. In small and rural communities, most health care services are co-located at or near the hospital making it more convenient for patients to access their physician clinics, lab services, clinical procedures, and therapy services at one facility or campus.

Depending on the type of services, the team may want to locate telemedicine units at the local rural health clinic (RHC), federally qualified health center (FQHC), long-term care facility, behavioral health provider, or primary care clinic to provide ongoing patient education, disease management and follow-up services. For example, the team may want to locate telepsychiatry at a primary care clinic to enhance the patient evaluation and treatment plan in a primary care setting and better integrate primary and behavioral health care. The team may decide that a second telemedicine unit should be available in the ED to address the needs of a patient who presents there during a psychiatric crisis. The team may also decide to position telemedicine units in multiple locations in the community, so that providers throughout the community can link to consultants for services. Overall, the team must identify the most appropriate location for patients to access services. The Federal Benefits Improvement and Protection Act rules allow reimbursement for telehealth consults for Medicare and Medicaid patients at the originating site (see page 6 for list of eligible originating sites).

Technology

Based on the location and services to be provided, the team must decide what type of technology is needed to deliver the telemedicine services. The team must discuss the amount of broadband available at each location and the overall number of units needed. Most rural hospitals and providers are utilizing mobile bedside units in various departments within the hospital. However, for telepsychiatry counseling, outpatient follow-up discussions, or diabetes medication management services, a larger screen with specific room settings, lighting and equipment may be more appropriate. A list of potential telemedicine companies that provide consultation services can be found on the American Telemedicine Association website-- **http://atatelemedicinedirectory.com/.**

The technology and equipment used to provide telemedicine can include: videoconferencing, cameras, internet, satellites, wireless communications, and medical devices. The technology used in your telemedicine project will need to be compatible with the partnering distant site's technology. The distant site may already have telemedicine technology in place which will require the originating site to utilize a compatible system. Prior to researching telemedicine vendors, it is important to contact the potential distant site to have a dialogue about what equipment that hospital currently uses.

The American Telemedicine Association website also offers a list of telemedicine vendors broken down into various categories. Simply search the website to identify vendors in Illinois. In addition, the following vendors are recommended by the SIU Telehealth Networks and Programs staff.

SKC – www.skccom.com
Kent Boekenhauer – Account Executive located in Sycamore, IL
913-543-7246

Solutionz, Inc. – www.solutionzinc.com
Brad Pence –Sales Account Executive used by SIU School of Medicine
262-721-1041

Visual Systems Group Inc. (VSGI) – www.vsgi.com
Mike Schrettenbrunner –Major Accounts Manager for the Midwest
630-358-7148

Electronic Communication Systems (ECS) – www.ecsdav.com
Max Muchow –Sales Associate used by SIU School of Medicine
563-445-4391
This company provides complete telemedicine room installations.

No matter which telemedicine vendor you choose, it is crucial to ensure the equipment is compatible with your overall health information technology plan. The vendor should be willing to offer training to staff members. Be mindful that technology advances quickly, and systems and applications will need to be upgraded and warranties will need to be renewed. There can be substantial costs involved with upgrades and warranty renewals, so include these costs in the project budget.

Staff

The team will need to review the amount of staff needed at the originating site of the telemedicine services. Depending on the services provided and where, staff time will need to be allocated to the telemedicine consults along with any necessary follow-up services. The team must also identify staff training, licensing and credentialing needs for the telemedicine program.

Medicaid reimbursement for telemedicine services requires a physician, or other licensed health care professional qualified to bill Medicaid in Illinois, to be present at all times with the patient at the originating site. For telepsychiatry services, a physician, licensed health care professional, or other licensed clinician, mental health professional, or qualified mental health professional (as defined in 59 IL Admin Code 132.25), must be present at all times with the patient at the originating site. A mental health professional (as defined in the Illinois Administrative Code) is:

"An individual who provides services under the supervision of a qualified mental health professional and who possesses: a bachelor's degree; a practical nurse license under the Nurse Practice Act [225 ILCS 65]; a certificate of psychiatric rehabilitation from a DHS-approved program plus a high school diploma plus 2 years of experience in providing mental health services; a recovery support specialist certified and in good standing with the Illinois Alcohol and Other Drug Abuse Professional Certification Association, Inc., plus one year experience in providing mental health services; an occupational therapy assistant licensed under the Illinois Occupational Therapy Practice Act [225 ILCS 75] with at least one year of experience in a mental health setting; or a minimum of five years supervised experience in mental health or human services. A supervised internship in a mental health setting counts toward the experience in providing mental health services. Any individual meeting the minimum credentials for an LPHA (licensed practitioner of health arts) or QMHP (qualified mental health professional) under this part is deemed to also meet the credentialing requirements of an MHP (mental health professional)."

In 2011, CMS released rules that eased the process of the credentialing and privileging telehealth practitioners. Previously, CMS required hospitals to grant privileges to remotely located physicians and other practitioners after they reviewed qualifications for each individual practitioner. In effect, practitioners could not provide care using telehealth technology unless they had received privileges from their home hospital and the hospital where the telehealth services would be delivered.[7] As long as certain conditions are met, the new rule will let hospitals receiving telehealth services rely upon credentialing and privileging information from the entity providing telehealth services. However, Illinois hospitals will need to ensure they are compliant with the Hospital Licensing Rules that require telemedicine providers to be licensed within the state of Illinois.

The telemedicine project may require additional staff education and training particularly on the telemedicine equipment and technology. In addition, there may be specific educational and training needs that are exclusive to the treatment procedures of your telemedicine project. If the team utilizes a vendor, most will provide training for staff on the necessary equipment and software programs. However, there are two universities in Illinois that provide educational opportunities In telemedicine:

- The University of Illinois **(www.medicine.uic.edu/telehealth/telehealth_resource_center/);** and
- Southern Illinois University **(www.siumed.edu/telehealth/).**

[7] (Zigmond, Modern Physician, 5/2).

DEVELOPING YOUR FINANCIAL PLAN

The team will need to develop a financial plan to implement the telemedicine program. The team should focus on quantifiable program costs and revenues through utilization and projections. However, the team should also discuss the potential return on investment (ROI) related to reductions in unnecessary transports, ED utilization, inpatient hospitalizations, and re-admissions. The team should budget for the increased use of preventive and primary care services and its impact on inpatient hospitalizations and ED use. ROI has traditionally been difficult to measure, but should be discussed as it relates to the organization's budget for the program.

Currently, rural hospitals serving underserved areas are eligible to be reimbursed for telemedicine services through a variety of funding sources. The following are potential revenue sources for your telemedicine program.

Medicare Reimbursement

Medicare will pay for a limited number of Part B services that are furnished by a physician or practitioner to a beneficiary via a telecommunications system. For eligible telemedicine services, the use of a telecommunications system is substituted for a face-to-face encounter. Medicare pays for both the originating site, the site where the patient is located, and the distant site, the site where the telemedicine practitioner is located.

Medicare beneficiaries can receive telemedicine services only if they are located in a rural health professional shortage area, or in a county outside of a Metropolitan Statistical Area. The Center for Rural Health at IDPH website[8] provides a list of professional shortage areas as define by the state and federal government (see appendix A).

In addition, entities that participate in the federal telemedicine demonstration project approved by the Secretary of DHS as of December 31, 2000, qualify as originating sites regardless of geographic location.

[8] Center for Rural Health at IDPH website, October 2012, http://www.idph.state.il.us/about/rural_health/rural_shortage.htm. (Appendix F)

Medicare authorizes the following as originating sites:

- A physician's or practitioner's office;
- Hospitals;
- Rural health clinics;
- Federally qualified health centers;
- Hospital-based renal dialysis centers (including satellite locations);
- Skilled nursing facilities; and
- Community mental health centers.

Note: Independent renal dialysis facilities are not recognized by Medicare as an originating site.

Medicare will pay for the following practitioners at the distant site to provide telemedicine services:

- Physicians;
- Nurse practitioners;
- Physician assistants;
- Nurse midwives;
- Clinical nurse specialists;
- Clinical psychologists;
- Clinical social workers; and
- Registered dietitians or nutritionists.

Requirements for Care Reimbursement: An interactive audio and video telecommunications system must be used that allows for real-time communication between the patient and the physician. Store-and-forward technology is only permitted in federal telemedicine demonstration programs that are conducted in Alaska and Hawaii, and is not reimbursable in other states. Medicare will reimburse for the following telemedicine services conducted in real-time for Illinois:

- Consultations (CPT codes 99241-99255);
- Office or other outpatient visits (CPT codes 99201-99215);
- Individual psychotherapy (CPT codes 90804-90809);
- Pharmacologic management (CPT code 90862);
- Psychiatric diagnostic interview exams (CPT code 90801);
- Individual medical nutrition therapy (Healthcare Common Procedure Coding System code G0270 and CPT codes 97802-97803);

- Neurobehavioral status exams (CPT code 96116);
- Follow-up inpatient telemedicine consultations (Healthcare Common Procedure Coding System codes G0406 - G0408); and
- End-stage renal disease (ESRD) - related services included in the monthly capitation payment (CPT Codes 90951, 90952, 90954, 90955, 90957, 90958, 90960, and 90961). For ESRD-related services, there needs to be at least one face-to-face, hands on visit (not via telemedicine) at least each month to examine the vascular access site by a physician, nurse practitioner, physician assistant, or clinical nurse specialist.

Billing and Payment: Distant site physicians and practitioners bill Medicare for telemedicine services using the appropriate CPT or HCPCS code for the service, along with the telemedicine modifier GT, "via interactive audio and video telecommunications system." For example, pharmacologic management would be billed 90862 GT. By coding and billing the GT modifier with a covered telemedicine procedure code, the distant site physician/practitioner certifies that the patient was present at an eligible originating site at the time of service. Distant site physicians/practitioners are paid 80% of the appropriate Medicare Physician Fee Schedule amount, while the beneficiary is responsible for payment of the remaining 20%.

For telemedicine services, originating sites are paid an originating site facility fee. This fee is billed separately.

Medicaid Reimbursement

The Centers for Medicare & Medicaid Services (CMS) requires that reimbursement for Medicaid covered services, including those with telehealth applications, must also satisfy federal requirements of efficiency, economy, and quality of care. On January 12, 2011, the Illinois Department of Healthcare and Family Services (HFS) expanded telemedicine and telepsychiatry services. Under the expansion, physicians, advanced practice nurses, podiatrists, FQHCs, RHCs, and Encounter Rate Clinics, are allowed to offer telemedicine services. Additionally, telepsychiatry services are covered when the physician providing the services has completed either a general or a child/adolescent psychiatric residency program. HFS will reimburse one provider at the originating site (site where the patient is located) and one or more providers at the distant site, depending on the patient's clinical needs.

Eligibility: For telemedicine services, a physician or other licensed healthcare professional qualified to bill Medicaid in Illinois, must be present at all times with the patient at the originating site. For telepsychiatry services, a physician, licensed health care professional, or other licensed clinician, mental health professional, or qualified mental health professional (as defined in 59 IL Admin Code 132.25), must be present at all times with the patient at the originating site. The following provider locations are eligible to receive reimbursement from HFS as an originating site:

- Physician's office;
- Podiatrist's office;
- Local health departments;
- Community mental health center;
- Licensed hospital outpatient departments as defined in 89 IL. Adm. Code 148.25(d); and
- Substance abuse treatment centers licensed by the Department of Human Services - Division of Alcoholism and Substance Abuse.

The following provider types are eligible to receive reimbursement from HFS as a distant site provider: a physician, a podiatrist, an advanced practice nurse that is licensed by the state of Illinois or by the state where the participant is located. Services offered by an APN can be billed under the collaborating physician's National Provider Identifier (NPI), or if the APN is enrolled, under the APN's NPI. When medically appropriate, more than one distant site provider may bill for services provided during the telemedicine visit.

For telepsychiatry services, the practitioner that provides the service at the distant site must be a physician licensed by the state of Illinois or by the state where the patient is located, who has completed an approved general or child and adolescent psychiatry residency program. To be eligible for reimbursement by HFS for telepsychiatry services, physicians must have an HFS 3882, Psychiatric Residency Certification form, on file with the department. Group psychotherapy is not a covered telepsychiatry service.

Billing and Payment for Non-Encounter Clinics: The originating site is reimbursed a facility fee of $25 per telemedicine service. In order to receive payment as an originating site, the provider shall bill HCPCS Procedure code Q3014.

Physicians/Practitioners providing telemedicine services at the distant site shall be reimbursed the department's rate for the CPT code[9] for the rendered service. As with Medicare, the appropriate CPT code must be billed with the modifier GT.

Enrolled distant site providers may not seek reimbursement from the department when the originating site is an encounter clinic. The originating site encounter clinic is responsible for reimbursement to the distant site provider. Providers not enrolled in the Medicaid program that provides services as a distant site provider may be reimbursed by the originating site provider.

Billing and Payment for Encounter Clinics: An encounter clinic serves as the originating site and shall be paid their medical encounter. The encounter clinic must bill procedure code T115 with the appropriate CPT code and modifier GT. Additionally, the distant side provider's name and NPI must be included on the claim. Since the encounter clinic is responsible for reimbursement to the distant site provider, it is up to the originating site to ensure and document that the distant site provider meets the department's requirements for telemedicine and telepsychiatry services.

The distant site shall be reimbursed as follows: If the originating site is an encounter clinic, the distant site provider or encounter clinic may not seek reimbursement from the department for their services. It is up to the originating site encounter clinic to reimburse the distant site encounter clinic. If the originating site is not an encounter clinic, the distant site encounter clinic shall be reimbursed their medical encounter.

The following are billing examples for Telemedicine Services from the HFS website as of October 2012.[10]

Example 1

Originating Site – Physician's office
Bill HCPCS Code Q3014
Reimbursement is $25.00

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[9] Current Procedural Terminology code set is maintained by the American Medical Association through the CPT Editorial Panel. CPT is a registered trademark of the American Medical Association.
[10] Illinois Department of Healthcare and Family Services (HFS) website, **http://www.hfs.illinois.gov/html/011210n2.html.**

Distant Site – Podiatrist's office
Bill the appropriate CPT code with modifier GT.
Reimbursement will be the fee schedule rate for the CPT code billed.

Example 2

Originating Site – Local Health Department
Bill HCPCS Code Q3014
Reimbursement is $25.00
Distant Site – APN's office
Bill the appropriate CPT code with modifier GT.
Reimbursement will be the fee schedule rate for the CPT code billed.

Example 3

Originating Site – Physician's office
Bill HCPCS Code Q3014
Reimbursement is $25.00
Distant Site – Local Health Department
Not a valid provider – there is no billable service.

Example 4

Originating Site – Encounter clinic
Bill the encounter HCPCS Code T1015 and any appropriate detail code(s) with modifier GT.
Reimbursement will be the facility's medical encounter rate.
Distant Site – Encounter clinic
There is no billable service; the Originating Encounter clinic is responsible for payment to the Distant Encounter clinic provider.

Example 5

Originating Site – Encounter clinic
Bill the encounter HCPCS Code T1015 and any appropriate detail code(s) with modifier GT.
Reimbursement will be the facility's medical encounter rate

Distant Site – Physician's office
There is no billable service; the Originating Encounter clinic is responsible for payment to the Distant Encounter clinic provider.

Example 6

Originating Site – Physician's office
Bill HCPCS Code Q3014
Reimbursement is $25.00
Distant Site – Encounter clinic
Bill the encounter HCPCS Code T1015 and any appropriate detail code(s) with modifier GT.
Reimbursement will be the facility's medical encounter rate. The rendering provider's name and NPI must also be reported on the claim.

The following are billing examples for **telepsychiatry** services:

Example 1

Originating Site – Physician's office
Bill HCPCS Code Q3014
Reimbursement is $25.00
Distant Site – Physician who has completed an approved general or child/adolescent psychiatry residency program
Bill the appropriate CPT code for services provided.
Reimbursement will be the fee schedule rate for the CPT code billed.

Example 2

Originating Site – Encounter clinic
Bill the encounter HCPCS Code T1015 and any appropriate detail code(s) with modifier GT.
Reimbursement will be the facility's medical encounter rate.
Distant Site – Encounter clinic
There is no billable service; the Originating Encounter clinic is responsible for payment to the Distant Encounter clinic provider.
Provider rendering the service must be a physician who has completed an approved general or child/adolescent psychiatry residency program.

Example 3

Originating Site – Physician's office
Bill HCPCS Code Q3014
Reimbursement will be $25.00
Distant Site – Encounter clinic
Bill the encounter HCPCS Code T1015 and any appropriate detail code(s) with modifier GT.
Provider rendering the service must be a physician who has completed an approved general or child/adolescent psychiatry residency program.
Reimbursement will be the facility's medical encounter rate.

Example 4

Originating Site – Encounter clinic
Bill the encounter HCPCS Code T1015 and any appropriate detail code(s) with modifier GT.
Reimbursement will be the facility's medical encounter rate.

Distant Site – Physician's office
There is no billable service; the Originating Encounter clinic is responsible for payment to the Distant Encounter clinic provider.
Provider rendering the service must be a physician who has completed an approved general or child/adolescent psychiatry residency program.

Private Insurance

Since Illinois does not mandate that telemedicine services be covered via health insurance, it is up to the individual companies to decide whether or not to offer it as a covered service. As a result, your hospital will need to contact private insurance companies and negotiate a reimbursement rate for services provided via telemedicine.

Contractual Arrangements

Most Illinois rural hospitals enter into a capitated financial arrangement with a distant provider to pay per consultation, while some pay for a number of hours per month, regardless of demand. In this arrangement, the originating site pays the

distant site for the service and submits the reimbursement form for their portion of the reimbursement. Although the cost of the consultation may be higher than the reimbursement, rural hospitals do save transportation costs associated with patient transfers and keeps the patient local for pharmacy and rehabilitative services. Most importantly, patients can receive a higher level of care without leaving their community than would be available without telemedicine.

Step 4: Identify Program Expenses

Based upon the design of the telemedicine program, the team will need to assess start-up and ongoing costs of the program including: equipment, technology, software, staff time and training, credentialing/licensing, facility preparation, legal costs associated with contract development, consulting services, and evaluation of the program. If you choose to use a vendor during the planning phase of the project, you can consult with the vendor on the costs associated with the project.

The team should also project the costs associated with integrating telemedicine programs into the quality improvement initiatives and health information technology planning underway within the hospital. Staff time and planning will need to be included to ensure telemedicine services are integrated into the existing hospital system and that hospital protocols are adequately integrated into the telemedicine program.

While the analysis of the component costs of the telemedicine program will result in the determination of a hospital "charge" for the service, insurance payments will be dictated by the specific terms governing the patient's insurance. The difference between the hospital's charge to the patient for this service and the amount ultimately paid is known as a "contractual adjustment" or "contractual allowance."

IMPLEMENTING & EVALUATING YOUR PROGRAM

Step 5: Implement the Program

Before you officially launch your telemedicine project, you may want to test the program with the distant site. A mock consultation should be facilitated to test the equipment, participating staff, and the connections. The more you can learn from these initial encounters the better off you will be when you start to treat patients on a regular basis. The following is a brief checklist of issues that will need to be finalized for the implementation of your telemedicine project:

- Is the facility space ready for patients?
- Are your EMR systems connected with the telemedicine project?
- Are contracts/agreements with distant sites finalized and executed?
- Are the equipment, room and technology ready at your distant partner site?
- Are the contracts with vendors finalized and executed?
- Is your staff fully educated and trained to operate the necessary systems?
- Is your financial division ready and able to bill for telemedicine services?
- Have you properly tested the equipment in a case study?
- Have you properly tested the staff's ability to utilize the technology in a case study?
- Have you developed a process to measure, track, and evaluate your program?
- Have you begun to schedule appointments?

Further monitoring and evaluation will be necessary at this point to ensure you continually adapt your program to meet your patients' needs.

Step 6: Evaluate the Program

The team will need to develop an evaluation process for the telemedicine program. Based upon the goals of the program, the team will develop anticipated outcomes and indicators to measure progress towards the goals. The key to any effective evaluation tool is measurable criteria. There must be clearly identifiable and measurable evaluation criteria that can identify program goals, objectives and outcomes. The evaluation should be both quantitative and qualitative. The following are examples of some general criteria that can be used to evaluate the progress and success of your telemedicine project:

- Number of patients served by telemedicine services;

- Number of telemedicine consults;
- Number of employees trained to use telemedicine;
- Number of practitioners providing telemedicine consults;
- Average amount of reimbursement per consult;
- Average cost of telemedicine consults;
- The number of scheduled appointments or telemedicine procedures;
- Number of ED visits by telemedicine consumers;
- Number of inpatient hospitalizations by telemedicine consumers;
- Patient satisfaction surveys; and
- Provider satisfaction surveys.

The team will need to develop tools to evaluate patient and provider satisfaction and to collect data related to the users of telemedicine services. The team should integrate changes into the telemedicine program based upon consumer and provider feedback. Depending on the scope of your project, a regular meeting schedule should be developed for the telemedicine team to monitor and evaluate the progress of the project.

The evaluation and monitoring meetings are important, allowing you to make timely adjustments to improve the performance of your telemedicine project. While measurable criteria are central to evaluation, regular monitoring and evaluation meetings will also afford stakeholders the opportunity to address other qualitative aspects of the program.

APPENDIX A

State of Illinois
Professional Healthcare Shortage Areas

AREAS OF ILLINOIS HAVING STATE PHYSICIAN SHORTAGE AREAS AND/OR FEDERAL HEALTH PROFESSIONAL SHORTAGE AREAS IDENTIFIED BY ILLINOIS DEPARTMENT OF PUBLIC HEALTH, CENTER FOR RURAL HEALTH

	STATE DESIGNATION				**FEDERAL HPSA DESIGNATION**			
	Entire County Designated		Service Area Name or Population Group	Last Updated	Entire County Designated		Service Area Name or Population Group	Last Updated
COUNTY	Yes	No			Yes	No		
Adams		x			x		Medicaid Eligible	11/14/2011
Alexander	x			8/27/08	x			08/14/2012
Bond	x			8/18/08	x		Low income	06/19/2012
Boone		x		4/6/2010	Partial		Low inc - Belvidere	4/6/2010
Brown	x			9/5/08	x			06/19/2012
Bureau	x			12/17/10	x		Low Income	2/8/11
Calhoun	x			9/3/08	x			08/23/2012
Carroll	x			2/7/07	x			02/29/2012
Cass	x			6/19/07	x			02/01/2012
Champaign	Partial		1. Mahomet SA (Brown,Condit,East Bend,Hensley,Mahomet,Newcomb,Scott) 2. Rantoul SA (Compromise,Harwood,Kerr,Ludlow,Rantoul) 3. Philo SA (Ayers,Colfax,Crittenden,Pesotum,Philo,Raymond,Sadorus,Sidney ,South Homer,Tolono)	1. 8/18/08 2. 8/18/08 3. 8/18/08	x		Low income	08/01/2011
Christian	x			2/9/07	x		Low income	06/19/2012
Clark	x			1/30/08	x		Low Income	08/14/2012
Clay	x			10/31/07	x			06/20/2012
Clinton	x			4/25/08	x			8/19/08
Coles		x		8/29/08	x		Low Income	11/14/2011
Cook	Partial		Call the Center for Rural Health for assistance, (217) 782-1624.		Partial		Go to HPSA listing Go to online map	
Cook (facilities only)	x		Resurrection Family Practice Center 7447 W Talcott, Chicago 60631	11/16/09				
Crawford	x			8/28/08	x		Low Income	06/07/2012
Cumberland	x			8/19/08	x		Low Income	08/17/2012
De Kalb	Partial		1. Sandwich SA (Afton, Clinton, Milan, Paw Paw, Sandwich, Shabbona, Somonauk, Victor townships)	1. 4/26/06	Partial		1. Mendota Service Area 2. Low Income DeKalb Service Area	1. 10/13/10 2. 5/15/2012
DeWitt	x			5/24/2010	x			12/21/2011
Douglas	x			2/9/07	x			04/13/2012
Edgar	x			1/30/08	x		Low Income	08/14/2012
Edwards	x			8/5/10	x		Low Income	11/9/2010
Effingham	Partial		1. Altamont SA (Banner, Jackson, Liberty, Mason, Moccasin, Mount, Summit & West townships) 2. Watson SA (Bishop, Lucas, Union & Watson townships)	1. 8/18/08 2. 8/18/08	x		Medicaid Eligible	04/17/2012
Fayette	x			6/22/06	x			05/05/2011
Ford	Partial		Paxton SA	11/8/06	Partial		Low Income -	02/04/2011

			(Button, Dix, Lyman, Patton, Peach Orchard and Wall townships)				Artesia/Loda/Pigeon Grove	
Franklin	x			10/19/06	x		Low income	05/18/2011
Fulton	x			7/20/2010	x		Low Income	10/29/2010
Gallatin	x			8/12/08	x			08/14/2012
Greene	x			8/18/08	x		Low income	06/19/2012
Grundy	Partial		Minooka SA (Aux Sable township)	9/7/06		x		
Hamilton	x			11/14/06	x			12/21/2011
Hancock	x			9/14/06	x		Low income	06/16/2011
Hardin	x			8/21/08	x			06/19/2012
Henderson	x			12/28/09	x			4/6/2010
Henry	x			8/20/08	x			08/14/2012
Iroquois	x			8/12/08	Partial		Hoopeston Service Area	09/08/2011
Iroquois, continued					Partial		Low Inc - Watseka Service Area	2/22/2011
Iroquois, continued					Partial		Low Income -Artesia/ Loda/Pigeon Grove Service Area	2/4/11
Jackson		x		7/21/2010	Partial		Low Income	10/19/2010
Jasper	x			6/9/09	x		Low income	04/24/2012
Jefferson		x			x		Medicaid Eligible	10/18/2011
Jersey	x			9/3/08	x			08/23/2012
JoDaviess	x			3/7/06	x		Low income	05/22/2012
Johnson	x			2/7/07	x			02/29/2012
Kane	Partial		Hampshire SA (Burlington, Hampshire, Plato, Rutland townships)	8/13/08	Partial		1. Low Inc - Aurora Service Area 2. Low Inc-Elgin Service Area 3. Hampshire Service Area	1.05/15/2012 2.05/16/2012 3.11/4/08
Kankakee	Partial		1. Momence SA (Ganeer, Momence, Yellowhead townships) 2. Pembroke SA (Pembroke and St. Anne townships) 3. Herscher SA (Essex, Limestone, Norton, Otto, Pilot, Salina townships)	1. 6/17/05 2. 6/20/06 3. 2/12/09	x		Medicaid Eligible	07/18/2011
Kendall	x			9/29/06		x		
Knox	x			4/16/08	x		Low income	06/19/2012
Lake		x			Partial		Low Inc - Waukegan/Zion/Benton Service Area	05/15/2012
LaSalle	x			2/22/08	Partial		1. Mendota Service Area 2. Low Inc-Peru Service Area 3, Streator Service Area	1.10/13/10 2.3/20/08 3.10/12/2012
Lawrence	x			1/2/07	x		Low income	02/13/2012
Lee	Partial		Ashton SA (Alto, Amboy, Ashton, Bradford, Brooklyn, China, Lee Center, May, Reynolds, Sublette, Viola, Willow Creek, Wyoming)	9/1/06	Partial		1. Low Inc - Dixon Service Area 2. Mendota Service Area	1.03/15/2012 2.10/13/2010
Livingston	x			11/19/08	Partial		1. Streator Service Area 2. Low Inc -	1.03/20/2008 2.02/04/201

							Artesia/Loda/Pigeon Grove Service Area	1
Logan	x			9/2/09	x		Low income	03/23/2011
Macon	Partial		Blue Mound/Macon/Mt. Zion SA (Blue Mound, Milam, Mount Zion, Pleasant View, South Macon, South Wheatland townships)	7/18/08	Partial		Low Inc - Decatur City Service Area	04/18/2012
Macoupin	x			6/29/07	x			12/28/2011
Madison	Partial		Highland S.A. (Alhambra, Hamel, Helvetia, Jarvis, Leef, Marine, New Douglas, Olive, Omphghent, Pin Oak, Saline, St. Jacob townships)	9/16/08	Partial		1. Low Inc - Alton / Wood River Service Area 2. Highland Service Area	1.04/10/2008 2.12/23/2008
Marion		x			x		Low income	11/14/2011
Marshall	x			01/19/2011	x			10/12/2011
Mason	x			8/12/2010	x			11/9/2010
Massac	x			2/7/07	x		Low income	03/22/2012
McDonough	x			5/18/2010	x		Low income	06/20/2012
McHenry	Partial		Marengo SA (Marengo, Seneca, Riley and Coral townships)	8/29/08		x		
McLean	Partial		1. Chenoa SA (Anchor, Blue Mound, Chenoa, Cropsey, Gridley, Hudson, Lawndale, Lexington, Martin, Money Creek, Towanda, Yates townships) 2. Le Roy SA (Arrowsmith, Bellflower, Cheneys Grove, Dawson, Downs, Empire, Old Town & West townships)	1. 7/21/08 2. 7/21/08	Partial		Low income - Bloomington-Normal Service Area	04/18/2012
Menard	x			5/17/07	x			12/22/2011
Mercer	x			8/2/2010	x			11/8/2010
Monroe	x			12/13/07	Partial		Chester/Red Bud Service Area	9/25/09
Montgomery	x			8/12/08	x		Low Income	1/28/09
Morgan		x		6/11/2010	x		Low Income	9/28/10
Moultrie	x			2/9/07	x			08/18/2011
Ogle	x			3/24/10	x			10/12/2011
Peoria	Partial		Chillicothe SA (Akron, Brimfield, Chillicothe, Hallock, Jubilee, Medina, Millbrook, Princeville, Radnor townships)	7/18/08	x		Medicaid Eligible	09/29/2011
Perry	x			12/18/08	x		Low income	01/17/2012
Piatt	x			5/3/07	x			03/15/2012
Pike	x			12/26/07	x			3/20/08
Pope	x			8/21/08	x			06/19/2012
Pulaski	x			8/27/08	x			08/14/2012
Putnam	x			12/17/10	x		Low income	2/8/11
Randolph	Partial		Red Bud SA (Bremen, Brewerville, Chester, Ellis Grove, Evansville, Kaskaskia, Palestine, Prairie de Rocher, Red Bud, Rockwood, Ruma, Wine Hill townships)	7/20/09	Partial		1 Chester/Red Bud Service Area 2. Low Income Sparta Service Area	1. 9/25/09 2.08/06/2010
Randolph, cont.	Partial		Sparta SA (Coulterville, Tilden, Baldwin, Walsh, Central, Sparta, Percy, Steeleville, Blair, Palestine, Bremen, Wine Hill townships)	2/7/08				
Richland		x		1/7/08	x		Low income	06/19/2012
Rock Island		x		8/5/10	Partial		Low income-Rock Island Service Area	06/19/2012
Saline		x		8/8/08	x		Low Income	1/28/09
Sangamon	Partial		1. Auburn SA (Auburn, Divernon, Pawnee, Talkington) 2. New Berlin SA	1. 7/18/08 2. 7/18/08	x		Low Income	06/28/2011

			(Cartwright, Island Grove, Loami, Maxwell, New Berlin)					
Schuyler	x			6/19/07	x			02/01/2012
Scott	x			12/26/07	x			3/20/08
Shelby	x			1/2/08	x			06/07/2012
St. Clair	Partial		1. East St. Louis SA (Canteen, Centreville, East St. Louis, Stites townships) 2. Marissa SA (Engleman,Fayetteville,Freeburg, Lenzburg, Marissa, Millstadt, New Athens, Prairie DuLong, Smithton townships)	1. 2/9/07 2. 7/18/08	Partial		1.East St. Louis Service Area 2.Low Income - Sparta Service Area	1.02/29/2012 2.08/06/2010
Stark	x			8/20/08	x			08/14/2012
Stephenson		x		8/29/08	x		Low income	04/17/2012
Tazewell		x		8/5/10	Partial		Low Inc - East Peoria/Pekin Service Area	05/15/2012
Union		x			x		Low income	06/16/2011
Vermilion	x			11/14/08	Partial		1. Hoopeston Service Area 2. Low Income-Danville Service Area	1.09/08/2011 2.9/22/09
Wabash	x			8/5/10	x		Low income	11/9/2010
Warren	x			8/13/08	x		Low income	1/28/09
Washington	x			9/20/06	x			01/04/2011
Wayne		x		8/5/10	x		Low income	06/07/2012
White	x			8/20/08	x		Low income	2/23/09
Whiteside	Partial		Morrison S.A. (Albany, Clyde, Erie, Fenton, Fulton, Garden Plain, Genesee, Hopkins, Lyndon, Mount Pleasant, Newton, Portland, Prophetstown, Union Grove, Ustick))	11/19/07	x		Low income	05/04/2012
Will	Partial		1. East Side Joliet S.A. (Census tracts 8812, 8813, 8819-8825, 8830, 8831) 2. Channahon SA (Channahon, Jackson, Manhattan, Wilton, Florence, Wilmington, Reed, Custer, Wesley townships)	1. 9/16/09 2. 2/7/07	Partial		East Side Joliet Service Area	9/16/09
Will, continued	Partial		Crete SA (Crete, Monee, Green Garden, Peotone, Will and Washington townships)	2/7/07				
Williamson		x		9/24/09	x		Low Income	12/23/2009
Winnebago	Partial		1. Pecatonica S.A. (Burritt, Durand, Harrison, Laona, Pecatonica, Seward, Shirland, Winnebago townships) 2. Roscoe SA (Harlem, Owen, Rockton, Roscoe townships)	1. 7/18/08 2. 2/17/09	Partial		Low Inc - Rockford Westside Service Area	04/20/2012
Woodford	x			6/26/09	x			9/17/09

***** - Indicates service area or population group with underserved designation

P - Partial county designation for service area, population group or facility

APPENDIX B

Illinois Hospital Survey & Results
2011

Telemedicine Needs Assessment Survey
June 14, 2011

Please answer the following questions to the extent possible.

1. Have you used telemedicine technology to deliver care? **Yes** **No**
   If yes, in what clinical specialties? ______________________

2. Is your hospital a member of a health care system? **Yes** **No**
   If yes, does your system utilize telemedicine to provide clinical services to member hospitals? **Yes** **No**
   For teleconferencing? **Yes** **No**

3. What are the medical specialties that are currently available in your area (**please circle all that apply**)?

Psychiatry, Neurology, Stroke, Dermatology, Cardiology, General Surgery, Urology, Orthopedics, Pulmonary, ENT, Pediatric Specialties, Endocrinology/Diabetes Mgmt., Oncology, Burn/Wound, Plastic Surgery, Other ______________________

4. Does your hospital have hospitalists? **Yes** **No** An ICU? **Yes** **No**
   Do you currently have physician manpower shortages in these areas? **Yes** **No**

5. Would you value a telemedicine service that offers multiple specialty services for a monthly on-call fee and upfront purchase of consults (roll over if unused)? **Yes** **No**

6. Would you value telemedicine training for your staff regarding process, procedures, and care protocol development? **Yes** **No**

7. What specialties would you find most useful (**please circle all that apply**)?

Psychiatry, Neurology, Stroke, Dermatology, Cardiology, General Surgery, Urology, Orthopedics, Pulmonary, ENT, Pediatric Specialties, Endocrinology/Diabetes Management, Oncology, Burn/Wound, Plastic Surgery, Other ______________________

8. What questions do you have about telemedicine regarding reimbursement, credentialing, or operations/implementation?

____

____

9. Do you have any concerns related to telemedicine services?

____

____

Feel free to include, on the following page, the contact information (name and email address) for the staff member at your facility that would be open to communication with SIU regarding additional needs analysis data.

Hospital Name:____

Contact Name: ____

Title: ____

Type of Data Collected: ____________________________________

Email: ____

Telephone: ____

SIU School of Medicine

Telemedicine Email Survey Summary
07-13-2011

Overview
Executive staff members of small and rural hospitals were asked to complete a survey focusing on the need for telemedicine services at their respective facilities. A total of 32 surveys were returned. The information listed below includes the on-site and email survey results. This review is for informational purposes and should not be viewed as a comprehensive analysis.

Survey Results (n=32)
60% of CAH have not used telemedicine to deliver care. Seven of the 13 hospitals that are active in telemedicine use the service for radiology only. Four hospitals use telemedicine for psychiatry services, one hospital participates in eICU telemedicine services and one hospital participates in occupational telemedicine and telestroke services.

Top On-Site Specialty Services	**Top Requests for Telemedicine Services**
Cardiology (28)	Psychiatry (22 requests)
General Surgery (28)	Endocrinology and Diabetes Management (15 requests)
Orthopedics (25)	Dermatology (13 requests)
Oncology (21)	Peds (10 requests)
	Stroke (9 requests)

Cardiology, general surgery and ICU were the least requested telemedicine services (one request, respectively). 72% of respondents would value a telemedicine service that offers multiple specialty services for a monthly on-call fee and upfront purchase of consults. 84% of respondents would value telemedicine training regarding process, procedures and care protocol development.

APPENDIX C

American Telemedicine Association Definition List

Telemedicine Services

- **Specialist referral services** typically involve a specialist assisting a general practitioner in rendering a diagnosis. This may involve a patient "seeing" a specialist over a live, remote consult or the transmission of diagnostic images and/or video along with patient data to a specialist for viewing later. Recent surveys have shown a rapid increase in the number of specialty and subspecialty areas that have successfully used telemedicine. Radiology continues to make the greatest use of telemedicine with thousands of images "read" by remote providers each year. Other major specialty areas include: dermatology, ophthalmology, mental health, cardiology, and pathology. According to reports and studies, almost 50 different medical subspecialties have successfully used telemedicine.

- **Patient consultations** using telecommunications to provide medical data, which may include audio, still or live images, between a patient and a health professional for use in rendering a diagnosis and treatment plan. This might originate from a remote clinic to a physician's office using a direct transmission link or may include communicating over the web.

- **Remote patient monitoring** uses devices to remotely collect and send data to a monitoring station for interpretation. Such "home telehealth" applications might include a specific vital sign, such as blood glucose or heart ECG or a variety of indicators for homebound patients. Such services can be used to supplement the use of visiting nurses.

- **Medical education** provides continuing medical education credits for health professionals and special medical education seminars for targeted groups in remote locations.

- **Consumer medical and health information** includes the use of the Internet for consumers to obtain specialized health information and on-line discussion groups to provide peer-to-peer support.

Delivery Mechanisms

- **Networked programs** link tertiary care hospitals and clinics with outlying clinics and community health centers in rural or suburban areas. The links may use dedicated high-speed lines or the Internet for telecommunication links between sites. Studies by the several agencies within the U.S. Department of Health and Human Services, private vendors and assessments by ATA of its membership place the number of existing telemedicine networks in the United States at roughly 200. These programs involve close to 2,000 medical institutions

throughout the country. Of these programs, it is estimated that about half (100) are actively providing patient care services on a daily basis. The others are only occasionally used for patient care and are primarily for administrative or educational use.

- **Point-to-point connections** using private networks are used by hospitals and clinics that deliver services directly or contract out specialty services to independent medical service providers at ambulatory care sites. Radiology, mental health and even intensive care services are being provided under contract using telemedicine to deliver the services.
- **Primary or specialty care to the home connections** involves connecting primary care providers, specialists and home health nurses with patients over single line phone-video systems for interactive clinical consultations.
- **Home to monitoring center** links are used for cardiac, pulmonary or fetal monitoring, home care and related services that provide care to patients in the home. Often normal phone lines are used to communicate directly between the patient and the center although some systems use the Internet.
- **Web-based e-health patient service sites** provide direct consumer outreach and services over the Internet. Under telemedicine, these include those sites that provide direct patient care.

APPENDIX D

State of Illinois Telemedicine Laws

(225 ILCS 60/49.5)

The State of Illinois has limited statute or administrative rules applied to telemedicine services. The law that established telemedicine as a viable medical practice can be found in the Illinois Statutes at 225 ILCS 60/49.5. This brief acknowledgement to telemedicine is located in the Medical Practice Act of 1987. Telemedicine is also referenced in the State's Medicaid regulations. These regulations deal primarily with how the State will reimburse for telemedicine services through the Medicaid program. These regulations can be found in Title 89, Section 140.403 of the Illinois Administrative Code which covers medical payments to social service entities. The following is a link to this section of the Illinois Administrative Code:

http://www.ilga.gov/commission/jcar/admincode/089/089001400D04030R.html

Check with the Illinois Department of Public Health and the Illinois Department of Healthcare and Family Services before implementing a new telemedicine program to ensure that programmatic changes have not occurred since the publication of this guide in November 2012.

(225 ILCS 60/49.5)

(Section scheduled to be repealed on December 31, 2012)

Sec. 49.5. Telemedicine.

(a) The General Assembly finds and declares that because of technological advances and changing practice patterns the practice of medicine is occurring with increasing frequency across state lines and that certain technological advances in the practice of medicine are in the public interest. The General Assembly further finds and declares that the practice of medicine is a privilege and that the licensure by this State of practitioners outside this State engaging in medical practice within this State and the ability to discipline those practitioners is necessary for the protection of the public health, welfare, and safety.

(b) A person who engages in the practice of telemedicine without a license issued under this Act shall be subject to penalties provided in Section 59.

(c) For purposes of this Act, "telemedicine" means the performance of any of the activities listed in Section 49, including but not limited to rendering written or oral opinions concerning diagnosis or treatment of a patient in Illinois by a person located outside the State of Illinois as a result of transmission of individual patient data by telephonic, electronic, or other means of communication from within this State. "Telemedicine" does not include the following:

(1) periodic consultations between a person licensed

under this Act and a person outside the State of Illinois;

(2) a second opinion provided to a person licensed

under this Act; and

(3) diagnosis or treatment services provided to a patient in Illinois following care or treatment originally provided to the patient in the state in which the provider is licensed to practice medicine.

(d) Whenever the Department has reason to believe that a person has violated this Section, the Department may issue a rule to show cause why an order to cease and desist should not be entered against that person. The rule shall clearly set forth the grounds relied upon by the Department and shall provide a period of 7 days from

the date of the rule to file an answer to the satisfaction of the Department. Failure to answer to the satisfaction of the Department shall cause an order to cease and desist to be issued immediately.

(e) An out-of-state person providing a service listed in Section 49 to a patient residing in Illinois through the practice of telemedicine submits himself or herself to the jurisdiction of the courts of this State.

(Source: P.A. 90-99, eff. 1-1-98.)

APPENDIX E

Benefits Improvement and Protection Act of 2000

FEDERAL LAW:

The overarching federal telemedicine law was adopted in the Benefits Improvement and Protection Act of 2000. The portion of the Act that pertains to telemedicine can be found in Section 223. The following is the text of this legislation:

SEC. 223. REVISION OF MEDICARE REIMBURSEMENT FOR TELEHEALTH SERVICES.
(a) TIME LIMIT FOR BBA PROVISION- Section 4206(a) of BBA (42 U.S.C. 1395l note) is amended by striking `Not later than January 1, 1999' and inserting `For services furnished on and after January 1, 1999, and before October 1, 2001'.
(b) EXPANSION OF MEDICARE PAYMENT FOR TELEHEALTH SERVICES- Section 1834 (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:
(m) PAYMENT FOR TELEHEALTH SERVICES-
(1) IN GENERAL- The Secretary shall pay for telehealth services that are furnished via a telecommunications system by a physician (as defined in section 1861(r)) or a practitioner (described in section 1842(b)(18)(C)) to an eligible telehealth individual enrolled under this part notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary. For purposes of the preceding sentence, in the case of any Federal telemedicine demonstration program conducted in Alaska or Hawaii, the term `telecommunications system' includes store-and-forward technologies that provide for the asynchronous transmission of healthcare information in single or multimedia formats.
(2) PAYMENT AMOUNT-
(A) DISTANT SITE- The Secretary shall pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system.
(B) FACILITY FEE FOR ORIGINATING SITE- With respect to a telehealth service, subject to section 1833(a)(1)(U), there shall be paid to the originating site a facility fee equal to--
(i) for the period beginning on October 1, 2001, and ending on December 31, 2001, and for 2002, $20; and
(ii) for a subsequent year, the facility fee specified in clause (i) or this clause for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year.
(C) TELEPRESENTER NOT REQUIRED- Nothing in this subsection shall be construed as requiring an eligible telehealth individual to be presented by a physician or practitioner at the originating site for the furnishing of a service via a telecommunications system, unless it is medically necessary (as determined by the physician or practitioner at the distant site).
(3) LIMITATION ON BENEFICIARY CHARGES-
(A) PHYSICIAN AND PRACTITIONER- The provisions of section 1848(g) and subparagraphs (A) and (B) of section 1842(b)(18) shall apply to a physician or practitioner receiving payment under this subsection in the same manner as they apply to physicians or practitioners under such sections.
(B) ORIGINATING SITE- The provisions of section 1842(b)(18) shall apply to originating sites receiving a facility fee in the same manner as they apply to practitioners under such section.
(4) DEFINITIONS- For purposes of this subsection:
(A) DISTANT SITE- The term `distant site' means the site at which the physician or practitioner is located at the time the service is provided via a telecommunications system.
(B) ELIGIBLE TELEHEALTH INDIVIDUAL- The term `eligible telehealth individual' means an individual enrolled under this part who receives a telehealth service furnished at an originating site.
(C) ORIGINATING SITE-
(i) IN GENERAL- The term `originating site' means only those sites described in clause (ii) at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system and only if such site is located--
(I) in 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));
(II) in a county that is not included in a Metropolitan Statistical Area; or

(III) from an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000.
(ii) SITES DESCRIBED- The sites referred to in clause (i) are the following sites:
(I) The office of a physician or practitioner.
(II) A critical access hospital (as defined in section 1861(mm)(1)).
(III) A rural health clinic (as defined in section 1861(aa)(s)).
(IV) A Federally qualified health center (as defined in section 1861(aa)(4)).
(V) A hospital (as defined in section 1861(e)).
(D) PHYSICIAN- The term `physician' has the meaning given that term in section 1861(r).
(E) PRACTITIONER- The term `practitioner' has the meaning given that term in section 1842(b)(18)(C).
(F) TELEHEALTH SERVICE-
(i) IN GENERAL- The term `telehealth service' means professional consultations, office visits, and office psychiatry services (identified as of July 1, 2000, by HCPCS codes 99241-99275, 99201-99215, 90804-90809, and 90862 (and as subsequently modified by the Secretary)), and any additional service specified by the Secretary.
(ii) YEARLY UPDATE- The Secretary shall establish a process that provides, on an annual basis, for the addition or deletion of services (and HCPCS codes), as appropriate, to those specified in clause (i) for authorized payment under paragraph (1).'.
(c) CONFORMING AMENDMENT- Section 1833(a)(1) (42 U.S.C. 1395l(1)), as amended by section 105(c), is further amended--
(1) by striking `and (T)' and inserting `(T)'; and
(2) by inserting before the semicolon at the end the following: `, and (U) with respect to facility fees described in section 1834(m)(2)(B), the amounts paid shall be 80 percent of the lesser of the actual charge or the amounts specified in such section'.
(d) STUDY AND REPORT ON ADDITIONAL COVERAGE-
(1) STUDY- The Secretary of Health and Human Services shall conduct a study to identify--
(A) settings and sites for the provision of telehealth services that are in addition to those permitted under section 1834(m) of the Social Security Act, as added by subsection (b);
(B) practitioners that may be reimbursed under such section for furnishing telehealth services that are in addition to the practitioners that may be reimbursed for such services under such section; and
(C) geographic areas in which telehealth services may be reimbursed that are in addition to the geographic areas where such services may be reimbursed under such section.
(2) REPORT- Not later than 2 years after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under paragraph (1) together with such recommendations for legislation that the Secretary determines are appropriate.
(e) EFFECTIVE DATE- The amendments made by subsections (b) and (c) shall be effective for services furnished on or after October 1, 2001.

The following are some valuable resources to learn new national developments in the world of telemedicine regulation:

- atawiki – a Wikipedia-style website devoted to telemedicine issues - **http://wiki.americantelemed.org/index.php?title=Main_Page**

- Center for Telehealth and e-Health Law (CTEL) – An organization dedicated to legal and regulatory telehealth issues - **http://ctel.org/**

APPENDIX F

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.

[Federal Register Volume 76, Number 87 (Thursday, May 5, 2011)]
[Rules and Regulations]
[Pages 25550-25565]
From the Federal Register Online via the Government Printing Office [www.gpo.gov]
[FR Doc No: 2011-10875]
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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 Sec. 482.12(a)(2) and Sec. 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 (Sec. 482.12 and Sec. 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: Sec. 482.12, ``Governing body,'' and Sec. 482.22, ``Medical staff.''

For the Governing body CoP, we proposed to add a new paragraph, Sec. 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 Sec. 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 Sec. 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 Sec. 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 Sec. 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 (Sec. 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 Sec. 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 Sec. 482.12(a)(8) and Sec. 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 (Sec. 482.12(a)(9) and Sec. 482.22(a)(4) for hospitals; Sec. 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 Sec. 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 Sec. 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 Sec. 485.635(c)(4)) that, like Sec. 482.12(e) for hospitals, pertains to contactors 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 Sec. 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

Sec. 485.635(c)(1). Therefore, in this final rule, we are adding a new paragraph at Sec. 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 Sec. 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 comment'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 Sec. 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 (Sec. 485.616 and Sec. 485.641)

We proposed to make revisions to the CAH CoPs at Sec. 485.616, ``Agreements,'' and Sec. 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 Sec. 485.616(c). At Sec. 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 Sec. 482.12(a). This language delineates the responsibilities of the governing body for the professional staff privileging process.

At Sec. 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 Sec. 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 (Sec. 482.12(a)(9) and Sec. 482.22(a)(4) for hospitals; Sec. 485.616(c)(3) and Sec. 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 Sec. 482.12(a)(1) through Sec. 482.12(a)(7) and Sec. 482.22(a)(1) through Sec. 482.22(a)(2) for hospitals, and at Sec. 485.616(c)(1)(i) through Sec. 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 Sec. 482.22(c)(6) and Sec. 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 Sec. 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 Sec. 485.635(c)(1). We have added a new paragraph at Sec. 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 (Sec. 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 Sec. 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 Sec. 482.12(a)(8).

B. ICRs Regarding Condition of Participation: Medical Staff (Sec. 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 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) 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 Sec. 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 Sec. 482.22(a)(4)(i) through (iv) are met. Specifically, Sec. 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 hold 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 Sec. 482.22(a)(3).

C. ICRs Regarding Condition of Participation: Agreements (Sec. 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 Sec. 485.616(c)(1)(i) through (vii) and Sec. 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 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) 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 Sec. 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 Sec. 485.616(c)(4)(i) through (iv) are met. The burden associated with this third-party disclosure requirement at Sec. 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 Sec. 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 (S)	Total Cost ($)
Sec.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
Sec.482.22(a)(3)and (4).....	0938-New	4,860	155,520	1	155,520	34	5,287,680	0	5,287,680
Sec.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
Sec.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

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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 (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	....

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Therefore, we estimate the total initial cost to develop the agreement for all 4,860 hospitals to be $9.7 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	$86	12	$1,032	....
Physician	103	4	412	$1,996
Hospital Administrator	69	5	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 cost to develop the agreement for all 1,314 CAHs to be $2.6 million. The annual cost to review agreements for all CAHs is estimated at $678,024.

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 annual cost to prepare and send individual performance reviews for telemedicine services (third-party disclosure) for all 4,860 hospitals to be $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

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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

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

Sec. 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 Sec. 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 Sec. 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 Sec. 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.

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Subpart C--Basic Hospital Functions

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3. Section 482.22 is amended by--

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A. Adding new paragraphs (a)(3) and (a)(4).

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B. Revising paragraph (c)(6).

The addition and revision read as follows:

Sec. 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 Sec. 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 Sec. 482.12(a)(1) through (a)(7) and Sec. 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 Sec. 482.12(a)(8) and (a)(9), and Sec. 482.22(a)(3) and (a)(4).

* * * * *

PART 485--CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

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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)

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

Sec. 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 Sec. 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.

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

Sec. 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.

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

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

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(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

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(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