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December 22, 2011

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Reference file code CMS–3244–P

Dear Acting Administrator Tavenner:

We urge CMS to revise Medicare's Conditions of Participation for hospitals (42 CFR 482) to address new needs and opportunities for patient safety and quality of care.

24/7/365 Staffing for Key Services

Hospitals that create and operate special services should be expected to assure that such services are sufficient, appropriate, and always available for those patients with critical and immediate needs. Congress and CMS have recognized the importance of this for safety and quality through such laws and regulations as the Emergency Medical Treatment and Active Labor Act (EMTALA). With over twenty years of experience using telemedicine to access remote medical expertise in thousands of health facilities throughout the country, the time is right (if not overdue) to update the conditions of participation accordingly.

Such a change will have the unique result of proving beneficial for patients, providers and hospitals.

- Patients will benefit from the ability to access emergency and specialist care whenever needed.
- Providers will be able to provide such services without having to travel in to the facility in the middle of the night or travel long distances.
- Hospitals will be able to efficiently provide such services in off hours through sharing arrangements with other facilities reducing the burden of duplicative and costly staffing.

1. Amend 42 CFR 482.55 on emergency services

The change suggested here **does not** create a new standard of participation or require the use of telemedicine but provides the opportunity for a facility to meet certain standards through the use of video conferencing or other appropriate forms of telemedicine. This will allow facilities to significantly lift the burden of maintaining on site staffing on a continuous basis.

We recommend that 42 CFR 482.55 be amended under (b) *Standard: Personnel* to add the text in boldface to read:

> (2) There must be adequate medical and nursing personnel qualified in emergency care**, available in-person or by video conferencing,** to meet the written emergency procedures and needs anticipated by the facility.

2. Amend 42 CFR 482.55 to allow hospitals to provide access for stroke care

According to the National Stroke Association:

> "researchers estimate that up to 40 percent of stroke patients could have improved outcomes based on use of tissue plasminogen activator (tPA), actual rates of use remain stubbornly low. This is especially true for stroke patients who live in more rural settings, where distances to hospitals can significantly impact time to treatment. Access to the medical specialists required for evidence-based stroke care is limited to larger urban centers, and there are significant disparities in access to specialty care across the United States. The recently published Acute Cerebrovascular Care in Emergency Stroke Systems (ACCESS) study concluded that only about 50 percent of the U.S. population has timely access to a primary stroke center. Rural hospitals also lack knowledge about, and comfort with, thrombolytic therapy. It is important to note that similar problems are encountered in some suburban-based "community" hospitals where bed size (e.g., <200 beds) is associated with the absence of 24-7 neurology support, a key requirement for guidelines-based stroke care." (www.stroke.org)

Stroke is the third leading cause of death and leading cause of disability in the United States. The costs of stroke are astounding (taken from the University of Medicine and Dentistry of New Jersey based on multiple sources http://www.theuniversityhospital.com/stroke/stats.htm):

- The total cost of stroke to the United States is estimated at $43 billion per year.
- The direct costs of medical care and therapy are estimated at $28 billion per year.
- Indirect costs from lost productivity and other factors are estimated at $15 million per year.
- The average cost of care for a patient up to 90 days after stroke is $15,000.
- For 10 percent of patients, the cost of care for the first 90 days after a stroke is $35,000.

The percentage breakdown of the direct costs of care for the first 90 days after a stroke is:

Initial hospitalization – 43 percent
Rehabilitation – 16 percent
Physician costs – 14 percent
Hospital Readmission – 14 percent
Medications and other expenses – 13 percent

Providing accurate stroke diagnosis and treatment within the first golden hour has become a national priority. Yet hospitals are struggling to provide such care given the complexity of such diagnoses and the burden of providing access to stroke specialists for emergency cases. It is no

surprise that over the last ten years telestroke initiatives have been instituted in practically every state with the participation of virtually every major tertiary care center in the nation.

It is now time for CMS to take the next step to allow hospitals the use of telemedicine to eliminate the burden and cost of maintaining their own stroke specialists for every emergency room and allow patients access to the critical help they need. Accordingly, we recommend that 42 CFR 482.55 be amended to add the following new provision:

> (3) There must be adequate medical personnel, available in-person or by video conferencing, qualified in ischemic stroke diagnosis to order appropriate treatment including timely thrombolytic therapy where appropriate.

3. Add a new Condition of Participation regarding intensive and critical care services

Since intensive and critical care units are one of most important hospital activities for patient safety and quality of care, patients expect the existence of appropriately standards for hospitals choosing to offer such care. It is surprising that among the 29 sections of Part 482, there is no Condition of Participation for intensive and critical care services. There is only one pertinent reference to intensive care – a requirement for emergency power and lighting.

Sufficient staffing, even at night, on weekends, and on holidays, is a particular patient expectation. Telehealth is a valuable resource for meeting intensive and critical care patient needs, often unexpected – at all times.

Over ten years ago, the Leapfrog Group issued a recommendation, later endorsed by the National Quality Forum, calling for the use of intensive care unit (ICU) staffing by physicians experienced in critical care medicine. According to their study: "Staffing ICUs with doctors who have special training in critical care medicine, called 'intensivists', has been shown to reduce the risk of patients dying in the ICU by 40%." (source: Leapfrog Group Fact Sheet). Hospitals across the nation have struggled to meet this recommendation but face a heavy burden providing onsite intensivists for facilities with smaller number of beds such as a rural critical care hospital. Help is needed from CMS to make sure local facilities can use remote critical care services to augment local staff.

We recommend a new "482.58" provision, modeled on the emergency services provision:

> 482.58. Condition of participation: Intensive and critical care services.
> (a) Standard: Organization and direction. If designated intensive care or critical care are provided in a hospital—
> (1) The services must be organized under the direction of a qualified member of the medical staff;
> (2) The services must be integrated with other departments of the hospital;
> (3) The policies and procedures governing medical care provided are established by and are a continuing responsibility of the medical staff.
> (b) Standard: Personnel.

(1) The intensive and critical care must be supervised by a qualified member of the medical staff.
(2) There must be adequate medical and nursing personnel qualified in appropriate specialties, available in-person or by video conferencing, to meet the written emergency procedures and needs anticipated by the facility.

The recommendations contained in these three sections are practical standards for hospitals today and are reasonable Conditions of Participation for Medicare.

Discharge Planning to Address Readmission Risk

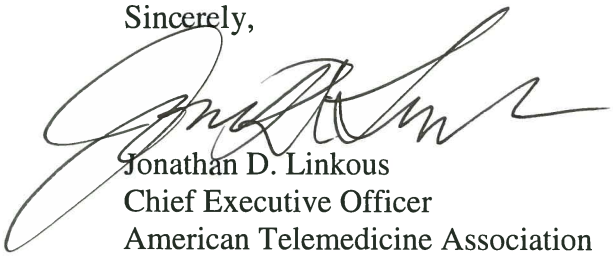
Despite some recent CMS changes, there are still powerful perverse incentives under Medicare payment methodology regarding avoidable readmissions.

To help hospital patients get appropriate care and to support hospital behavioral change, we recommend that section 42 CFR 482.43 that addresses discharge planning specifically include the patient's risk of readmission for the diagnosis by amending (b)(3) to add the text in boldface to read--

(3) The discharge planning evaluation must include an evaluation of the likelihood of a **patient's readmission for related care and** an evaluation of the likelihood of a patient needing post- hospital services and of the availability of the services.

The change suggested here **does not** create a new standard of participation or require the use of telemedicine but directs the discharge planning staff to assess the likelihood of a patient being readmitted to the hospital. Such a change will augment the priority of CMS to reduce unnecessary readmissions across the country.

Sincerely,



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