

March 5, 2010

Charlene Frizzera  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

**RE: CY 2010 revised policies for physician supervision of “incident to” outpatient therapeutic services**

Dear Ms. Frizzera:

We write today on behalf of Iowa patients and providers to request that CMS take immediate action regarding the direct physician supervision for outpatient therapeutic services policy included in the Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) final rule for calendar year 2010. We are concerned that, without action, this ruling could significantly impair access to medical services in our state, particularly in rural areas. Specifically, we request:

1. CMS instruct its contractors that no enforcement actions should be initiated or pursued regarding this policy, and
2. CMS change its direct physician supervision for outpatient therapeutic services policy when the 2011 rulemaking begins. We urge CMS to return to the former policy long understood by the hospital and physician communities by defining “direct supervision” to mean that the physician or non-physician practitioner (NPP) must be present on the same campus or in a location in close proximity to the campus and able to respond in a timely manner, in accordance with the hospital’s or critical access hospital’s policies, procedures, guidelines, and/or bylaws, so as to be able to furnish assistance and direction throughout the performance of the procedure.

We request immediate action because this rule is currently in effect and significantly threatens the ability of hospitals, in Iowa and across the country, to continue offering essential outpatient services to the people in their communities. While we appreciate CMS’ attempts to provide greater flexibility for hospitals in the 2010 OPPS/ASC final rule, hospitals in Iowa are extremely concerned they are not able to meet the requirements for reasons explained below. Furthermore, by way of “clarification” in the 2009 OPPS/ASC final rule, CMS “clarified” this policy has actually been in effect since 2001 which potentially exposes hospitals to being out of compliance for 8 years and subject to significant fines and enforcement scrutiny. Iowa hospitals simply cannot afford this. Over the years our providers have acted in good faith that they have worked in accordance with regulations. This clarification and ruling pose great harm to our state and health care infrastructure. CMS must act quickly to change its policy and prevent further harm to hospitals and the patients they serve.

## **CMS must act to prevent the elimination of services and to preserve patient access to care.**

### **1. Shortage of physicians and non-physician practitioners.**

CMS' intended flexibility in allowing NPPs to provide direct supervision for certain outpatient therapeutic services does not provide adequate relief to the hospitals that struggle with these workforce shortages. Hospitals in Iowa have reminded us that NPPs, as well as physicians, are in short supply in their communities. These hospitals have to work hard to attract physicians and NPPs, and many communities may have only one physician or NPP available. Some communities are only able to arrange for a physician or NPP to travel intermittently into the community to provide services at the hospital. A hospital that is successful in recruiting a physician or NPP would likely not be bringing them in for supervisory duties only, rather these practitioners would be put into service as direct patient care providers furnishing services in their own practices which may or may not be located on a hospital campus or provider-based department. CMS must change this policy because there is a limited and short supply of people in Iowa available to provide CMS' required level of direct supervision.

### **2. "Immediately available" interpretation is unattainable because it is in direct conflict with the CAH Conditions of Participation, creates an unnecessary level of supervision for outpatient services, and eliminates adequate patient access to care.**

In the 2010 OPPTS/ASC final rule, CMS stated the supervisory physician or NPP must be physically present and immediately available to furnish assistance and direction throughout the performance of the procedure. To further clarify this policy, CMS stated:

- It has not previously defined the phrase "immediately available," but CMS has "previously established that direct supervision requires immediate physical presence."
- A supervisor could not be immediately available while performing another procedure or service that he or she could not interrupt.
- It has not defined the word, "immediate," for direct supervision in terms of time or distance, but CMS noted the "general definition of the word means 'without interval of time.'"

The Critical Access Hospital (CAH) Conditions of Participation (CoP), section 485.618, require CAHs to provide emergency care services to meet the needs of inpatients *and outpatients*. The CoP for CAHs also state that CAHs must ensure that a practitioner with training and experience in emergency care is on call and immediately available by telephone or radio, and available onsite within 30 minutes, 24 hours a day.

### **Serious and unintended consequences have resulted from CMS' direct supervision policy:**

Directly conflicts with CAH CoP. Of the 118 community hospitals in Iowa, 82 are CAHs, and all 118 are required to have an emergency department. Most CAHs in Iowa do not have a physician or NPP onsite 24 hours a day, but they do have appropriate practitioners available as required by the CAH CoP. The immediate, physical presence requirement has serious implications for services like observation and blood transfusions that are provided all hours of the day. Furthermore, it remains vague and difficult to prove whether an emergency room (ER) supervisor can be "immediately available" due to his/her need

to be available for emergent care, and hospitals are forced to make a judgment call about whether the ER practitioner may perform the direct supervisor duties.

Unnecessary level of supervision. Medicare covers and pays for outpatient therapeutic hospital services as services furnished “incident to” a physician’s service, as described in *Social Security Act* § 1861(s)(2)(B). The law does not mandate a specific level of physician supervision for “incident to” services. It is entirely within CMS’ regulatory discretion to determine the appropriate level of supervision for these services. Taken to its extreme, the policy CMS has chosen to implement has the effect of creating a requirement of “personal observation” because CMS states the supervisor cannot be performing another procedure or service that he or she could not interrupt. Frustrated hospitals in Iowa have said it would be extremely costly and a poor use of limited resources, even if it were possible to find and hire additional supervisors to do nothing other than supervise.

Eliminates adequate patient access to care. Many hospitals in Iowa simply do not have the resources and/or the supply of supervisors to comply with CMS’ requirements and therefore must stop offering outpatient therapeutic services such as: clinic/emergency department visits; outpatient psychiatric services; drug infusions and blood transfusion; wound debridement; cardiac rehabilitation; and pulmonary rehabilitation. For many patients, this will mean they must drive two or more hours to another community in order to receive these outpatient services. Given the frequency of chemotherapy treatment, for example, patients are burdened with unnecessary stress and hurdles to maintain employment requirements and other obligations while frequently traveling long distances to receive life-saving treatments.

The rationale for CMS’ change in policy in 2001 remains vague, but CMS has not indicated it acted because of safety or quality concerns. The way in which hospitals provide supervision of outpatient services varies tremendously and the fact that these supervision arrangements may not technically meet the limitations of CMS’ policy does not in any way diminish the fact that these services are currently provided in a high quality and safe way. CMS has the ability to act now to change this policy and prevent further harm to hospitals and their communities and we request your immediate attention on this matter.

Sincerely,

Iowa Delegation