July 5, 2011

KANSAS HOSPITAL ASSOCIATION

Tom Bell
President and CEO

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3213-P
P.O. Box 8010
Baltimore, Maryland 21244-8010

RE: CMS-3213-P, Medicare Program; Medicare and Medicaid Programs; Influenza Vaccination Standard for Certain Participating providers and Suppliers; Proposed Rule (Vol. 76, No. 86), May 4, 2011

Dear Dr. Berwick:

The Kansas Hospital Association (KHA), on behalf of its hospital, health system and other health care organization members, appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services’ (CMS) proposed rule which addresses an influenza standard for certain providers and suppliers and creates a new Condition of Participation for all hospitals, rural health clinics and End Stage Renal Disease facilities.

Hospitals are committed to improving the quality and safety of the care that they provide every day. The goal of offering influenza and pandemic influenza immunizations to all Medicaid and Medicare patients makes good sense; however, KHA has some concerns and recommendations that are addressed in our comments below.

**TIMELINE REQUIREMENTS**

The proposed rule states that the final rule addressing this new Condition of Participation will be issued in early fall with implementation of the final rule to begin September 1, 2011. As you are aware, the flu season also starts in the fall. To get this program off the ground with any degree of success would be difficult due to the many items that need to be in place a month or two after the final rule is issued. Any new program requires the creation of policies and procedures and education for staffs, providers and patients and their families as well as the ability to obtain and store vaccine in sufficient amounts. These logistics may take several months to achieve.

**Due to the extremely tight timeline as presented and CMS' desire to establish this new program immediately after the final rule is issued, KHA strongly recommends that the start date to offer influenza immunizations be reconsidered. We suggest an initial implementation date beginning in the fall of 2012.**
LOGISTICS

In the proposed rule, hospitals must offer all patients, whether inpatients or outpatients a seasonal influenza vaccination. What each hospital will need to decide is when to offer the immunization. With inpatients, this could occur upon presentation to an emergency department, a nursing unit, just prior to discharge or sometime in-between. Most hospitals in Kansas currently offer inpatients the opportunity to receive an influenza immunization. The goal to have hospitals offer all inpatients a seasonal influenza vaccine should be achievable in Kansas.

With outpatients, the picture gets much hazier as many scenarios must be explored. If an out-patient presents to the lab, or to x-ray is he or she offered a flu shot? Would the lab or x-ray tech have vaccine available in their department and if so, do these employees have the training to provide immunizations? If not, a plan must be in place to send the patient to another department or person such as the infection preventionist or the emergency room. The hospital’s plan will need to address the patient who presents to the hospital at 10:00 p.m. on a Sunday night. Once the patient receives the immunization, where will this intervention be documented? The proposed rule makes the assumption that the patient will have a chart in hand at the time of their encounter with an outpatient department. This is not the case. Departments such as lab and radiology work off of a physician’s order. If a facility has an electronic medical record, life will be a bit easier, but without an EHR, there is no viable way to chart such a procedure for an outpatient. It should be noted that hospitals using an EHR will also need to make adjustments to their electronic record to include the proper place to document immunization information. At any hospital, information technology employees are being pulled in many different directions to ensure that their hospital is compliant with meaningful use, medication management, core measures and other pressing issues. These already over-loaded employees will be required to take on another unfunded mandate with insufficient time to prepare if the timeline remains as proposed.

What could be a common occurrence, especially with the elderly, is confusion or a true lack of knowledge as to whether they have already received an influenza immunization. If a patient states that they do not know if they have received an immunization, providers will need to decide how to verify whether the immunization was given. Although the state of Kansas maintains The Kansas Registry which is a repository for providers to send patient immunization information, this resource is not consistently used by providers.

For the reasons outlined above, KHA urges CMS to consider initiating a seasonal influenza program in two stages. Stage One would require hospitals to offer influenza immunizations to all in-patients beginning in the fall of 2012. Stage Two would extend this program to all out-patients by the fall of 2013.

VACCINE SUPPLY

Vaccine supply has been an issue in recent years and is normally ordered six to eight months prior to the fall flu season. KHA appreciates CMS’ position that providers and suppliers would not be expected to meet a requirement to offer an influenza vaccine if the supply of vaccine was limited. If a pandemic flu epidemic were to reoccur, other concerns would surface. Our experience with the 2009 H1N1 pandemic taught us many lessons, namely, that hospitals had limited access to vaccine and coordination with public health entities varied across the country. KHA is very concerned that a lack of vaccine could impede the goal of offering influenza vaccinations to all patients.

COST

The proposed rule acknowledges that even with Medicare and Medicaid coverage of influenza vaccines and vaccine administration cost, the net impact on providers would be approximately $90 million. This amount
assumes that the annual gross costs of approximately $330 million to provide influenza vaccines would be offset by third-party payers. This is a sizable amount of money that may, or may not be recouped by third party payments. The proposed rule intimates that the financial impact on most affected entities would be “only a few thousand dollars per year.” While a “few thousand dollars per year” does not sound like a vast sum of money, this unfunded mandate implies that facilities have sufficient funds to absorb this cost. This assumption may not be true for many of our Kansas hospitals.

There are many good locations at which individuals can, and do, receive influenza vaccinations including, primary care physicians’ offices, clinics run by state and local public health departments and convenient sites such as local pharmacies and employer health clinics. These organizations are able to offer vaccinations to all individuals during the influenza season at a minimal price. By contrast, it would be extremely difficult and costly to operationalize CMS’ proposed requirement that hospitals offer vaccinations to all patients, especially as it would apply to the millions of patients in a multitude of hospital outpatient settings. Many outpatient departments are not staffed by individuals trained to provide immunizations or more importantly, to care for patients should they experience a reaction to the vaccine. For instance, an off-campus provider-based outpatient department offering physical therapy services or a partial hospitalization program would not typically have the appropriate types of or adequately trained staff to administer vaccinations to their patients, and adding the necessary staff would drive up costs. Also, most outpatient departments would not have the adequate storage space needed to manage the supplies of vaccine in appropriate conditions. Further, those departments that are staffed with professionals capable of providing vaccinations, such as emergency departments, are frequently already operating at full capacity and would not have the time or additional resources to carry out the functions of a vaccination clinic in addition to the other critical services dictated by their mission.

We are concerned that this proposed CoP may result in the unintended consequence of shifting influenza vaccination from a lower cost setting of care to a higher cost setting of care. As noted above, influenza vaccination is administered primarily in primary care physicians’ offices, pharmacies, employer health clinics and clinics run by local public health departments. These settings are more cost effective for vaccine administration than hospital inpatient and outpatient departments because they have staff licensed to provide vaccination available at the time and location of the encounter and ready access to equipment and storage appropriate for handling, controlling and administering vaccine. However, since many hospital inpatient and outpatient departments currently do not offer vaccination services, the cost to furnish them with the appropriate staff, equipment, storage space and training necessary to carry out vaccinations would be prohibitive. Alternatively, the hospital may order vaccine directly from the hospital’s pharmacy and appropriately licensed pharmacy staff would need to come to the unit to deliver and administer the vaccine. This also would be burdensome and costly, particularly to the hospital pharmacy, and it would delay patients’ treatment or discharge from the hospital, making care in hospitals more costly in general. Although CMS states that hospitals may bill insurers for vaccination, the average payment offered for vaccine and its administration by Medicare and other insurers would not come close to approaching the cost that hospitals would accrue in implementing these burdensome proposed rule requirements. Also, hospitals would face increased uncompensated care costs for vaccinating patients who are uninsured.

KHA requests that CMS put funding sources in place to reimburse providers and suppliers for the estimated $90 million in costs that would be incurred by these groups to provide and administer influenza vaccine.

OUTPATIENT CLARIFICATION:

CMS should more clearly define, for the purposes of this CoP, what an “outpatient” is. For instance, hospitals asked whether an individual who comes to the hospital only for a blood draw or a lab test would be considered an outpatient to whom vaccination must be offered. CMS should also clarify
whether an individual presenting to the hospital’s commercial pharmacy to fill a prescription would be considered an outpatient.

CMS also should clarify whether patients who return frequently to a hospital outpatient department for a course of care during the months of influenza season, such as for physical therapy sessions, chemotherapy or other infusions, or partial hospitalization program services, must be offered influenza vaccination each time they present to the hospital. Patients already complain when they are asked the same questions more than once.

NEW CONDITION OF PARTICIPATION

Although creating a new Condition of Participation would certainly get the attention of all providers, we do not feel this is the right route to take to implement a significant clinical change in our hospitals. The penalty for non-compliance is too high and too many unresolved issues have been raised including the proposed timeline, internal logistics, vaccine supply and funding. Consideration could be given to adding a quality reporting measure that would focus on increasing the number of patients receiving influenza immunizations. For these reasons, KHA requests that CMS not create a new Condition of Participation to address the issue of offering influenza vaccine to all in-patients and out-patients.

SUMMARY

KHA understands CMS’ desire to have health care providers offer seasonal influenza vaccinations to all Medicare and Medicaid in-patients and out-patients. To accomplish this goal, hospitals will need sufficient time to prepare for this change including the time needed to write policies and procedures and educate various groups including employees, providers and the public. Vaccine will need to be located, ordered and adequately stored. Documenting the patient interaction surrounding the offer and the administration or refusal of the vaccine will also need to be finalized at each facility as patients present to hospitals at any time of the day and night when a medical record is not always accessible. Attempting to eliminate the duplicate administration of the vaccine, especially in the elderly, is also an issue that needs resolution. KHA recommends that the timeline to implement the final rule once published be extended and encourages CMS to look at alternatives to creating a new Condition of Participation regarding the offering of seasonal or pandemic influenza vaccine.

KHA appreciates the opportunity to comment on this proposed rule. If you have any questions or need additional information, please feel free to contact me at (785) 233-7436 or by e-mail at tbell@kha-net.org

Very truly yours,

Thomas L. Bell
President and CEO

CC: Deborah Stern
Vice President Clinical Services and General Counsel