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June 21, 2011

Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

Re: CMS-3213-P, Medicare & Medicaid Programs; Influenza Vaccination Standard for Certain Participating Providers and Suppliers

Dear Dr. Berwick:

The Association for Professionals in Infection Control and Epidemiology (APIC) appreciates the opportunity to provide input to the proposed rule on Influenza Vaccination Standard for Certain Participating Providers and Suppliers. APIC is pleased that the Centers for Medicare and Medicaid Services (CMS) recognizes the importance of reducing vaccine preventable illness, particularly influenza.

APIC is a nonprofit, multidisciplinary, international organization representing over 14,000 Infection Preventionists (IPs), whose mission is to improve health and promote safety by reducing the risks of infection and adverse outcomes in patients and healthcare personnel. We welcome federal efforts to improve the quality of patient care and appreciate activity to reduce influenza illness, one of the most common causes of death by vaccine-preventable illness in the U.S. each year. APIC looks forward to continuing to assist CMS in these efforts by sharing our expertise in instituting infection prevention processes in healthcare facilities.

APIC supports universal immunization for influenza, and the goal of rapid implementation is laudable. However, the very fact of making universal immunization a condition of participation (CoP) with implications of loss of certification, licensing and reimbursement is a major step, especially when there is very little time to achieve compliance with such a wide-ranging rule to the usual expectations of CMS. This proposed rule makes no statement regarding penalties or fines, nor is there a grace period for beginning a new program affecting many new populations, other than a statement recognizing this as an unfunded mandate for hospitals. There are system constraints on this extraordinary and ambitious timeline of implementing universal immunization by the beginning of the 2011-2012 influenza season.

Supplies

Most critical is the issue of vaccine availability. In spring 2011, healthcare facilities must have already ordered and budgeted for their vaccine needs for the 2011-12 season. Manufacturers are processing and producing vaccine now, based on these orders and previous predictions. Historically it has been

challenging and often impossible for manufacturers to respond to sudden, unexpected increases in needs. This proposal is especially concerning since the final rule is expected to be published no sooner than September 2011, which is the start of the vaccination process for the 2011-2012 influenza season. This important program must be implemented as carefully as any other patient intervention in order to be effective, and we cannot risk failure because of inadequate time to develop vaccine or the necessary processes to effectively implement this program.

To implement such a requirement by September 1, 2011 could potentially impact our country's supply chain. In addition, most facilities use "just in time" delivery of supplies and would need time to greatly increase inventory orders to accommodate the amount of these supplies anticipated for such an extensive implementation process. This would likely lead to supply shortages, as was seen in many facilities during vaccine production and other shortages associated with the H1N1 pandemic.

The proposed rule would also require increased immunization efforts in outpatient clinics. Not all outpatient areas with trained staff are equipped with sufficient supplies for vaccination at such short notice. These supplies include alcohol wipes, needles, syringes, monitored medication refrigerators and sharps disposal boxes. Furthermore, many outpatient areas are not equipped with locations to securely store these supplies.

Administrative Considerations

Policy/procedures: CMS correctly assumes that all providers and suppliers would need to develop new policies and procedures. The estimate of five hours "to develop, implement and annually maintain the policies and procedures for influenza vaccination" seriously miscalculates the time required to develop multidisciplinary policies and procedures which involve the Infection Prevention department (where this rule is placed in the CoP) as well as Occupational Health/Human Resources department, the Medical Staff, Pharmacy and Patient services and Senior Leadership. The proposed timeline of implementation to begin September 2011 does not allow adequate time for complete and thorough policy and procedure development. It also does not allow time to educate all hospital staff on this new program within weeks given the current proposed timeline. APIC does not believe this is achievable in the time allowed.

Specific program training demands: Given the sheer volume of patients (particularly outpatients), many hospitals do not have staff with sufficient training in the knowledge and skills involved in safe administration of medications in outpatient settings. As a result, we believe the insufficient timeframe to educate and train additional staff could result in potential patient harm.

An example of such an outcome is the recent unsafe influenza injection event at a pediatric clinic in Colorado. An assistant incorrectly prepared syringes and reused them between patients, and patients were administered incorrect doses. Dosing regimens in pediatrics requires that the provider fully understand all of the scenarios involving age, dosage, number of doses, injection technique and documentation for administering vaccine to this population. It also requires that communications systems be set up in order to ascertain when and where initial and/or second doses are given to the pediatric population. This episode dramatically demonstrates that it is unrealistic, given the timeframe for implementation of the program, to develop a system to safely administer the vaccine on a much

larger scale than the current standard for patients over 65. The current short timeframe for implementation does not allow for safe implementation of such a program.

Definitions and procedural interpretations: APIC urges CMS to clarify the definition of "outpatient" for purposes of the program. The final rule must specify, for example, whether every patient coming to an outpatient laboratory for a simple blood test or a patient coming to a pharmacy to pick up or order a prescription is included in the vaccination requirement.

Frequently seen patients: APIC also urges CMS to clarify whether patients frequently seen in the emergency room or outpatients seen routinely in hospital clinics such as hematology/oncology would be considered outpatients for the purpose of this program. If so, CMS must clarify whether the unit must document that the patient was offered a vaccination with every visit.

Patient education

APIC believes that all patients/clients should be given complete education on vaccination benefits and risks so an informed decision can be made. Adequate explanation, including answering patient questions, requires more than the three minutes estimated by CMS.

APIC also urges CMS to reconsider the amount of time required to properly document education and vaccination procedures. Manual and even many electronic health records would require more time than CMS estimates.

The Role of Public Health in both Seasonal and Pandemic Flu

All of the concerns expressed for implementation of a planned seasonal flu program apply exponentially more to a pandemic situation, presuming vaccine is even available. Importantly, during a pandemic it is likely, based on lessons learned from 2009 that priority will be given to healthcare personnel so they can continue to care for patients. APIC urges CMS to allow for flexibility in implementing this program during an influenza pandemic to allow for immediate public health needs to be met without concern for loss of revenue or other sanctions to healthcare facilities.

APIC Recommendation: APIC supports universal influenza vaccination but believes CMS has severely underestimated the amount of time it would take to safely develop and implement an effective program of this magnitude. APIC recommends a tiered approach to the implementation of this comprehensive vaccination program. Ideally, the first year (2011-2012) would be a demonstration project that would allow a startup year for staffing/resource planning, as CMS typically supports to determine effectiveness of a program. Planning could include development of educational materials for posting along with information on locations where outpatients could obtain flu vaccination during year two. The second year (2012-13) would implement the vaccination program only for the inpatient population. In the first two years, CMS should thoroughly study the impact of this proposal on the interaction with the outpatient population affecting the hospital. During the 2013-2014 influenza season, the outpatient population would be incorporated into the program. This would allow program development to consider the needed definitions and logistics for outpatient management and proper training, or potential alternatives that are convenient for patients.

APIC appreciates the opportunity to comment on the proposed measure and continue to applaud CMS's commitment to improving quality and promoting patient safety. We stand ready to assist CMS in efforts to promote improved healthcare for patients.

Sincerely,

Russell N. Olmsted, MPH, CIC
2011 APIC President