



**American Hospital
Association**

Liberty Place, Suite 700
325 Seventh Street, NW
Washington, DC 20004-2802
(202) 638-1100 Phone
www.aha.org

Submitted electronically

July 1, 2011

Donald M. Berwick, M.D., M.P.P.
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

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

Dear Dr. Berwick:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on influenza vaccination for certain participating providers and suppliers. To obtain advice and input from our members, we discussed the provisions of the proposed rule at our six governing councils and committees and at our nine regional policy boards in May and June. Our comments reflect the opinions and reactions of more than 500 hospital leaders across the country.

We recognize that through this proposed rule, hospitals are being asked to improve the health of the community. The AHA agrees that from a public health perspective, increasing the number of individuals who receive the annual influenza vaccination is a key factor in decreasing the morbidity and mortality rates from influenza. However, doing so in any hospital-based setting (including short-term acute care, critical access, long-term acute care, psychiatric, rehabilitation, children's and cancer hospitals) in the manner that CMS proposes would be overly complex to implement and not the most cost effective way to accomplish the agency's goal. Collaboration with public health departments is a better approach to achieving these goals.

We also are concerned that CMS' proposal translates into an unfunded mandate for hospitals in the midst of a difficult economic climate and that the agency's impact analysis vastly underestimates the cost and burden posed by this rule.



We believe that it is inappropriate to use the Medicare and Medicaid conditions of participation (CoPs) for these purposes. According to CMS, the CoPs are “minimum standards for patient health and safety, and CoPs focus on creating a foundation to ensure quality and safe care for beneficiaries throughout a given facility.”¹ In other words, the CoPs are supposed to articulate the processes and structures hospitals should have in place to ensure safe and effective delivery of the services they have chosen to provide, not introduce requirements for expanded services.

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 an adverse 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.

If the influenza vaccination standard is finalized as written, hospitals have reported to us that they would have to hire additional nursing and pharmacy staff to comply with the new requirements. Further, documenting compliance would be extremely challenging in hospital-based settings. For instance, hospital outpatient department staff would have no simple way to verify a patient’s account of whether he or she has contraindications to the vaccine or has already been vaccinated prior to the current request. Verification is essential for safe patient immunization practices. By contrast, when the patient’s primary care physician office furnishes vaccination services, there is ready access to the patient’s medical record, including a history that documents medical contraindications to vaccination and whether the patient has already been vaccinated during the current influenza season.

CoPs ARE THE WRONG APPROACH

The AHA urges CMS not to use the CoPs to implement these requirements but rather to use the existing quality reporting system to hold hospitals accountable for doing their part to address this public health issue. Imposing the proposed requirement via the CoPs is unnecessarily heavy-handed in that enforcement may result in terminating hospitals from the

¹ 75 *Federal Register* 72001 (November 24, 2010)

Medicare and Medicaid programs for violations that do not pose a threat to the health and safety of the patients while they are in the hospital. Offering patients influenza vaccination, while important to individual wellness and reducing the societal burden of influenza, does not rise to the level of a “minimum standard for patient health and safety” in the same way that the fire safety or anesthesia care CoPs do. We believe that CMS has gone too far in its proposed change to the CoPs for influenza vaccination.

CMS has other options that it can use to increase vaccination rates. We know that public reporting of quality measures has driven improvement and is an appropriate way to hold hospitals accountable for the patients they serve. The agency recently finalized a global influenza immunization measure that will be implemented for the fiscal year 2014 inpatient quality reporting program. Inpatient acute hospitals are required to begin submitting data to CMS during the first quarter of calendar year 2012. The introduction of this quality measure marks the correct approach to tackling CMS’ concerns about influenza vaccination. **We urge CMS not to implement the proposed changes to the CoPs, but instead to move forward with the new global influenza immunization measure as planned. Further, CMS may choose to review whether a companion outpatient measure is feasible and desirable.**

TIMING FOR IMPLEMENTATION IS UNREALISTIC

Beyond hospital objections related to using the CoPs, our members have voiced other serious concerns regarding the proposed rule. Among the most strongly voiced and consistent concerns we heard from hospitals is that CMS’ intent to implement a final regulation for this coming influenza season is unrealistic. Logistically, it would be nearly impossible to implement the rule within this extremely short timeframe.

First, hospitals, other providers and suppliers generally pre-order their influenza vaccine six to nine months in advance of influenza season. Since the proposed rule was issued long after most hospitals would have pre-ordered vaccine, adequate supplies will not be on hand in hospitals to comply with the requirements of the CoPs in the 2011-2012 influenza season. Also, since vaccine manufacturers would not have been able to predict this additional demand for vaccine, imposing the rule this year could contribute to a shortage of influenza vaccine. It also would pit hospitals against primary care physician offices and public health departments in a competition for limited supplies of vaccine.

Second, there is not enough lead time for hospitals to create and implement the policies and procedures mandated by this proposed rule. Implementation will involve the work of multiple hospital committees to operationalize the process, the development of staff and patient education materials, weeks of in-service training and education about the new requirements for hospital staff in all the inpatient and outpatient departments, and the modification of information systems to track compliance. To implement and enforce the rule before all hospital inpatient and outpatient departments are educated, trained, staffed and equipped to comply could result in breaches of safe vaccination practices, putting patients at risk.

VACCINE SHORTAGE PROVISION ARE UNCLEAR

Although CMS would not require providers to offer vaccination in the event of a vaccine shortage, the manner in which this discretionary authority would be applied is important. In the event of a seasonal vaccine shortage or in a pandemic situation, it would be best to use the limited supplies of vaccine to protect hospital health care workers first, rather than the majority of patients, who likely would not be prioritized under recommendations from public health authorities. This approach preserves the ability of hospitals and their staff to continue to provide health care services. CMS should address whether prioritizing vaccinating health care workers over patients would be permitted under its discretionary authority. It also is unclear how CMS would inform hospitals that the CoP would be lifted for a period. Moreover, there are different types of shortages, sometimes affecting only a region of the country or only the hospitals that obtain vaccines from a particular source. We question whether CMS is willing to differentiate among hospitals in requiring compliance with this CoP.

These types of decisions that CMS would need to make in order to operationalize the proposed rule is further evidence that the CoPs are an inappropriate mechanism to use in accomplishing the public health goals that CMS has identified. That is, applying CoPs in a flexible way is, at its core, inappropriate and inconsistent with the purpose and intent of Medicare CoPs to serve as baseline health and safety standards for hospital care.

The degradation of hospital and physician “good will” is another reason not to impose this new CoP requirement. That is, many hospitals already offer influenza vaccination to their patients, not to mention other primary care services. However, these programs are voluntary and offered within the context of community outreach. Discounting the voluntary nature of such hospital programs by requiring vaccination through the CoPs will eliminate the good will that surrounds the many vaccination clinics offered by hospitals nationwide during influenza season. It also would provide an incentive for community primary care physicians to cease offering influenza vaccination to their patients and could incentivize commercial insurers to no longer cover, or reduce coverage, of vaccination. If hospitals are required to offer vaccination as a cost of doing business, as the CoPs typically are considered, regardless of whether the services will be reimbursed, we question whether insurers would continue to cover the service.

INAPPROPRIATE SHIFTING OF CARE TO HIGHER COST SETTINGS

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.

BURDEN

CMS uses burden estimates contained in its regulatory impact analysis to conclude that the costs associated with the proposed rule would be far outweighed by the monetized benefits expected in terms of decreased medical care costs and savings in patient time. CMS also concludes that the proposed rule would have little consequential adverse impact on provider costs, net of insurance reimbursement. We disagree with these conclusions and believe that CMS' estimates of burden and overall impact analysis vastly underestimate the cost and burden hospitals would face in complying with this proposed rule.

Policies and procedures. Under its *Collection of Information Requirements* CMS estimates that it would take each of the 5,100 hospitals five hours annually to develop, implement and maintain policies and procedures for influenza vaccination, for a cumulative total of 25,500 hours annually. Based on feedback from our members, it is clear that CMS has significantly underestimated the burden associated with this requirement. **The AHA recommends that CMS re-estimate the burden associated with developing, implementing and maintaining policies and procedures to account for each of the necessary steps outlined below.**

In order to implement this requirement, hospitals would need to:

- Consult with inpatient infection control, occupational health, pharmacy and patient services staff to begin development of new policies and procedures.
- Convene and seek agreement from several hospital committees, including infection control and pharmacy regarding the policies and procedures.
- Discuss the proposed changes with and seek agreement from the hospital's governing body.
- Assess the impact of implementing the policy on staffing in all of the hospital's inpatient and outpatient departments, and then implement staffing changes as necessary.
- Undertake legal analyses to assess the potential increase in the hospital's liability exposure as a result of implementing the new requirements.
- Develop patient education materials and other necessary forms (e.g. releases) in English and in other language, as appropriate.
- Institute compliance tracking system changes to the hospital's medical record system.
- Undertake programming of the hospital information technology (IT) system to accommodate additional protocols for patient "check in" relevant to the requirements in the proposed rule.

- Identify all inpatient and outpatient departments where extensive staff education and training would be necessary regarding the rule and the hospital's new policies and procedures and then conduct such education and training.
- Develop a follow-up measurement system to ensure compliance with the CoPs.
- Verify the coverage and payment for the administration of influenza vaccination for various payors, such as Medicare, Medicaid and commercial insurers.

One health system CEO reported that her contractor estimates that in order to update her IT system's software to comply with the proposed rule, it would take two weeks to develop training materials, several weeks for all staff in their multiple outpatient sites to be trained, 200 hours of total time for analysts to test and install the software update, and 40 hours to write auditing reports to give operational leaders information on compliance. As a result, the health system estimates that one additional full-time equivalent (FTE) employee would be required for the development of materials and training and several new FTEs would be required for compliance in their 50-plus on-site and off-site clinics. This example highlights the complexity and burden that hospitals face in implementing the rule's policies and procedures.

Compliance burden. CMS also significantly underestimates the burden associated with complying with the proposed rule's provisions applicable to patients. For example, the rule requires that during flu season, all patients are counseled about the risks, benefits and side effects of vaccination; that hospital staff administer vaccination to those patients who agree and that certain required information be documented in every patient's medical record. In estimating the compliance burden for each of these provisions, CMS begins with an initial estimate of 20 million hospital patients, which CMS states represents one-half of annual hospital discharges. However, the requirements CMS describes in the proposed CoP would apply to both hospital inpatients *and* outpatients. While 20 million may be an adequate estimate of the number of hospital inpatients seen during the six months of influenza season, CMS completely ignores the approximately 300 million outpatient visits² that also take place during these months. In doing so, CMS has vastly underestimated the burden and cost of the regulation for hospitals.

Therefore, the AHA strongly recommends that CMS re-estimate the burden associated with these patient-specific provisions using both 20 million inpatient discharges and an additional 300 million outpatient visits.

Patient education. CMS estimates that it would take each hospital three minutes to perform the patient education on the risks, benefits and side-effects of influenza vaccination. We believe that this also is an under-estimate. While it may take only three minutes to provide such counseling for those patients who have previously been vaccinated and are knowledgeable about these issues, it would take far longer to educate patients who have never previously received an influenza vaccination, those who have cognitive or sensory disabilities, those who are non-English speaking, and patients with multiple co-morbid conditions. On average, given the range of patients for whom hospitals provide care, we believe that three minutes for patient education is a significant under-estimate. **Therefore, the AHA recommends that CMS re-estimate the burden to include a longer time estimate for patient education.**

² AHA Hospital Statistics reports approximately 600 million outpatient hospital visits annually.

Documentation. The rule also would require that patients' vaccination status be documented in their medical record. In the *Regulatory Impact Analysis*, CMS estimates that the documentation would take approximately 36 seconds per patient. It is difficult to determine whether this estimate is accurate because it largely depends on the sophistication of the hospital's IT system and its ease of use. If hospitals already have sophisticated IT systems in place and are able to rapidly work with their vendors to make necessary changes to IT systems, then this estimate might be about right. However, as IT systems changes can take a long time, many hospitals would need to document compliance long-hand, which would take longer. Also, documentation would take much longer if CMS requires that hospitals verify patients' assertions regarding their vaccination status.

Administering vaccine. CMS also estimates that it would take six minutes per patient to perform the vaccination and to dispose of sharps. We think that this time estimate would only be accurate for those hospital inpatient and outpatient departments in which influenza vaccination already takes place, such as in hospital primary care clinics and on some inpatient units. These departments would have to have staff licensed to provide vaccinations available at the time and location of the encounter and ready access to equipment and storage appropriate for handling, controlling and administering vaccines. However, for those outpatient departments that do not typically offer vaccination services, the process would likely take much longer. Vaccine would have to be ordered and delivered from the hospital's pharmacy and appropriately licensed staff would need to come to the unit to administer the vaccine. Since CMS' estimate of six minutes per patient would only be a reasonable estimate for a limited number of hospital inpatient and outpatient departments, **the AHA recommends that CMS re-estimate the burden for administering vaccine to include a longer time estimate.**

ADDITIONAL RECOMMENDATIONS

While we do not believe that the proposed rule should be finalized, our members have identified several other issues that are unclear and should be addressed.

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 also should 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. Repeatedly making such offers to patients who do not wish to receive the influenza vaccination could upset and annoy them and possibly affect their level of satisfaction with hospital services.

Hospitals also are concerned about how the proposed rule would apply to patients without representatives or surrogates and who are unable to understand or communicate. For instance,

psychiatric hospitals often care for homeless or otherwise socially isolated psychotic patients who are too ill to provide informed consent and who either do not have or refuse to contact family or other representatives. Patients with dementia and patients who are unconscious also fall into this category. For these types of patients, CMS should make an exception to the general rule that hospitals must offer influenza vaccination to all patients.

We urge CMS to clarify how the Medicare and Medicaid reimbursement systems would cover and pay for each of the sites of service to which this proposed rule would apply. For example, CMS should clarify whether and how roster billing – a billing process that allows mass immunizers to submit one claim form with a list of immunized beneficiaries – may be used as a mechanism to reimburse each type of hospitals mandated to offer influenza vaccination to Medicare inpatients. It also would be helpful for CMS to assess whether and to what extent the major commercial insurers would cover influenza vaccination in hospital inpatient and outpatient settings. CMS should recognize that its proposal would result in hospitals incurring more uncompensated care for those individuals without insurance.

With regard to the documentation requirements, if the patient is in a department of the hospital that is not equipped to provide vaccination, and is referred to another department on the same campus for vaccination, it may be difficult for the hospital staff to ensure that the required documentation in the patient's medical record accurately reflects the date that the vaccine was actually administered. For the purposes of such a situation, CMS should revise its regulations to allow the hospital to record the date on which the patient was *referred* to the other department for vaccination rather than the date that vaccination was furnished.

Some hospitals also have asked whether CMS would expect them to verify the patient's assertion that they have already been vaccinated in the current influenza season or that they have a medical contraindication to vaccination. Such a requirement would add another layer of burden and complexity to the proposed rule as it would require hospital staff to contact each patient's primary care physician or another source of information about the patient's vaccination status. While some hospitals might choose to do so as part of the process for compliance that they put into place, we do not recommend that this be considered as a requirement of the rule.

However, such verification would be far less burdensome if appropriate vaccine registries were established in all the states. The Medicare and Medicaid Electronic Health Record Incentive Programs include a mandate that hospitals be able to send data to vaccine registries as part of meaningful use. However, to date, very few states have systems that they can connect with, let alone query about a patient's influenza vaccine status. Until this information is freely available electronically, using the same standards in all states, hospitals do not have an efficient mechanism to check a patient's vaccine history. **In order to support the ability of hospitals and other providers to obtain this information and avoid over-vaccination, the AHA urges the Department of Health and Human Services to actively work with state departments of public health to accelerate the development of freely accessible, minimally burdensome, standards-based electronic vaccine registries in all states.**

Donald M. Berwick, M.D., M.P.P.

July 1, 2011

Page 9 of 9

Finally, hospitals are concerned about the potential medical liability they would face if the proposed rule is finalized. Although we are aware that serious adverse reactions related to the influenza vaccination are very rare, they sometimes occur. And given the large increase in the numbers of individuals who would be receiving vaccination as a result of this regulation, one would expect to see more adverse reactions. It is important that CMS clarify whether the National Vaccine Injury Compensation Program would provide protection to hospitals that administer influenza vaccination to their patients and the extent of that protection.

Thank you again for the opportunity to comment on this proposed rule. If you have any questions, please feel free to contact me or Roslyne Schulman, director for policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

/S/

Rick Pollack

Executive Vice President