American Hospital Association

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

January 18, 2007

Ben Schwartz, M.D.
Senior Science Advisor
National Vaccine Program Office
Department of Health and Human Services
200 Independence Avenue, SW, Room 434-E
Washington, DC 20201

Re: Request for Information: Guidance for Prioritization of Pre-pandemic and Pandemic Influenza Vaccine

Dear Dr. Schwartz:

On behalf of the American Hospital Association (AHA) and our nearly 5,000 member hospitals, health systems and other health care organizations, and our 37,000 individual members, we appreciate this opportunity to provide comments to the Department of Health and Human Services (HHS) on its plan to develop guidance on prioritizing the distribution and administration of pre-pandemic and pandemic influenza vaccine.

Pandemic influenza is one of many possible disasters for which hospitals develop "all-hazards" emergency management and operations plans. The AHA has urged its members to develop plans that address the intra-pandemic and pandemic period and include disease reporting, staff health assessment, patient triage, appropriate worker precautions, infectious disease procedures and surge capacity.

We have advocated for the federal government to take a number of steps to help prepare the nation for a pandemic and are encouraged that many of these steps already are underway. We support:

- Increasing the stockpile of anti-viral drugs and pre-pandemic vaccine;
- Increasing research on non-egg vaccine production;
- Developing an allocation plan for anti-viral drugs and pandemic influenza vaccine that recognizes the importance of hospital staff, physicians and emergency medical personnel;
- Increasing the number and capacity of vaccine manufacturers, preferably manufacturers with domestic facilities;
- Establishing the federal government as the sole purchaser of pandemic influenza vaccine to assure adequate production and controlled distribution;

- Providing liability coverage for researchers, vaccine and anti-viral drug manufacturers, providers and practitioners; and
- Ensuring that hospitals are able to continue to prepare for pandemic influenza by avoiding reductions in payments for services under the Medicare and Medicaid programs.

If an influenza pandemic were to occur in the United States, the Centers for Disease Control and Prevention (CDC) estimates, based on experience with past pandemics, that it would spread to all states within 30 days. Moreover, the CDC predicts that a severe 1918-type pandemic could impose an almost unfathomable burden on the health care sector with 90 million people sick, 45 million people requiring outpatient care and nearly 10 million sick enough to require hospitalization (of these, 1.5 million requiring intensive care unit level services and more than 740,000 persons requiring mechanical ventilation). Finally, the agency estimates 1.9 million deaths.

With this daunting scenario being considered, and with an expectation that at the beginning of a pandemic there will be scarce supplies of pre-pandemic influenza vaccine and pandemic influenza vaccine, we are encouraged that HHS is now engaging in a comprehensive public process to develop guidance on how to prioritize a limited supply of vaccine for distribution and administration.

We also recognize that with regard to huge demand for vaccine and limited supply, two competing priorities emerge. One is to protect and preserve the health care system's response capability and continuity of operations. The other is to try to reduce the transmission within communities. The nation needs to plan to accomplish both priorities.

The AHA has had several discussions with our hospital and health system members as well as our state, regional and metropolitan hospital association affiliates on these topics. We also have been an active participant in such discussions with federal and public health officials and appreciate the ability to do so again. With these discussions in mind, we offer the following comments on the questions raised in HHS' Request for Information.

Question 1: What objectives, principles, strategies, criteria, assumptions and rationales should be considered in pandemic vaccine prioritization determinations?

The AHA believes that a key objective should be to preserve the health care treatment capability in the nation. Since health care workers will be expected to work in an environment with large numbers of pandemic influenza victims, we need to take all reasonable steps to protect these workers so that they will be willing and able to provide services to the ill. However, the expectation of scarce supplies of vaccine at the beginning of a pandemic argues for a tiered allocation strategy that would establish priorities for vaccination among identified groups of health care workers. We describe these three tiers under Question 3.

Question 2: What is the relative importance of the three goals and what are the associated implications for vaccine prioritization?[1]

As noted above, of primary importance in a pandemic is the preservation of the health care treatment capability in the nation, which we believe falls under Goal 2 (limit the domestic spread of the pandemic and mitigate the disease, suffering and death). This implies prioritization for facility and community health care workers, in a tiered structure, as described below. However, in a pandemic of any significant duration, even if the clinical and support staff within health care facilities and in the community are protected, the ability to provide health care services would nevertheless rapidly disintegrate in the absence of a coherent national infrastructure for the provision of critical needs such as food, water, power, communications, transportation and financial services. Therefore, we believe that Goal 3 (sustain infrastructure and mitigate impact to the economy and functioning of society) is the next most important goal. Workers in these sectors of the economy should also be given prioritization for vaccination.

Question 3: Which population group(s) should have priority for receiving pre-pandemic vaccine? Which should have priority for receiving pandemic vaccine? What is the rationale?

The limited and incremental availability of pre-pandemic and pandemic vaccines requires that their use be targeted and tiered. We agree with the CDC's initial assumptions that pre-pandemic vaccine should be administered to groups that provide critical services and have occupational exposure and that pandemic vaccine should be provided to groups that provide critical services, preserve national security, and those most at risk of severe illness and death.[2] We believe that this supports the notion that top priority is given to health care facility and community health care workers for both pre-pandemic and pandemic vaccine.

However, as we have already stated, the expectation of scarce supplies of vaccine at the beginning of a pandemic argues for a tiered allocation strategy, which would establish priorities for the administration of vaccine among identified groups of health care workers. Individuals would be eligible for vaccination depending on the supply of vaccine available and other factors of the pandemic, such as the specific populations affected, how rapidly the disease is spreading and its associated morbidity and mortality.

The AHA recommends the following tiers:

> Tier 1: Clinical staff within health care facilities and in the community who would be in direct contact with individuals who are ill. Within the hospital, this would include emergency department clinical staff, infectious disease staff, intensive care/critical care

[1] The three goals of the federal response are: (1) Stop, slow, or otherwise limit the spread of the pandemic to the United States; (2) Limit the domestic spread of the pandemic and mitigate the disease, suffering and death; and (3) Sustain infrastructure and mitigate impact to the economy and functioning of society.

[2] Presentation by Ben Schwartz, M.D., Senior Science Advisor, National Vaccine Program Office, CDC, before the Health Sector Coordinating Council on October 27, 2006.

clinical staff, respiratory therapy staff and radiology technicians. In the community, this would include primary care providers and emergency medical service providers.

Tier 2: Individuals who are not clinical staff, but who have direct contact with the pandemic influenza patients. In health care facilities, this would include support staff, such as patient registration, food service workers, housekeepers and others who have close contact with infected patients.

Tier 3: Support staff of the health care facility who do not have direct patient contact but who are critical to supporting the ongoing operation of the facility. This would include such categories as food service workers who remain in the kitchen, staff who run the hospital's information technology system, security staff and engineering staff.

Pre-pandemic vaccine will be the only vaccine available with any potential to protect individuals from illness before the pandemic gains a foothold in the United States. Further, in the early stages of a pandemic, there will be inadequate supplies of pre-pandemic vaccine available to reach all three tiers, but priority should be given to protecting at least the first tier in order to ensure that illness does not eliminate those caregivers who represent the first line of defense in the health care system. As additional supplies of pre-pandemic and pandemic vaccine become available, priority should be expanded to all three tiers, as identified above.

Question 4: How can fairness, equity, efficiency and related principles be reflected in the determination of priority groupings for receipt of pre-pandemic or pandemic vaccine?

The AHA recommends that the CDC consider applying a set of principles on legal and ethical issues on allocation decisions involving scarce resources in public health emergencies that were developed at a June 2006 summit sponsored by the Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities.[3] Based on input and discussion provided by participants (including AHA staff), a set of 10 principles grouped into three broad categories was established. The three categories include: obligations to community; good preparedness practice; and balancing personal autonomy and community well-being/benefit.

The principles also could be organized as substantive and procedural in nature. Substantive grounds for these principles include allocation decisions that should be driven and supported by good data; non-discriminatory and sensitive to the needs of vulnerable populations; and revisable. Procedural grounds underlying these principles include the need for transparency to all stakeholders; public participation to the greatest extent possible; and accountability.

Question 5: For priority groups, how should vaccine be allocated, distributed and administered? Who (federal, state or local authorities) should determine when and how the vaccine is distributed and administered?

[3] "Principles of Law and Ethics to Guide Allocation Decisions Involving Scarce Resources in Public Health Emergencies," available at http://www.publichealthlaw.net/Resources/BTlaw.htm

With regard to seasonal influenza, the federal government primarily provides guidance to state, local and public health authorities regarding the allocation of vaccine to priority populations and, as necessary, works with private sector vaccine manufacturers and distributors to track vaccine supply and distribution and encourage appropriate use.

The AHA believes that an influenza pandemic justifies a strategy in which the federal government would go beyond this current role. In the interest of fairness and equity, we believe the federal government should become the sole purchaser of pandemic influenza vaccine and should direct the allocation, distribution and administration of the vaccine. Federal ownership of the vaccine supply and control over allocation and distribution will help ensure adequate production and controlled distribution of the vaccine.

That said, the federal government has neither the capacity nor adequate resources to physically carry out the distribution and administration of vaccine at the sub-state level. Therefore, the AHA believes that the states should take on these tasks under the purview of strict federal guidelines and stipulations.

If you have any questions, please contact me, Jim Bentley, senior vice president of strategic policy planning, at (202) 626-4631, or Roslyne Schulman, senior associate director for policy, at (202) 626-2273.

Sincerely,

Rick Pollack
Executive Vice President