



Association of Immunization Managers
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National Vaccine Program Office
Office of the Assistant Secretary for Health
Department of Health and Human Services
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The Association of Immunization Managers (AIM) represents the 64 state, territorial and local immunization programs designated by the Centers for Disease Control and Prevention (CDC) to receive federal immunization grants. We appreciate the opportunity to review and comment on the Pandemic Influenza Response and Preparedness Plan.

AIM commends the Department of Health and Human Services (DHHS) for its leadership in the development of a comprehensive national pandemic influenza response plan. We hope that the release of this plan will facilitate broader engagement and enhanced preparedness in stakeholders and the public.

The plan outlines issues of critical importance to a successful pandemic influenza response, but lacks specificity in some areas. Of greatest concern to AIM is the lack of a detailed plan for vaccine procurement and distribution and the lack of targeted priority groups for use of vaccine and anti-viral drugs likely to be in limited supply. We urge DHHS to work with stakeholders to develop specific guidance in these areas in order for states and local areas to effectively plan and prepare for a pandemic flu outbreak.

- **Role of government in the purchase and distribution of vaccine.** Experience has shown that the current system of influenza vaccine purchase and distribution is not adequate to effectively prioritize vaccine delivery to specific populations. Federal purchase of vaccine and distribution through the public sector will be needed at least initially to assure delivery of vaccine to targeted individuals.
- **Determination of priority groups for use of limited supplies of vaccine and anti-viral drugs.** A pandemic influenza outbreak will be a national public health emergency. While states need some flexibility to determine specific providers of essential services, national leadership will be critical to maintain public order and assure the efficient delivery of vaccine. National recommendations to prioritize the limited quantities of vaccine should be developed through a consensus process before the start of a pandemic. State and local areas cannot effectively prepare delivery strategies without knowing who will be the focus of such

strategies. National guidance is also needed to prioritize conditions for the use of anti-viral drugs. Decisions as critical as these should not vary by locality.

This year's vaccine shortage has demonstrated the need for enhancements to our current private sector purchase and distribution system in times of public health emergency. We urge DHHS to work with stakeholders to address these issues in future versions of the pandemic flu plan.

- **Prioritization of early vaccine.** Vaccine is likely to be manufactured in a continuous process, with an expected quantity shipped weekly. As we have seen in this shortage, it is not likely that there will be enough vaccine to target all the high risk populations, even with manufacturing output at a high capacity. Priorities within the high risk populations should be determined ahead of time, with vaccination expanding to more target groups as more vaccine becomes available.
- **Ability to assess supply and demand for vaccine.** This year's vaccine shortage has highlighted the difficulty that public health officials face in trying to assess where vaccine is within the community. State and local public health agencies are spending countless hours and staff resources calling, faxing and cajoling providers into sharing information on their vaccine orders, deliveries and distribution plans. It would be extremely helpful to have an agreement in place with vaccine manufacturers and distributors to share vaccine ordering and delivery information with public health officials in a time of crisis. State and local public health agencies cannot effectively ensure equitable and targeted delivery of vaccine in a timely fashion if they don't have a good handle on where the vaccine doses are being shipped.
- **Ability to rapidly acquire and distribute vaccine that may be available in other countries.** If vaccine is available that has been licensed and approved for use in other countries, there must be a mechanism for the federal government to acquire it and fast track its approval for use in this country. Currently, we have states negotiating with manufacturers in other countries to purchase vaccine, and the federal government stating that if international vaccine is acquired it would have to be distributed under complex Investigational New Drug (IND) protocols. The Food and Drug Administration (FDA) should develop a plan to assure the ongoing safety of foreign vaccine so that in times of crisis it can be imported without a lengthy approval process.
- **Price gouging.** There should be a coordinated national effort to prevent and punish price gouging in times of crisis or public health emergency.
- **Support for the manufacture of vaccine.** The government needs to explore production guarantees or other incentives for manufacturers to produce vaccine for sale in the U.S. market. Reliance on a small number of manufacturers has put us in a difficult position.
- **Ensuring delivery of limited supplies of vaccine to the high risk.** Vaccine providers have been engaging in various strategies to target vaccine to the high risk, including lotteries, emergency declarations, expanded clinics, targeted providers, and appeals to the public. We recommend that evaluations of these

strategies be conducted and that HHS use this information to work with stakeholders to develop guidance on strategies to target the high risk.

- **Communication.** In times of vaccine shortage or other public health emergency, it is critically important that all stakeholders be informed and aware of policy decisions and recommendations. Clear, succinct, and frequent written communication from the Centers for Disease Control and Prevention and/or the HHS will reduce confusion in the field and keep all stakeholders on the same page.

AIM would also like to share some of the experience of state and local immunization programs during the implementation of the recent smallpox vaccination program. Lessons learned in the areas of data management, liability and injury compensation can be applied to pandemic flu preparedness and response.

- **Information and data systems.** Complex information systems and paperwork can be barriers to vaccination. Consent forms and education material should be as simple as possible. Data collection plans should utilize existing systems when possible. Data elements to be collected (name, age, etc.) should be developed and agreed to ahead of time so that states can be adequately prepared.
- **Liability and injury compensation.** The federal government must provide liability protections for those manufacturing and administering the vaccine and compensation to those adversely affected by the vaccine. These protections must be clearly articulated before vaccination begins.

Again, thank you for the opportunity to provide input to the national pandemic flu response plan. We look forward to continuing to work with you to improve the plan and enhance the country's preparedness for a potential national public health emergency involving widespread outbreak of flu.

Sincerely,

Claire Hannan, MPH
Executive Director

cc: Beth Rowe-West, AIM Chair