OBAMA-BIDEN TRANSITION PROJECT

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The Association of State and Territorial Health Officials (ASTHO) respectfully submits for the consideration of the Department of Health and Human Services' Transition Team and the new Administration, the following list of problematic issues warranting priority attention:

Public Health Workforce - Loan Forgiveness

In 2006 the student loan repayment demonstration project was passed by Congress to encourage service in governmental public health; however, the program still has not been funded. Assuring a qualified workforce is the most difficult challenge state and local public health agencies face in responding to terrorist events, emerging infectious diseases, and other public health threats and emergencies. The US has over 50,000 fewer public health workers today then 20 years ago and in some state public health agencies over one-half of the workforce will be eligible to retire by 2012. To strengthen the recruitment and retention of public health professionals and address the shortage of public health workers ASTHO supports **$10 million** in funding for the Public Health Loan Repayment program in Section 3381 of the Public Health Service Act (42 U.S.C. 254q-1).

Electronic Health Information - Public Health at the Crossroads

Executive orders were issued by 13 U.S. governors in recent years calling for HIT and HIE to improve health and healthcare. While two-thirds of states report that they are "stakeholders" in RHIO/HIE efforts in their states, only 7 state public health agencies are currently exchanging data with the clinical sector via RHIOs/HIEs. Of special interest to state public health is standardization of HIE; A public/private State Governance Model; and recognition of the bidirectional benefit of HIE: for clinical sector, improve quality of patient encounter through patient-centered alerts; for public health, improve quality of programs & services with better data; and for both, reduce medical errors, reduce costs, reduce multiple data entry, and reduce paperwork. Electronic lab reporting alone is estimated to provide over $100 million savings for public health. An imperative need for flexibility, sustainability, and accountability exists including a leadership vision and an investment to modernize the public health system to become optimally functional, interoperable and compatible with the clinical sector.

Biosurveillance and Public Health Infrastructure

Biosurveillance initiatives at CDC including the National Biosurveillance Strategy for Human Health, BioSense and BioPHusion intend to provide a real-time detection of an intentional or natural public health threat. Any national biosurveillance system should include a concept of operations and standards necessary to garner trust and confidence between federal and state and local governments and optimize data sharing and that data systems are interoperable. Additionally, these initiatives must consider the state and local public health workforce and capacity necessary to investigate and respond to a threat. A commitment to a biosurveillance system should also include a commitment to sustaining a workforce that can analyze disease-related information, investigate disease outbreaks and respond to mitigate the spread of disease. Decreases in the Public Health Emergency Preparedness cooperative agreement funding, Epidemiology and Laboratory Capacity grants, the loss of Pandemic Influenza Supplemental funding and state budget shortfalls threaten gains made in planning and responding to large-scale threats.

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Addressing Vaccine Safety Concerns

To shore up public support and trust in vaccines, and ensure that current high rates of vaccination are maintained, HHS should make vaccine safety a priority issue. The recently created Vaccine Safety Task Force should be maintained, provided with adequate funding to carry out their work, and expanded to include external partners. HHS and its agencies should consult with risk communications experts to ensure that all vaccine-related messages and educational campaigns are consistent with the tenets of risk communications. With that said, current vaccine safety challenges are not solely communications issues; HHS leadership should consult with experts in NVPO, CDC, NIH and FDA to evaluate current gaps in science and knowledge, and provide funding to conduct the necessary science to fill the gaps. Funding should also be provided to support research priorities identified in CDC's Immunization Safety Office Scientific Agenda. There are many entities in the federal government that have a role in vaccine safety; NVPO is best suited to coordinate and oversee these activities, and should have the requisite resources and authority.

Withdrawal of the Provider Conscience Regulation

On August 21, 2008 HHS proposed a regulation entitled, "Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law." The rule requires states and numerous other entities that receive Health and Human services funds to certify that they will not discriminate against employees or volunteers whose conscience prevents them from carrying out their duties, and expanding the scope of providers who may refuse to assist in the performance of an objectionable procedure to include any kind of public or private health care provider and employees whose duties are indirectly related to the provision of health care, …" ASTHO urges HHS to withdraw the Provider Conscience Regulation. As currently drafted, this rule posed a potentially significant threat to access to appropriate services for state populations and could result in state health agencies being unable to fulfill their core public health functions, individuals being denied access to health services as well as essential information used to make informed decisions about one's personal care, and states being made vulnerable to litigation with health entities.

HHS-ASPR and CDC-COTPER Coordination and Harmonization

Federal health preparedness programs have undergone major organizational changes since the first grants appeared for public health preparedness and hospital preparedness in 1999 and 2002. Most significantly, in 2006 the Pandemic and All Hazards Preparedness Act (PAHPA) established a new Assistant Secretary for Preparedness and Response, who was given direct administrative responsibility over the Hospital Preparedness Program and indirect responsibility for the Public Health Emergency Preparedness Program, which continues to be administered by CDC. Although both programs are operated under HHS, they are not aligned with respect to grant requirements and policies. Additionally, conflicts during field response have occurred further complicated by the myriad of federal regional placements of personnel from different secretariats of HHS and DHS. We ask that the administration clarify roles, responsibilities and functional "lanes" between ASPR and CDC (as well as DHS), and take advantage of opportunities to harmonize and align federal guidance and field response for the two health preparedness programs.

PAHPA Match and Maintenance of Funding Requirements

PAHPA mandates the implementation of Match and Maintenance of Funding (MOF) requirements for the federal preparedness cooperative agreements beginning in fiscal year 2009. Implementation of these requirements has become quite

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problematic necessitating the need to correspond to Secretary Leavitt on September 24, 2008 raising our serious concerns (correspondence attached). For these reasons and the current economic crisis, ASTHO is also urging the new Administration to work with Congress and, as part of the Stimulus Package, suspend for a defined period of time, these requirements.

Pandemic Influenza Operational Plan Submission and Evaluation Simplicity

PAHPA requires that states submit for annual review their operational plans for pandemic influenza. Plans are required to pass federal review as a condition of receiving continued grant funding. This process was implemented creating a significant administrative burden. State health agencies have reported that many of the measures against which they were assessed were not meaningful measures of preparedness, and that insufficient guidance and definitions created reporting challenges. We ask that the Administration review, streamline, and simplify the process for federal review of state pandemic influenza operational plans in coordination with ASTHO which can be accomplished while still meeting the spirit and intent of the law.

Stafford Act, NDMS, and CMS Reform

In recent emergencies, HHS has utilized a legal authority under Section 1135 of the Social Security Act to waive requirements that might impede provision of services under Medicare, Medicaid, and SCHIP. This has been a great benefit to the states directly affected by the emergencies, but has only applied to states for which there is a declared public health emergency and disaster declaration. Other states that have assisted in the response in ways such as taking in evacuees have not been allowed to take advantage of the waivers without their own emergency and disaster declarations. Unless waiver protections are expanded to these states and an improved system for cost recovery and reimbursement is developed especially for those entities participating in the National Disaster Medical System where interstate mutual aid is provided, it will be more difficult for states to assist one another by receiving medical special needs patients and other evacuees. We ask that the Administration examine HHS's legal authority to expand emergency declaration provisions and CMS waivers to all responding states; the need to harmonize the Stafford Act, the Public Health Services Act and the Social Security Act as it pertains to disasters and emergencies, reform/modernize NDMS as per the recommendations of recently submitted by the subcommittee of the National Bioscience Defense Board (http://www.hhs.gov/aspr/conferences/nbsb/ndms-rpt-0809.pdf) , and to propose a legislative remedy if necessary.

The Family Educational Rights and Privacy Act

The Family Educational Rights and Privacy Act (FERPA) was enacted in 1974 to protect the privacy of school education records. Information gathered in a school setting by school employees or institutions is governed by FERPA and cannot be released to state health agencies unless there is a health or safety emergency. While well intentioned, ASTHO believes that the current construct and/or interpretation of the law is counter to good public health practice in that it impedes collection of population-based data, obstructs the conduct of investigations and other disease prevention activities that would benefit school age children. This must be remedied through either revised administrative interpretation or revision to the statute. (Please refer to the attached fact sheet for more details.)

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VFC Delegation of Authority

The Vaccines for Children (VFC) Program must broaden its position and allow for federally qualified health centers and rural health clinics to "delegate authority" to public health clinics to administer VFC vaccine to underinsured children on behalf of the FQHC or RHC. ASTHO strongly believes that a child's eligibility and opportunity to receive VFC vaccine should not be based on where they are getting vaccinated and a legislative solution must be pursued to improve access to vaccinations in public health clinics. (Please refer to the attached fact sheet for more details).

Repeal Certain Provisions of the PREP Act Declarations

HHS has issued a series of Emergency Declarations authorized under the Public Readiness and Emergency Preparedness Act (PREP Act) that provides tort liability protection for activities related to developing, manufacturing, distributing, prescribing, dispensing, administering and use of medical anthrax, pandemic influenza, acute radiation syndrome, smallpox/orthopox, and botulism. Unfortunately, the declarations contain prominent language limiting the tort liability protections to only those entities obtaining/acquiring the covered medical countermeasures through *Voluntary Means* (e.g. means other than government taking or seizure). The current HHS leadership believes that private business concerns over state seizure of their medical countermeasure assets is significant enough that it is deterring many private entities from moving ahead and purchasing and stockpile countermeasures for their employees. ASTHO continues to reinforce the fact that seizure of private assets by states is an option of last resort, only after states exhaust all other means possible to avoid such an action, and only when such an action is unequivocally in the public's best interests. Nevertheless, Secretary Leavitt believes that the declaration should contain language that would remove as many "barriers to preparedness" as possible, including the concern over seizure. ASTHO and the National Governors Association believes that it is necessary to repeal this provision of the declarations and allow us to work with the private sector to develop a common and mutually acceptable framework to this issue as an alternate means to the same end.

Pandemic Preparedness and Shelf-life Extension of Pandemic Antivirals

States have purchased approximately 22-23 Million treatment courses of pandemic antivirals of the target 31 Million treatment courses as called for in the national strategy. There are a number of reasons for this, one being the reluctance of states to invest in this countermeasure with a limited use life originally of five years. Unlike federal assets of the VA, DOD, and HHS/SNS, shelf-life extension does not apply to state owned and managed assets. While we have been successful in having the label life of Tamiflu recently be extended from five to seven years, the formal creation of an enduring state shelf-life extension program is necessary to cover certain state assets. Efforts on this issue have been stalled. It is also necessary to reexamine the current framework of "shared responsibility" in light of the current fiscal situation, especially if impending new guidance may suggest that we now must consider stockpiling for prophylaxis in addition to treatment. (Please refer to our Position Statement on Antivirals Stockpiling which can be found at http://www.astho.org/pubs/AVpositionstatementFINAL.pdf .)

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