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June 30, 2008

U.S. Department of Health and Human Services
Room 434E
200 Independence Avenue, SW
Washington, DC 20201

Attention: Pandemic Influenza Antiviral Comments

**Re: Proposed Guidance on Antiviral Drug Use during an Influenza
Pandemic, 73 Federal Register, June 3, 2008**

To Whom It May Concern:

The American Health Care Association (AHCA) and the National Center for Assisted Living (NCAL) are committed to performance excellence and Quality First, a covenant for healthy, affordable, and ethical long term care. AHCA/NCAL represents nearly 11,000 non-profit and for-profit providers dedicated to continuous improvement in the delivery of professional and compassionate care for our nation's frail, elderly and disabled citizens who live in nursing facilities, assisted living residences, subacute centers and homes for persons with mental retardation and developmental disabilities.

AHCA/NCAL commends the Department of Health and Human Services (HHS) for preparing "Proposed Guidance on Antiviral Drug Use during an Influenza Pandemic." We appreciate the opportunity to offer our comments on the proposed guidance.

Executive Summary

This proposed guidance updates the 2005 HHS Pandemic Influenza Plan recommendations relating to antiviral drug use. In contrast to the 2005 recommendations that define treatment as the primary strategy for antiviral drug use, this guidance proposes prophylaxis of certain populations, including high-risk health care workers and emergency services personnel for the duration of community pandemic outbreaks, post-exposure prophylaxis of workers in the healthcare and emergency services sectors who are not at high exposure risk, and persons living in group settings such as nursing homes if a pandemic outbreak occurs at that facility.

AHCA/NCAL finds the recommendations to be well-thought out and soundly developed. We especially appreciate the inclusive process that HHS used in developing the recommendations and the high level of stakeholder engagement. We agree with most of the recommendations in the proposed guidance, but we do not agree that some of the recommendations should be implemented through private sector stockpiling. We strongly believe that the Federal government should increase the national strategic stockpile to support the new recommendations.

AHCA/NCAL recommends that HHS clarify that LTC facility direct care staff are considered essential healthcare workers who would be eligible for outbreak prophylaxis. Finally, we recommend strengthening the proposed recommendation on information and education.

AHCA/NCAL Recommendations

Direct Care Staff in LTC Facilities

- *AHCA/NCAL recommends that HHS clarify in the body of the proposed guidance and in the table, “Settings and strategies for antiviral drug use during an influenza pandemic and rationales,” that the LTC direct care workforce is targeted for outbreak prophylaxis in a pandemic influenza.*

Private Sector Stockpiles

- *AHCA/NCAL recommends that the Federal government expand the national strategic stockpile to match and support the new Federal recommendations of antiviral prophylaxis for healthcare and emergency personnel.*
- *AHCA/NCAL recommends that the Federal government expand its current contract, which subsidizes 25% of the cost of antiviral drugs for use in a pandemic influenza when purchased by states, to include the same subsidy when purchased by long term care facilities and other essential employers.*
- *AHCA/NCAL recommends that the statement in the proposed guidance that asserts that establishing private sector stockpiles is consistent with the role employers play in protecting their workers and operations against other types of risk is removed in the revised version of the guidance.*

Information and Education

- *AHCA/NCAL recommends that HHS assure implementation of the proposed recommendation to develop and disseminate information and education by including in the revised guidance an additional paragraph that describes responsible parties and provides a timetable for development and dissemination.*

Discussion

The proposed guidance is extremely thorough. The assumptions are clearly laid out and the explanations are helpful. The discussion on ethical perspectives provides useful principles. For the most part, we agree with the recommendations and our comments are limited to what we believe to be clarifications about the status of LTC facility direct care workforce and their priority for outbreak prophylaxis.

Though the proposed guidance states that it does not focus on implementation, several statements in the proposed guidance on implementing the guidance through private stockpiling require us to comment also on that issue. In short, contrary to the views expressed in both this proposed guidance and the companion draft guidance, *Considerations for Antiviral Drug Stockpiling by Employers in Preparation for an Influenza Pandemic*, AHCA/NCAL believes that the strategic national stockpile should be expanded commensurate with the expanded recommendations for prophylaxis treatment.

Direct Care Staff in LTC Facilities Should Be Targeted For Outbreak Prophylaxis in Pandemic Influenza

According to the proposed guidance, the treatment for workers with high-risk exposure is outbreak (pre-exposure) prophylaxis and the treatment for other healthcare workers is post-exposure prophylaxis (PEP). The guidance refers to the Occupational Safety and Health Administration's (OSHA) risk pyramid to help define risk. Workers with exposures to persons known to be infected with pandemic influenza are defined as being at very high and high risk; those who have unavoidable and frequent close contact with persons not known to be infected are defined as being at medium risk. Based on OSHA's risk pyramid, it appears that LTC employees do not fit into the high risk category. In addition, there is no clear recommendation in the proposed guidance that the LTC direct care workforce is recommended for outbreak prophylaxis

The risk pyramid may make sense from OSHA's perspective, which is limited to protecting employees. However, the risk pyramid creates confusion in this proposed guidance where the stated purpose is much broader, i.e., to help achieve the national pandemic response goals of mitigating disease, suffering and death, and minimizing impacts on the economy and functioning of society.

The proposed guidance acknowledges other considerations to help identify whether a population should be targeted for outbreak prophylaxis or PEP. We believe that these other considerations positively result in LTC facility direct care staff being targeted for outbreak prophylaxis even if they are not defined under OSHA's risk pyramid as high risk. For example, under "Ethical Perspectives" the proposed guidance notes that *"Minimizing the harms of an influenza pandemic may require targeting resources to specific groups that protect health and safety and provide essential community services. The Ethics Subcommittee of the CDC Advisory Committee to the Director advises that targeting limited resources to protect societal interests is ethically appropriate."* Since LTC facilities are charged with caring for a very vulnerable population who need to be protected from infection by their caretakers and who require an adequately staffed

workforce to meet their care needs, it is clear that LTC workers fall under this ethical principle.

In addition, the fifth recommendation under “Recommended target groups and strategies for antiviral drug use,” refers to *kitchen and medical records staff at hospitals*” as an example of workers in healthcare who are important to the delivery of essential services, but are not at high risk for exposure and should receive PEP rather than outbreak prophylaxis. AHCA/NCAL does not believe that HHS would place LTC facility direct care staff in the same category as kitchen and medical records staff in a hospital.

Whether LTC facility direct care staff are recommended for outbreak prophylaxis becomes exceedingly important when it is considered in conjunction with HHS priority levels for the pandemic influenza vaccine. Since medically fragile, elderly and disabled individuals living in LTC facilities are not prioritized high (they are at tier 4) for the vaccine, it will be imperative that these vulnerable individuals are protected from infection by the very staff who care for them.

Also important is the expectation that LTC facilities may be surge sites for hospitals in a pandemic influenza. LTC facility direct care staff will not only be taking care of their own vulnerable residents, but also may be caring for hospital overflow patients. The need to maintain a viable workforce is obvious. Outbreak prophylaxis likely would reduce absenteeism among the LTC workforce thus helping LTC facilities to maintain a reasonable staff-to-patient ratio.

The issue is further confused by the Table entitled “Settings and strategies for antiviral drug use during an influenza pandemic and rationales.” This table groups together healthcare and emergency service workers as one target, suggests different treatments--utilizing the OSHA pyramid term, “high-risk exposure” for outbreak prophylaxis and PEP for other workers--and then combines the rationale for both. Thus, the table does not help to clarify whether and why PEP or outbreak prophylaxis is the recommended treatment. We assume that the OSHA term “high-risk” was utilized in this table for convenience and not to exclude the critical LTC direct care workforce from outbreak prophylaxis, but this needs to be clarified. Therefore, AHCA/NCAL makes the following recommendation:

- ***AHCA/NCAL recommends that HHS clarify in the body of the proposed guidance and in the table, “Settings and strategies for antiviral drug use during an influenza pandemic and rationales,” that the LTC direct care workforce is targeted for outbreak prophylaxis in a pandemic influenza.***

Dependence on Private Sector Stockpiles Is Unwise

AHCA/NCAL strongly disagrees with the proposed guidance’s assumption that, *Implementation of recommendations for prophylaxis of healthcare and emergency services workers who have high-risk exposures and for PEP in recommended settings will depend largely on private sector organizations and businesses purchasing and stockpiling antiviral drugs for their employees.*” This assumption completely ignores the

wide disparities in employer resources and does not recognize the economic stresses faced by LTC facilities.

Medicaid and Medicare together pay nearly 70% of post-acute and LTC costs and Medicaid chronically underfunds LTC facilities. A recent *BDO Seidman/Eljay, LLC* study shows that states cumulatively underfunded the actual cost of providing quality nursing facility care by \$4.4 billion in 2007. The analysis further shows the average shortfall in Medicaid nursing home reimbursement was \$13.15 per patient day in 2007 – a 45% increase from 1999.

The shortfall is likely to get worse during these difficult economic times. Medicaid is consistently one of the first programs targeted for cuts at the onset of state budget shortfalls and, according to the National Governors Association, the recent economic downturn has left at least 18 states with budget shortfalls and 21 states with projected shortfalls in 2009.

Nursing facilities also may experience cuts in Medicare reimbursement beginning fiscal year 2009. The Centers for Medicare and Medicaid Services issued a proposed rule for fiscal year 2009 payments to skilled nursing facilities that would cut Medicare Part A payments for skilled nursing care by \$770 million in the first year alone, or \$5 billion over five years.

Additional information on the complexities involved in determining whether a LTC facility should stockpile antivirals in preparation for an influenza pandemic are described in AHCA/NCAL's comments to HHS' companion draft guidance entitled, *Proposed Considerations for Antiviral Drug Stockpiling by Employers In Preparation for an Influenza Pandemic*. That comment letter is attached to this letter, but the recommendations made in the other comment letter bear repeating here. In that letter, we state:

Given the economic constraints of the LTC industry, the unanswered questions as to effectiveness and side-effects of antivirals, the potential for seizure and, yet, the importance of maintaining a workforce to protect and care for its vulnerable residents in a pandemic, AHCA/NCAL offers the following recommendations:

- ***AHCA/NCAL recommends that the Federal government expand the national strategic stockpile to match and support the new Federal recommendations of antiviral prophylaxis for health care and emergency personnel.***
- ***AHCA/NCAL recommends that the Federal government expand its current contract that subsidizes 25% of the cost of antiviral drugs for use in a pandemic influenza when purchased by states to include the same subsidy when purchased by long term care facilities and other essential employers.***

AHCA/NCAL disagrees also with the statement in this proposed guidance that establishing private sector stockpiles “is consistent with the role employers play in protecting their workers and operations against other types of risk.” Unlike other

protections against risk, the cost for antiviral stockpiling is significant to the point of being prohibitive and additional complexities, such as the possibility that the antivirals may expire before they are used and the state may seize a private stockpile, further complicates the issue.

Unlike other employee protections, there are clear legal, regulatory, ethical, logistical, and economic issues that would be encountered in ordering, storing, securing and dispensing prescription medications.¹ Unlike other employee protections that are usually mandatory, the companion draft guidance makes clear throughout that it does not establish the requirement or expectation that employers will stockpile antiviral drugs, noting that antivirals are only one tool among many to mitigate a pandemic influenza. That draft guidance states: “The Federal Government encourages employers to consider stockpiling antivirals for use during an influenza pandemic if stockpile plans are consistent with their overall pandemic preparedness plan and they have carefully considered the legal, ethical, regulatory, logistical, and economic implications of stockpiling antiviral medications.” Therefore, AHCA/NCAL makes the following recommendation:

- ***AHCA/NCAL recommends that the statement in the proposed guidance that asserts that establishing private sector stockpiles is consistent with the role employers play in protecting their workers and operations against other types of risk is removed in the revised version of the guidance.***

Information and Education are Very Important

AHCA/NCAL agrees with the recommendation in the proposed guidance that information and educational materials should be developed by Federal agencies and advisory groups and disseminated to states and other stakeholders to support appropriate use of antiviral treatment and prophylaxis during an influenza pandemic, emphasize adherence with recommended regimens and promote effective implementation. Education and information is extremely important, particularly since scientific and technological advances likely will lead to changing strategies and the need for updated, continuing information. Strategies also are likely to change once a pandemic occurs and more is known about the characteristics of the virus epidemiology of disease and impacts on society. Therefore, AHCA/NCAL provides the following recommendation to strengthen and support the proposed recommendation on information and education:

- ***AHCA/NCAL recommends that HHS assure implementation of the proposed recommendation to develop and disseminate information and education by including in the revised guidance an additional paragraph that describes responsible parties and provides a timetable for development and dissemination.***

¹ Pointed out by HHS’ companion draft guidance, *Proposed Considerations for Antiviral Drug Stockpiling by Employees In Preparation for an Influenza Pandemic*.

Conclusion

The many unknowns relating to pandemic influenza make planning and preparation challenging. Plans must be flexible as we learn more or circumstances change. In this case, the Federal government proposes to change its recommendations for antiviral usage in a pandemic because the supply has increased. We agree with the expanded recommendations, but the national strategic stockpile also should be increased to support the new recommendations. In addition, the essential LTC direct care workforce should be clearly identified as a priority for outbreak prophylaxis.

Sincerely,

A handwritten signature in black ink, appearing to read "Bruce Yarwood". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Bruce Yarwood
President and CEO