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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 Employer Antiviral Comments

**Re: Employer Antiviral Stockpiling Draft Guidance, 73 Federal Register,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 drafting *Considerations for Antiviral Drug Stockpiling by Employers in Preparation for an Influenza Pandemic*. We appreciate the opportunity to offer our comments on the proposed guidance.

Executive Summary

This proposed guidance was prepared to assist employers to determine whether they should stockpile or otherwise arrange for influenza antiviral drugs to be available for their employees during a pandemic. The guidance notes that private stockpiles, in coordination with public health stockpiles, i.e., the national strategic stockpile and state stockpiles, would extend protection more broadly than could be achieved through the public sector alone and would improve the ability to achieve the national pandemic response goals of mitigating disease, suffering and death, and minimizing impacts on the economy and functioning of society.

AHCA/NCAL finds the guidance to be well-thought out and comprehensive. Our major concern is that the guidance stops short where we most need it—there is no discussion on assistance to cover the costs of providing antivirals to long term care (LTC) facility employees. Very few LTC facilities have funds in reserve to purchase the large amount of antiviral drugs that would be required to provide antiviral prophylaxis to employees. This is a very expensive proposition.

LTC facilities are chronically underfunded by Medicaid. The majority of nursing facility patients, as well as residents in intermediate care facilities for people with mental retardation, are Medicaid patients. Any decision to stockpile antiviral medication must be considered in conjunction with other potential uses of the LTC facility's limited funds, including maintaining quality of care and services.

Discussion

The draft guidance is thorough and helpful as an educational and planning tool. It clearly defines the considerations involved in undertaking the significant effort of antiviral drug stockpiling and planning its effective use. The difficulty for LTC facilities is not the recommendations, but the implementation of the recommendations.

Along with this draft guidance, HHS also released a companion proposed guidance, *Proposed Guidance on Antiviral Drug Use during an Influenza Pandemic*. The companion proposed guidance recommends expanding the use of antivirals in a pandemic influenza to include prophylaxis for certain populations. The draft guidance on stockpiling, which we are commenting on in this letter, places the responsibility for implementing the expanded recommendations on private employers, rather than suggesting that the Federal government increase the national strategic stockpile to cover the expanded recommendations. AHCA/NCAL is very concerned about this approach.

The companion proposed guidance states clearly that stockpile targets developed in 2005 “were established when production capacity and supply were limited.” Now that antiviral supplies are no longer limited, AHCA/NCAL firmly believes that the Federal government must step up to the plate and increase the strategic national stockpile targets to accommodate the newly released recommendations for prophylaxis treatment. **Thus, 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.**

The Institute of Medicine of the National Academies (IOM) states in its recently released report, *Antivirals for Pandemic Influenza: Guidance on Developing a Distribution and Dispensing Program*, that private employer stockpiling on a large scale is unlikely due to administrative constraints, fiscal limits, and other private-sector concerns about stockpiling.

Yet this HHS draft guidance on stockpiling makes the assumption that “employers will have to take the lead role for protection of their workforce if these recommendations are to be implemented.” This expectation ignores the potential for increasing the Federal

stockpile, ignores the concerns expressed by the IOM and completely ignores the wide disparities in employer resources.

It is important to recognize the economic stresses faced by LTC facilities. Medicaid and Medicare together pay nearly 70% of post-acute and LTC costs. Medicaid chronically underfunds LTC facilities. A recent *BDO Seidman/Eljay, LLC* study illustrates 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 projecting shortfalls in 2009.

Beginning fiscal year 2009, nursing facilities also may experience cuts in Medicare reimbursement. 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.

Given the serious economic realities and the magnitude of the anticipated cuts that LTC faces, the decision to spend limited dollars to stockpile antivirals is extremely difficult. On the one hand, LTC facilities must maintain their workforce and keep their workforce and vulnerable residents safe in a pandemic influenza. On the other hand, stockpiling antivirals for employee prophylaxis is an exorbitant proposition for LTC facilities that clearly do not have the resources to cover that expense.

To alleviate some of the fiscal stress of purchasing a portion of antivirals for prophylaxis, **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 LTC facilities and other essential employers.**

The decision to stockpile antivirals is made even more challenging because there is no guarantee that the antivirals will be effective against a new influenza strain or that there won't be rapid drug resistance. The potential complications and side-effects of the antivirals also are not clear. The two agents, oseltamivir and zanamivir, that are being purchased for the strategic national stockpile and state stockpiles have never been used in a pandemic and their effectiveness against a pandemic influenza virus cannot be predicted. In addition, the current FDA-approved expiration date for the two agents is 5 years from the date of manufacture and once expired, would have to be disposed of by employers. How can a LTC facility choose to use its very limited resources that are needed to maintain quality and quality improvement initiatives on antivirals that may or may not work and may expire before needed?

The antiviral expiration problem would be reduced if the Federal government's Shelf-Life Extension Program, which tests batches of drugs several months before expiration to determine their viability, is extended to include private entities that are stockpiling antivirals for use in an influenza pandemic. The recently released IOM report recommends that the Shelf-Life Extension Program be expanded to include private sector employees that stockpile antivirals for use in an influenza pandemic. The IOM further recommends that HHS develop a process to use the knowledge acquired by the Food and Drug Administration in the operation of the Shelf-Life Extension Program to facilitate the use of properly stored, recently expired medications that exist in supplies outside the Shelf-Life Extension Program in the event these medications are needed because of a shortage. **AHCA/NCAL agrees with and echoes, in our recommendations, these recommendations of the IOM.**

Also complicating the decision to expend LTC facilities' very limited resources on antivirals is the concern that a state or local government could seize an employer's stockpile during a pandemic. While the draft guidance discourages the potential appropriation of privately held stockpiles of antivirals by governmental authorities, it also acknowledges the responsibility of a state to coordinate all assets within its jurisdiction to respond to public health emergencies, including pandemics. Thus, in determining whether or not to use its limited fiscal resources on an antiviral supply, the LTC facility must include in its decision making, the potential that the antiviral stock could be seized by the state.

In addition, the draft guidance notes that decisions on stockpiling should be made in the context of comprehensive pandemic planning that includes a range of protective measures to minimize employee infections during a pandemic. Other protective measures also are expensive, e.g., the Occupational Safety and Health Administration recommends the purchase and stockpiling of respirators and face masks.

Recommendations

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 recommends that the Federal government's Shelf-Life Extension Program be expanded to include private sector employees, including LTC facilities, that stockpile antivirals for use in an influenza pandemic.*
- *AHCA/NCAL recommends that HHS develop a process to use the knowledge acquired by the Food and Drug Administration in the operation of the Shelf-Life Extension Program to facilitate the use of properly stored, recently expired medications that exist in supplies outside the Shelf-Life Extension Program in the event these medications are needed because of a shortage.*

Conclusion

Outbreak antiviral prophylaxis of LTC workers would help maintain a workforce to care for LTC patients in an influenza pandemic. Also, it would reduce the risk of direct care staff transmitting infection to their vulnerable patients. This is especially important as LTC residents are not a high priority for receiving pandemic influenza vaccine. Budget challenges, opportunity costs, and other considerations will make it very difficult for LTC facilities to stockpile enough antivirals for prophylaxis of their employees. To implement the newly proposed recommendation of prophylaxis for these essential health care workers, the Federal government should expand the strategic national stockpile, subsidize the cost of the antiviral drugs for health care and other essential workers and broaden shelf-life extension programs.

Sincerely,



Bruce Yarwood
President and CEO