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Executive Council of Iowa

CAPITOL BUILDING
DES MOINES, IOWA 50319
PHONE: 515 281-5368
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July 28, 2006

RECEIVED

JUL 28 2006

**LEGISLATIVE SERVICES
AGENCY**

Dennis Prouty, Director
Legislative Services Agency
State Capitol
L-O-C-A-L

Dear Director Prouty:

Pursuant to Senate File 2373, section 7, which amended Iowa Code section 7D.29, I am writing to notify the Legislative Services Agency that the Iowa Department of Public Health has requested funds for the purchase, storing and distribution of antiviral medications for prevention and treatment in the event of an influenza pandemic. This request is authorized under Senate File 2373, section 7 and House File 2797, section 54. Enclosed is background information that has been provided to the Executive Council by the Department in support of this request.

The Department is on the Executive Council agenda for Monday, July 31, 2006, to present information in support of the request. In accordance with Senate File 2373, section 7, the Executive Council will not vote to approve or deny the request for two weeks following issuance of this notice.

We anticipate the matter will be placed on the agenda for a vote on August 14, 2006.

Executive Council of Iowa


Georg Anna Madsen
Executive Secretary

Enclosure

Jp/gm



THOMAS J. V. BRACK
GOVERNOR

OFFICE OF THE GOVERNOR

SALLY J. PASTERNAK
FIRST LADY GOVERNOR

June 29, 2006

Ms. Trivia Brooks, Public Health Advisor
Centers for Disease Control and Prevention
Division of State and Local Readiness
Coordination Office for Terrorism Preparedness
and Emergency Response
1600 Clifton Road, NE
MS-D29
Atlanta, GA 30333

Dear Ms. Brooks:

Please find this letter to serve as Iowa's response to Supplemental Guidance (Catalog Federal Domestic Assistance Number: 93.283) through the *Public Health Preparedness Cooperative Agreement* for the purpose of further supporting pandemic influenza preparedness and response.

Specifically this letter is addressing item **G. Critical task to be performed**,
5. Determine whether to purchase antiviral drugs in concert with HHS and if so report to the CDC Project Officer by July 1, 2006, the number of treatment courses that the recipient wishes to acquire in this manner. Note that most or all of the recipients purchase will be eligible for a 25% subsidy by HHS of the supplemental guidance

It is the intent of the State of Iowa to purchase 308,887 courses of antivirals at the 25% subsidy rate offered by HHS, however a final purchase decision will be based upon receipt of information promised by HHS regarding further details on the federally negotiated contracting mechanism available for the purchase of antiviral drugs, including description of the contractual arrangements under which states can purchase antiviral drugs eligible for this cost sharing. Additionally, the final purchase decision will be based on details yet to be released by HHS regarding the options for storage of purchased antiviral caches, and options for distribution to and within our state's jurisdiction.

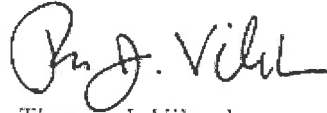
In accordance with Iowa Code 71D.29 the Iowa Department of Public Health has authority to request funding for the purchase of vaccines and or pharmaceuticals through the executive council as follows: *"The executive council shall receive requests from the IDPH, relative to the purchase, storing, and distribution of vaccine and medication for prevention, prophylaxis or treatment. Upon review and after compliance with subsection 2, the ex. council may approve the request and may incur the necessary expense and pay the same out of any money in the state treasury not otherwise appropriated."*



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Ms. Trivia Brooks
June 29, 2006

If you should have any questions regarding this letter of intent please contact Mary J. Jones, Division Director, Acute Disease Prevention and Emergency Response, Iowa Department of Public Health at (515) 281-4355 or email her at mjones@idph.state.ia.us.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Tom J. Vilsack". The signature is written in a cursive, flowing style.

Thomas J. Vilsack
Governor



Iowa Department of Public Health
Advancing Health Through the Generations

Thomas J. Vilsack
Governor

Sally J. Pederson
H. Governor

Mary Mincer Hansen, R.N. PhD
Director

MEMORANDUM

EXECUTIVE COUNCIL
2006 JUL 26 AM 7:11

TO: Executive Council
Health and Human Services Caucus Staff

FROM: Mary Mincer Hansen
Director - IDPH

REFERENCE: Pandemic Influenza Preparedness
Antiviral Purchase

DATE: July 24, 2006

I am writing this memo to update you on a specific pandemic influenza planning activity. In accordance with a requirement from the Department of Health and Human Services (HHS) Pandemic Influenza Supplemental Grant Application please find attached the letter of intent from Governor Vilsack regarding the purchase of 308,887 courses of antivirals to cover 25% of Iowa's population. All states are required to submit a letter of intent in order to be eligible for a 25% subsidy by HHS for the purchase of antivirals. The letter of intent is not a binding agreement; rather it expresses Iowa's interest in participating in the subsidy program. Please note in the letter that a final purchase decision will be based on receipt of further details regarding the federally negotiated contractual arrangements, options for distribution to and within our state and storage for the antivirals.

In anticipation of making a future request to the executive council for funding, I want to brief you on what we know at this time. The current CDC recommendation is to purchase 308,887 courses of antivirals to cover 25% of Iowa's population using a split of 80% Tamiflu antiviral and 20% Relenza antiviral purchase. The cost for purchase of one course of Tamiflu will be \$14.43 per course. At \$14.43 per course for 247,110 courses (80% of our cache) the total cost for Tamiflu is \$3,565,797.30. Price for purchase of Relenza has not yet been established. As soon as the purchase price for Relenza has been established I will let you know. Additionally, this cost does not reflect stand-up costs associated with storage, planning, distribution, and maintenance of Iowa's anti-viral cache.

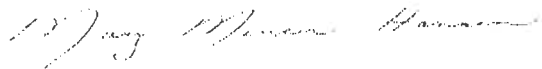
As caucus staff will recall, Legislation passed last session (Iowa Code 7D.29) gave the Department the authority to request funding for the purchase of vaccines and or pharmaceuticals through the executive council as follows: "The executive council shall receive requests from the IDPH, relative to the purchase, storing, and distribution of vaccine and medication for prevention, prophylaxis or treatment. Upon review and after compliance with subsection 2, the ex. council may approve the request and may incur the necessary expense and pay the same out of any money in the state treasury not otherwise appropriated."

Once we have received final details from HHS regarding the federally negotiated contractual arrangements, options for distribution to and within our state, storage for the antivirals, needed staff to develop and implement plans and a timeline for payment, we will submit a request for funds to the executive council.

I have not briefed our local public health and health care partners yet but will be doing so once we have more information

If you have any questions please feel free to contact me at (515) 281-8474 or by email at mary.hansen@idph.state.ia.us.

Thank you for your support.

A handwritten signature in cursive script, appearing to read "Mary Mincer Hansen".

Mary Mincer Hansen, R.N., PhD
Director, Iowa Department of Public Health

**Pandemic Influenza Preparedness and Response
 Executive Council Meeting July 31, 2006**

State of Iowa Antiviral Stockpile

REQUEST

In accordance with Iowa Code 7D.29, Iowa Code Section 135.142(1) and 135.141(2) of the Iowa Department of Public Health (IDPH) is requesting funds for the purchase, storing and distribution of antiviral medications (308,887 courses at a 25% federal subsidy rate) for prevention and treatment in the event of an influenza pandemic. The Federal government is in the process of purchasing 438,420 courses for Iowa (to be placed in the Strategic National Stockpile) and with the state purchase of 308,887 courses a total of 747,307 courses will be available for approximately 25% of Iowa's population as recommended by the Health and Human Services (HHS) Pandemic Influenza Response Plan, November 2005.

Pandemic Influenza Antiviral Stockpile

TOTAL: By December 2008 – 81 million courses*/IOWA 747,307 courses

HHS 24 million courses	HHS expected to purchase 24 million courses to be placed on the Strategic National Stockpile. (FY 2007) IOWA Allocation - 239,138 courses
States 31 million courses	States to purchase 31 million courses with 25% federal subsidy. (FY 2006) IOWA Purchase - 308,887 courses
HHS 20 million courses	HHS ordered 20 million courses to be placed on the Strategic National Stockpile. (FY 2006) IOWA Allocation - 199,282 courses
HHS 6 million	HHS courses on hand

*a course is the number of doses needed to treat one person

Legal Authority

Amendment to Iowa Code 7D.29 (Senate File 2273 section 7)

"The executive council shall receive requests from the Iowa department of public health, relative to the purchase, storing, and distribution of vaccines and medication for prevention, prophylaxis, or treatment. Upon review and after compliance with subsection 2, the executive council may approve the request and may incur the necessary expense and pay the same out of any money in the state treasury not otherwise appropriated."

Iowa Code section 135.142(1)

"The department may purchase and distribute antitoxins, serums, vaccines, immunizing agents, antibiotics, and other pharmaceutical agents or medical supplies as deemed advisable in the interest of preparing for or controlling a public health disaster."

Iowa Code section 135.141(2)f

“Coordinate the location, procurement, storage, transportation, maintenance and distribution of medical supplies, drugs, antidotes, and vaccines to prepare for or in response to a public health disaster.....”

BACKGROUND

Protecting human health is at the core of pandemic preparedness. The fundamental determinants of the public health response to a pandemic will be its severity, the prompt implementation of public health interventions, and the availability and efficacy of vaccine and antiviral medications. Decisions about the prioritization and distribution of medical countermeasures (vaccines and antivirals); the content of public information, the application of community infection control and public health containment measures (social distancing) and making adjustments in the way care is provided are all interrelated and will be determined based on the ability of the pandemic virus to cause severe illness and death and the availability and effectiveness of vaccine and antiviral medications. The optimal way to control the spread of a pandemic and reduce its associated illness and death is through the use of vaccine. It is estimated that it will take 6-9 months following the emergence of a pandemic influenza virus to manufacture the vaccine with partial shipments to states occurring over time until 100% of the population is covered.

Antiviral Medications

Antiviral medications, an adjunct to influenza vaccine, can be used for prevention or treatment of people exposed to influenza. Currently there are only two classes of medications (neuraminidase inhibitors and adamantanes) that demonstrate efficacy against circulating influenza viruses. Both are most effective if administered in the early stages of infection. It should be noted that adamantane resistance emerges fairly quickly and adamantane-resistant H5N1 influenza already circulates. Resistance to the oral neuraminidase inhibitor emerges more slowly but has been associated with treatment failure in patients with H5N1. At this time there are limited supplies of both classes of antiviral medications.

Tamiflu® and Relenza® (neuraminidase inhibitors) are the antiviral medications currently being stockpiled by the Federal Government with a 80/20 ratio of Tamiflu to Relenza and are the antivirals requested to be purchased by the Iowa Department of Public Health (IDPH). The Federal Government has established two primary goals for stockpiling antiviral medications: 1) establish and maintain stockpiles adequate to treat 75 million persons (25% of the US population) divided between Federal and State stockpiles; and 2) establish and maintain a Federal stockpile of 6 million treatment courses reserved for prevention/containment efforts when the virus initially emerges.

For **Tamiflu** a treatment course (number of doses needed to treat one person) for symptomatic patients 1 year of age or older is 2 capsules per day for 5 days (10 capsules). For prevention a course is 1 capsule per day for a minimum of 10 days and during a community outbreak may require administration up to 6 weeks. The shelf life (expiration date) for this antiviral medications is 5 years.



For **Relenza** the treatment course (number of doses needed to treat one person) for symptomatic patients 7 years of age or older is two inhalations (one 5-mg blister per inhalation for a total dose of 10 mg) twice daily (approximately 12 hours apart) for 5 days. For prevention a course is 10mg inhaled once daily for 10 days. The shelf life (expiration date) for this antiviral medications is 5 years.



With limited supplies of antivirals and because use of antivirals for prevention requires more medication, use of antivirals for prevention should be reserved only for initial containment efforts or other highly select circumstances. Focus will be placed on use of the stockpiled antivirals for treatment.

Federal Contract Overview

The Federal Government will be purchasing both Tamiflu and Relenza at an 80/20 ratio. Contracts with Roche Pharmaceutical and GlaxcoSmithKline have been finalized and distributed to State Health Officials for the purchase of Tamiflu and Relenza respectively.

- The federal contract price for Tamiflu, *before the 25% federal subsidy*, is \$19.24 and at the 25% subsidy is \$14.43/course. This price is effective through December 31, 2007, and includes the cost of shipping to one location per order. A new contract price will be negotiated prior to the expiration of the \$19.24 rate.
- The federal contract price for Relenza, *before the 25% federal subsidy*, is \$21.72 and at the 25% subsidy is \$16.29/course. This price is effective through December 31, 2007, and includes the cost of shipping to one location per order. A new contract price will be negotiated prior to the expiration of the \$21.72 rate.
- The 25% federal subsidy is available to states for the life of the contract (2 years).
- Delivery of courses ordered (beginning now) under the federal contracts will likely not occur before March 2007; delivery date will be determined by the date of order. Purchases under the federal subsidized program will receive priority delivery over purchases outside of this program.
- Funds must be obligated when the order is placed; payment will be due to pharmaceutical company upon receipt of the product. States may receive one order in multiple shipments.
- Any portion of the 31 million courses that states do not wish to purchase will be reallocated among states wishing to purchase additional courses beyond their allotment. The federal subsidy will still apply to these courses. States have **six months** from the beginning of the contract (June 29, 2006) to either layout a plan to purchase the entire allotment or affirmatively forfeit the remainder of the allotment, thereby allowing it to be reallocated among other interested states.
- All state-purchased antivirals must be managed by the state; these supplies will not be stored in the Strategic National Stockpile (SNS). HHS is still determining whether the state-managed supplies will be eligible for the FDA's Shelf-Life Extension Program (SLEP) and/or whether the stocks may be rotated with other state antiviral inventories. The SLEP allows for maintaining the medications past their expiration dates.

- The current shelf-life of Tamiflu and Relenza is 5 years. The terms of the contract preclude stock rotation in advance of an influenza pandemic. HHS is prepared to work with states and the manufacturers to see if it can create a rotation policy satisfactory to all parties. For now states should assume that their stocks of antiviral drugs will not be usable after they reach their rated shelf life – either the original shelf life or a later date if the particular state stockpile in question is participating in a shelf-life extension program.
- It is not known if or when generic antivirals will be available.
- Funds awarded to States for Pandemic Influenza or Bioterrorism may not be used for the purchase of antivirals or for storage, maintenance or distribution.

Storage Facility Requirements

Composition of the stockpile of 80% Tamiflu and 20% Relenza will require approximately 128 standard sized pallets. Each pallet requires 14 square feet of floor space. 128 pallets would require a total floor space of 1,792 square feet. Not included in these figures would be necessary aisle space to maneuver equipment. The building's layout will dictate the needed aisle space but could be estimated at an additional 300 – 500 square feet. Estimated aisle space and pallet floor space for cost estimates will be calculated at 2,300 square feet. The facility must meet the following requirements:

- Enclosed facility, interior protected from outside environment
- Automatic fire detection and fire suppression system(s)
- Facility shall be free of vermin and rodents
- Open floor space (no barriers)
- Smooth, level concrete floor, free of voids
- Standard height loading dock (36 inches)
- Ceiling height, 12 foot minimum
- Garage door entrance (12 ft X 10 ft) with electric opener
- HVAC system to control/maintain internal environment (59 – 86 degrees F)
- Electrical outlets (110 & 220 volts)
- Adequate overhead lighting
- Telephone line
- Alarm systems for temperature controls and security

Equipment will be needed for the storage facility to move the assets and annual re-occurring costs associated with management and monitoring of the medications is itemized in the budget request. Additional cost associated with Iowa's Antiviral Cache will be the distribution and transportation of the assets to local receiving sites once the assets are released for use.

Priority Groups

Priorities for antiviral medication use will vary based on the pandemic severity as well as the antiviral supply. Currently antiviral medications are in short supply, thus narrow targeting and efficient use is required. Antiviral medical use should be reserved for symptomatic individuals who are at high risk of serious illness or death. No single priority list is appropriate for all possible scenarios. Consideration may be given for limiting transmission (prevention) for those individuals exposed to the first case or two when the virus first emerges in Iowa.

When a pandemic is imminent, information will be obtained from the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC) or from other states regarding

target populations and high-risk groups if the virus emerges in another country and or state before it emerges in Iowa. IDPH will evaluate CDC's prioritization recommendations to address the antiviral prioritization within the State of Iowa. This will be done in consultation with the Iowa's Infectious Disease Advisory Committee (IDAC), and then IDPH will establish and deliver the antiviral prioritization strategy along with other prevention and control strategies to response partners and the public. Those who perform essential/critical services and their family members will all be considered when determining the best use of limited amounts of antivirals.

The severity of a pandemic cannot be predicted until the virus emerges, therefore the initial analysis of the characteristics of the virus and its epidemiology will tell us a lot about how the pandemic may unfold and will guide prevention and control strategy implementation, specifically antiviral use. Focus will be on the ability of the virus to cause severe illness and death and the availability and effectiveness of the antivirals medications. Decisions about prioritization and distribution of medical countermeasures, community infection control measures, and the content of public information releases will also be based on these factors.

Planning and Response

When using antivirals for prevention dispensing must occur within 2 days of exposure and for treatment administration must occur within 2 days of the onset of symptoms. This obviously presents significant logistical and operational challenges and will require comprehensive planning and collaboration between local, state, federal, and private partners. It is necessary to establish a management structure and develop and exercise specific countermeasure storage, maintenance and distribution plans and operating procedures that are fully integrated into local emergency plans and the State Public Health Emergency Response Plan, the State Pandemic Influenza Response Plan Annex and the Strategic National Stockpile (SNS) Operational Procedures.

States are responsible for the receipt, storage and distribution of the antiviral medications to be received from the SNS that will be pre-deployed (438,420 courses purchased by the Federal government for Iowa) when a pandemic is eminent and are responsible for the purchase, storage, maintenance, and distribution of the antiviral stockpile to be purchased by the State (308,887 courses purchased by the State of Iowa). This requires plans that cover storage, maintenance, dividing the allocation into units, and arranging for delivery of the medications to the local agencies and or healthcare providers responsible for dispensing and or administering the medications.

Budget Request

See attached excel budget request and summary.

**Executive Council Funding Request July 31, 2006
Pandemic Influenza Planning and Response:
State of Iowa Antiviral Stockpile**

Categories	Justification	Start-up Funding Request	Annual Ongoing Costs
Antivirals (cost reflects full antiviral cache of Tamiflu and Relenza)			
Antiviral - Tamiflu (247,110 Courses) 80% of allotment	Purchase of 247,110 courses (80% of ratio) of the medication (antiviral) Tamiflu at a 25% federal subsidy rate for prevention and treatment in the event of an influenza pandemic. Unit cost is \$14.43/course.	\$3,565,798	\$0 for 5 years (shelf life of medication)
Antiviral - Relenza (61,777 Courses) 20% allotment	Purchase of 61,777 courses (20% of ratio) of the medication (antiviral) Relenza at a 25% federal subsidy rate for prevention and treatment in the event of an influenza pandemic. Unit cost is \$16.29/course.	\$1,006,347	\$0 for 5 years (shelf life of medication)
Antiviral Storage and Maintenance (cost reflects full antiviral cache of Tamiflu and Relenza)			
Centralized Storage Facility	Contract to provide for the <u>annual</u> safe, secure and environmentally controlled storage of Iowa's Antiviral Cache of 308,887 courses of Tamiflu and Relenza. Total space needed is 2,300 sq ft. to store 6,669 cases of antivirals that totals 128 pallets at a weight of 45,312 lbs.	\$19,780	\$19,780 Facility Rental
Equipment	Purchase of equipment for the storage facility: Electric Fork Lift \$25,000 Pallet Rack System \$25,000 Monitoring Security System \$3,500 Four Directional Hand Pallet Trucks (4) \$2,200	\$55,700	\$2000 Monitoring service and phone service
Program Start-up			
Planning, Education, Exercises	Contract to provide for the development of operational plans and procedures for receipt of, storage, distribution and maintenance of the antiviral stockpile both state owned and receipt of federal assets. Develop and integrate federal, state and local distribution and storage plans. Collaborate with local, state and federal partners. Includes providing education, development of and participating in exercises. Includes salary, fringe and administrative costs.	\$156,718	\$156,718
Equipment and Supplies	To support purchase of computers and software licenses, office supplies and communication equipment. Includes printing and copying for education and exercises, plans, policies, procedures, development of CDs and DVDs.	\$7,420	\$3,500
Travel	Travel in state will be required for planning meetings, education and exercise participation with local and state partners. Additionally, out-of-state travel will be necessary for planning to receive antivirals by way of the Strategic National Stockpile.	\$6,000	\$6,000
TOTALS			
Start-up Funding Request	Iowas Antiviral Stockpile	\$4,817,763*	
Annual Ongoing Costs	Iowas Antiviral Stockpile		\$187,998**

*Does not include distribution costs at the time antivirals are released to local providers

** Does not include cost of living increases

Executive Council Funding Request July 31, 2006
 Pandemic Influenza Planning and Response:
 State of Iowa Antiviral Stockpile Budget Summary

Categories	Start-up Funding Request	Annual Ongoing Costs
Antivirals	\$4,572,145	\$0 for 5 years (shelf life of medication)
Antiviral Storage and Maintenance	\$75,480	\$21,780
Prgram Start-up and Coordination	\$170,138	\$166,218
TOTALS	\$4,817,763*	\$183,998**

*Does not include distribution costs at the time antivirals are released to local providers

** Does not include cost of living increases