

Pandemic Influenza Frequently Asked Questions

Version 2/March 17, 2006

Antiviral Purchase

Q: How many antiviral treatment courses has HHS purchased? How many courses is HHS planning to purchase?

A: HHS has plans to purchase or subsidize the purchase of 81 million treatment courses of antivirals:

- 6 million antiviral treatment courses will be reserved for prophylactic quenching of any localized outbreaks (similar to a ring vaccination strategy).
- 44 million antiviral treatment courses will be stored in the SNS, earmarked for states and other entities and made available to them when an influenza pandemic is judged to be imminent. These treatment courses will be allocated to PHEP grantees on a per capita basis.
 - Approximately 20 million courses will be purchased with FY 2006 funding. Most of this cache will consist of Tamiflu, while a small fraction will consist of Relenza.
 - HHS plans to purchase 24 million courses with yet to be appropriated FY 2007 dollars.
- HHS will subsidize the purchase of 31 million treatment courses by PHEP grantees. HHS will subsidize 25% of the cost, and grantees will pay the other 75%. Grantees may decide how many (if any) treatment courses to purchase with the assistance of the subsidy. The subsidy will be allocated on a per capita basis.
 - Grantees must remember that antivirals cannot be purchased with funds provided in this first phase of supplemental pandemic influenza funding. Grantees must use other funds for such purchases.
 - If any of the grantees elect not to use their full share of the subsidized purchase opportunity and others desire to purchase more than their originally allocated share, it is anticipated that HHS will redistribute the subsidy funds accordingly.
 - If grantees decide to purchase antivirals in this manner, they must notify their CDC project officer by July 1, 2006 of the number of treatment courses that they plan to purchase.

On March 1, 2006, HHS announced that it has purchased an additional 12.4 million treatment courses of oseltamivir (Tamiflu) and an additional 1.75 million treatment courses of zanamivir (Relenza). The SNS currently contains approximately 5.1 million treatment courses of Tamiflu and 84,000 treatment courses of Relenza. These new purchases are part of the 20 million treatment courses that HHS plans to purchase with FY 2006 funds and hold in the SNS for eventual distribution across the country when an influenza pandemic is deemed to be imminent.

Q: During a pandemic, how many courses of antivirals can each of the grantees expect to receive from the federal government?

A: The FY 2006 HHS budget allows HHS to purchase 20 million treatment courses of antivirals for subsequent distribution to PHEP grantees and to subsidize the purchase of 31 million treatment courses by the grantees (HHS will provide a 25% subsidy; \$170 million has been designated for this). The allocations for each grantee under these two scenarios will be calculated according to population within the jurisdiction.

Attachment 6 of the guidance includes a table that shows:

- (1) the number of antiviral treatment courses that will be provided free of charge to each grantee from the 20 million that HHS is purchasing with FY 2006 funds;

(2) the number of antiviral treatment courses that will be provided free of charge to each grantee from the 24 million that HHS expects to purchase with FY 2007 funds;

(3) the total number of antiviral treatment courses that will be provided free of charge to each grantee from the total 44 million that HHS expects to purchase with FY 2006 and FY 2007 funds; and

(4) the number of antiviral treatment courses that grantees can purchase with their own funds with the assistance of a 25% HHS subsidy (up to 31 million courses will be subsidized).

HHS is in the process of finalizing guidance documents outlining:

- the basic contract agreements that HHS is negotiating with Roche (for Tamiflu) and GlaxoSmithKline (for Relenza) to facilitate antiviral purchases by states and other entities;
- options for storage of grantee-purchased caches; and
- options for distributing drugs to and within grantees' jurisdictions in accord with plans the grantees develop as part of their applications for the supplemental pandemic influenza funds.

Q: Will grantees be able to purchase additional antivirals, beyond their subsidized allocation, under the HHS basic agreements with Roche and GlaxoSmithKline?

A: At present, we don't know all the details on the purchase additional antiviral treatment courses. Grantees should remember, however, that antivirals *cannot* be purchased with funds provided in this first phase of supplemental pandemic influenza funding. Grantees must use other funds for such purchases.

Q: Why can't funds provided in this first phase be used to purchase antivirals?

A: Though stockpiles of antiviral drugs are an important component of national, state, and local pandemic flu response strategies, the Congressional intent was that these emergency appropriations be used to support the development and exercising of state and local pandemic flu plans. Because there is no guarantee that antivirals will work against a particular strain of virus that might emerge during a pandemic, Congress and HHS want to ensure that state and local response plans focus on activities that will be effective and necessary regardless of the particular characteristics of the pandemic strain.

Q: It's not entirely clear who can purchase antivirals. Is this just to state and locals, or would a hospital be able to purchase as well? We need to eliminate any doubt in our language as to who is eligible to purchase.

A: More information is expected from HHS on antiviral purchase. We will be sure to pass on information to you, as well as your concerns to HHS.

Q: Any light you can shed on HHS plans for state/local stockpiling of antivirals would be greatly appreciated.

A: HHS is still working on this area. As soon as we know, we'll pass on the information to you.

Application Process

Q: When and how will the pandemic influenza funds be awarded to the states?

A:

- Congress recently provided \$350 million in emergency appropriations to upgrade state and local response capacity for pandemic influenza.
- The money will be distributed in two phases. In the first phase, \$100 million was awarded; this will be followed by a second phase of \$250 million.

- Current grantees of CDC's Public Health Emergency Preparedness Cooperative Agreement are eligible to receive the funding. The grantees include all 50 states, 7 territories (American Samoa, Guam, Northern Marianas Islands, Virgin Islands, Federated States of Micronesia, Marshall Islands, and Palau), Puerto Rico, the District of Columbia, New York City, Chicago, and Los Angeles County.
- The first phase of the funding has been awarded according to a base + population formula.
- For the first \$100 million of the funding, grantees were asked to submit a letter of intent to apply (LOIA) by March 3, 2006 to receive their allocated funds. Grantees were asked to include a basic budget estimate and brief justification in their LOIAs.
- Notification of grant award letters were sent to grantees by March 8, 2006 notifying them that 20% of their funds will be immediately available, with the remaining 80% restricted until they submit a full application and it is deemed satisfactory. On March 14, 2006, CDC's Procurement and Grants Office (PGO) released the guidance for grantees' applications for their full allocation of the first phase of supplemental funding.
- Grantees should plan to obligate the supplemental funds provided in this first phase by the end of the current budget period, which ends August 30, 2006.
- The remaining \$250 million will be awarded as part of grantees' FY 2006 Public Health Emergency Preparedness Cooperative Agreement funding, on the basis of performance (e.g., review of activities and progress by the end of the budget period [August 30, 2006]).

Q: [How many grantees have submitted their letters of intent to apply \(LOIA\)?](#)

A: As of March 3, 2006, all 62 grantees had submitted their LOIAs to receive their allocation of the first phase of supplemental funding.

Q: [When were notifications of grant award letters sent out?](#)

A: By March 8, 2006, CDC's Procurement and Grants Office (PGO) issued notification of grant award letters to all 62 grantees notifying them that 20% of their funds will be immediately available, with the remaining 80% restricted until they submit a full application and it is deemed satisfactory.

Q: [When will the guidance be released?](#)

A: The guidance was released by PGO on March 14, 2006.

Q: [What is the application deadline for the full application?](#)

A: The application deadline is April 8, 2006.

Q: [When must first phase funds be obligated?](#)

A: Funds received during this first phase (allocations from the first \$100 million) must be obligated by August 30, 2006.

Q: [Will carryover be allowed if grantees cannot obligate all of their funds by August 30, 2006?](#)

A: CDC's commitment to continuation of awards will be based on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. Grantees will be required to request carryover funds as per current procedures.

Q: [Since supplemental pandemic influenza funds will not be distributed as part of the HRSA Public Health Emergency Preparedness cooperative agreement, how is CDC coordinating with HRSA?](#)

A: While the supplemental funds are being awarded through the CDC Public Health Emergency Preparedness Cooperative Agreement, it is expected that HRSA will have substantial involvement in the technical assistance and support functions to be provided

by the federal government. CDC and HRSA, together, will assist with coordination and collaboration at the local and state levels. HRSA will work with CDC to ensure that any efforts carried out under this Supplement are not in conflict with other emergency preparedness efforts.

CDC/HHS Coordination

Q: We want you to make sure that the HRSA guidance on hospital preparedness coordinates with the CDC guidance. I think the real question is that HRSA guidance allows their funding for the purchase of anti-virals and the supplement does not. The larger PHEP cooperative agreement does allow funds for the purchase of anti-virals for public health responders. We do not anticipate that this will change.

A: To date, these two sets of guidance do coordinate. We will continue to verify this.

Coordinating Committee (for pan flu)

Q: Can grantees use one of their existing advisory committees as the “Pandemic Influenza Coordinating Committee” that is specified in the guidance?

A: Yes, to provide grantees with greater flexibility in meeting the goals of the guidance, an existing committee for pandemic influenza planning and preparedness may be used to meet this requirement if that existing committee engages all relevant stakeholders.

Deadlines/Competing Priorities

Q: We have a progress report due on April 15th – the same timeframe as the pan flu application due date. Can we change the progress report due date?

A: We will look into extending the deadline.

Q: When are the local assessments due? We will have over 100 - how will we get these to you?

A: CDC has not set a deadline for local assessment at this time. However, we do expect that substantial progress will be made in collecting and analyzing local data to identify gaps and propose activities for the next \$250 million.

Q: For the next \$250 million, can't we make the application process later? It would give us extra time to collect local assessments.

A: Unfortunately, this money has to go out before the end of COTPER's fiscal year. We know it's a tight timeline.

Definitions or “what does this mean?”

Q: What's the definition of a community? We have over 600 municipalities, many with less than 100 people. Do we have to have a plan for each community?

A: Each State should describe in their application how they intend to define municipality or other community for the purposes of reporting against the performance measures. We need to know how you have defined them and how many you have so we can benchmark progress throughout the project period. Suggested definitions include: by local public health agency, by district/regional public health agency, by county.

Exercises

Q: What type of exercises are appropriate? Can we do a tabletop exercise on pandemic influenza?

A: Yes, a tabletop is an appropriate exercise for this application. You might find this link on pandemic influenza exercises helpful -

<http://www.hhs.gov/nvpo/pandemics/tabletopex.html>

Q

Gap Analysis

Q: Required Gaps Analysis * CDC asks for our results and approach for addressing the most serious gaps. Is there any particular format expected for the gap analysis?

A: No. Each awardee should describe their gaps and propose activities to address them

Goals of the Supplemental Funding

Q: What are the goals of the supplemental pandemic influenza funding to states?

A: In December 2005, Congress provided \$350 million in emergency appropriations to upgrade state and local response capacity, particularly the planning and exercising of pandemic response plans by state and local officials. Recipients of these funds will be required to meet performance objectives that relate to the 9 specific Pandemic Preparedness Goals. The Pandemic Preparedness Goals have been developed within CDC's overarching preparedness framework of Prevention, Detection and Reporting, Investigation, Control, Recover, and Improve.

PREVENT:

(1) Increase the use and development of interventions known to prevent influenza.

DETECT/REPORT:

(2) Decrease the time needed to classify an influenza outbreak as terrorism or naturally occurring in partnership with other agencies.

(3) Decrease the time needed to detect and report an influenza outbreak with pandemic potential.

(4) Improve the timeliness and accuracy of communications regarding the threat posed by an influenza outbreak with pandemic potential.

INVESTIGATE:

(5) Decrease the time to classify causes, risk factors, and appropriate interventions for those affected by the threat of pandemic influenza.

CONTROL:

(6) Decrease the time needed to provide countermeasures and health guidance to those affected by the threat of pandemic influenza.

RECOVER:

(7) Decrease the time needed to restore health services and environmental safety when an influenza pandemic occurs.

(8) Improve the long-term follow-up provided to those affected by an influenza pandemic.

IMPROVE:

(9) Decrease the time needed to implement recommendations from after-action reports following a potential or real influenza pandemic.

Q: What support will HHS/CDC provide to the recipients to achieve these goals?

A: While the supplemental funds are being awarded through the CDC Public Health Emergency Preparedness Cooperative Agreement, it is expected that the Health Resources and Services Administration (HRSA) will have substantial involvement in the technical assistance and support functions to be provided by the federal government. CDC and HRSA, together, will assist with coordination and collaboration at the local and state levels.

CDC staff, assisted by HRSA, will be substantially involved above and beyond routine grant monitoring. Specific activities will include:

- Ensuring that pandemic influenza activities that relate to local, state, and tribal preparedness are coordinated across CDC areas (e.g., infectious diseases,

immunization, emergency preparedness) and coordinated with guidance provided by HRSA and other federal agencies.

- Technical Assistance
 - Integration/coordination of federal funding for preparedness
 - Subject matter expertise on preparedness activities (e.g., laboratory testing, epidemiology and surveillance, SNS preparedness, information systems and informatics)
 - Identification and evaluation of promising practices
 - Development of performance goals, standards, and self-assessment tools
 - Guidance on, and in some cases, the conduct of drills and exercises
- Facilitating inclusion of tribal, military, international, and federal activities into national public health preparedness efforts and coordinating the public health preparedness responsibilities as outlined in the National Response Plan (NRP) where CDC is the designated lead agency.
- Reviewing updated state pandemic influenza plans, especially as they relate to specific items such as antiviral drug distribution plans.

Local Health Departments

Q: What portion of funds will be directed to localities?

A: The ultimate goal is to ensure that all sectors and areas of a state can adequately respond to an influenza pandemic, since federal and state assistance may not be able to reach all areas affected by a pandemic. States have flexibility in determining how these supplemental funds can maximize preparedness within a state, but also must ensure that local jurisdictions receive the funding that they need to protect the health and safety of their residents. To help ensure that all Americans are protected, the guidance strongly suggests “that the vast majority of these funds be utilized by the local level.” The guidance also requires documentation of how the state health department engaged local health departments to reach consensus, approval, or concurrence for the proposed use of supplemental funds. State applicants will be required to provide signed letters of concurrence with their applications. {{{I think we need something along these lines but the wording probably isn't right}}} CDC understands that States may not have local assessments or gap analyses complete at this time. Therefore, we anticipate that plans will be developed to gather and analyze this information and that, until this process is complete, funds to the locals may be restricted or that funds may be used more centrally for activities that benefit locals.

Q: Our locals want us to develop more statewide tools, such as statewide communications (PSAs) and IT-type projects, rather than just give them money. Is this appropriate?

A: This is an excellent use of your funding to either plan or start implementation of these activities. Just make sure that you have **documented consensus** from at least 80% of your LHDs that they agree with your plan.

Purchases – what's appropriate?

Q: What types of equipment and supplies can be purchased with the first phase of the supplemental funding?

A: New equipment such as personal protective equipment, ventilators, etc. *are* allowable purchases. These funds *cannot* be used to purchase antiviral drugs nor vehicles of any kind.

Q: Can these funds be used to cover the costs of state pandemic flu summits that occurred prior to the receipt of these supplemental funds?

A: Yes, the costs of summits held prior to the official notice of award for funds can be charged to the supplemental allocation, and will be allowed as 'pre-award costs'.

Q: Can funds from the first phase of supplemental funding be used to hire staff?

A: Funds may be used either to retain staff or expand staff resources with the understanding that these are one time emergency supplemental funds.

Resources

Q: We're using pandemic influenza plans from other states/local health departments to help us in our planning. Is this appropriate?

A: Yes, it makes sense to share your good ideas.

Technical/ Application Process

Q: Where do we put the workplan? In other words, for each gap identified through use of the checklist, where do we put our planned activities? Our Timeline?

A: Please use the Excel spreadsheet template provided. In the template the last worksheet has a list of the critical tasks. Please enter your proposed activities in the column next to the critical tasks.

Q: Under the Application Content section Supplement Guidance, there is a requirement to provide an executive summary of the "current" pandemic influenza preparedness plan. Is it acceptable to provide an executive summary of the current draft plan? This is because the current published plan is not applicable any longer.

A: Yes.

Tribal Activities

Q: How must these funds be distributed to tribes?

A: The cooperative agreement requires documentation that describes the process used by the State health department to engage American Indian tribal governments, tribal organizations representing those governments, tribal epidemiologic centers, or Alaska Native Villages and Corporations located within their boundaries in preparedness activities. Recipients of this supplemental funding are required to document the process for providing funding to tribes and engage these entities in pandemic influenza preparedness activities as part of their overall preparedness strategy.