

**Questions and Answers Regarding Federal Contracts
for State-Purchased Antiviral Drugs
(Relenza® & Tamiflu®)
(12/20/06)**

Q40. Is the letter of commitment (purchase plan) requested by the November 15th letter from Dr. Robinson (and in accordance with Attachment 3 of the contracts) binding?

A40. The November 15th letter requests either a purchase plan or a letter forfeiting the state's remaining subsidized allocation. The purchase plan is not binding. HHS could refuse to approve or to subsidize orders from states that do not submit a purchase plan. In addition, if a state does not follow through with its purchase plan, HHS may re-allocate a state's unused, subsidized purchases to other states.

Q41: What type (treatment and/or prophylaxis) of use is allowed under the contract?

A41. Section H.3 Restrictions on Use of Product of the HHS contracts with Roche and GlaxoSmithKline used by the States and other Entities to purchase Tamiflu® and Relenza® antiviral drug products, respectively, for influenza as pandemic preparedness measures states that "Product is intended to be dispensed once a Pandemic Alert period (Phases 3, 4, & 5) and Pandemic Period (Phase 6) is declared in accordance with the November 2005 WHO Global Influenza Preparedness Plan." Thus the products purchased under these federal contracts may be used in the aforementioned scenarios.

It should be noted also that an additional restriction is in Section H.3 Restrictions on Use of Product of the HHS contract with Roche for the Tamiflu® product. That restriction prevents administration of the product into human unless a PREP Act declaration for this specific medical countermeasure has been issued by the Secretary of Health and Human Services. To date no declaration for any medical countermeasures has been issued by the HHS Secretary using the PREP Act for product liability relief.

The usage or administration of the Tamiflu® or Relenza® products purchased under these federal contracts should follow recommendations provided in the *HHS Pandemic Preparedness Plan* (Nov. 2005; see *www.pandemicflu.gov*) and in accordance with the State or other Entity Pandemic Preparedness Plans with regard to treatment and/or prophylaxis.

Q42. Does the letter of intent that we submitted to our CDC Project Officer in July 2006 satisfy the request for our letter of commitment (purchase plan) by the November 15th, 2006 letter from Dr. Robinson?

A42. No. The letter of intent was to fulfill the MOAs signed by the Secretary and governors. It was a loose estimate of the total number of treatment courses that might be in the state. The letter of commitment is a more detailed forecast for use in contract administration. Redistribution policy decisions will be made based on these purchase plans so that the federal subsidy usage will be maximized.

Q43. Will information contained in our purchase plan be shared with the public or the press?

A43. HHS has no intention of sharing entity-specific information. HHS 1) refers all requests for entity-specific information to the appropriate entity; and, 2) only provides aggregate data.

Q44. Can federal cooperative agreement or other funds be used to purchase antiviral drugs through this contract vehicle?

A44. It depends on the restrictions placed on the funding by the funding source. Check with the source (e.g., agency, program) of the funding to see whether it can be used for such purposes. This is not a contractual issue.

Q45. Will antiviral drugs delivered at the end of the period of performance be at the beginning of their shelf life or will they be a year old?

A45. It is expected that all product delivered to an entity is fresh – meaning that it is at the beginning of its shelf-life.

Q46. Some of the HHS staff members have moved to a different building. How might I contact RoseMary Mann (Contracting Officer)?

A46. RoseMary Mann
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Q47. Is stock rotation allowed?

A47. Stock rotation is not permitted due to the contractual provision which states that the antiviral drugs be used for pandemic purposes only.

Q48. Can the purchase plans, once submitted, be amended?

A48. Yes. The state will be required to submit an amendment to reflect the adjustment to the original purchase plan.