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North Carolina Strategic National Stockpile Q&A for Clinicians and Health Departments July 15, 2009

Should we dispose of the Tamiflu that expires in June?

The Tamiflu Suspension that is dated June 2009 has been extended and now expires in June 2011. We are awaiting information on re-labeling at this time.

Has the Tamiflu 75 mg that expires in October 2009 been extended?

At this time, there is no official word to extend the date of the Tamiflu 75 mg capsules dated 10/09. We are hopeful the FDA and SNS will provide guidance on this soon. Please hold on to the 75mg capsules until further notice.

When should state supplied (SNS) antivirals be used?

State supplied antivirals **should** be used for empiric antiviral treatment of H1N1 cases in patients who cannot afford antivirals or cannot obtain antivirals via normal methods such as local or hospital pharmacies due to supply shortages. These medications must be provided free of charge, however, an administration fee may be charged.

When can state supplied antivirals NOT be used?

State supplied antivirals **CANNOT** be used for prophylaxis of any kind including close contacts of probable or confirmed H1N1 cases. State supplied antivirals also cannot be used for treatment of influenza cases NOT related to this novel H1N1 influenza virus. For close contacts of H1N1 cases that are at high risk for disease related complications, the state may consider allowing use of SNS antivirals in cases where the patient could not otherwise afford them. You may contact the PHPR pager or Amanda Fuller for specific case by case guidance.

Will we receive additional SNS supplies in the Fall?

Many have seen that SNS has plans for distributing a second and third wave of antivirals and PPE. NO plans currently exist to push the remaining 75% of the SNS stockpile to the states. It is possible if the H1N1 profile changes from its current attack rate and severity that SNS will push additional antivirals and PPE to the states in the Fall. We will keep you updated on this.

Previous Q&A's

What should we do with leftover supplies?

The state will not be accepting supplies that are leftover. You may distribute them to other agencies or store them at the health department.

Is law enforcement presence still needed?

Once you have placed the items into storage that has controlled access continued law enforcement presence is not needed. Long term storage should have limited, controlled access and regular inventory should take place.

Is the phpr.sns@ncmail.net address still monitored?

Yes.



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Update of dispensing fees and administration charges.

According to DSNS they have “heard back from the Office of General Counsel on whether or not an administrative fee can be charged to cover dispensing antivirals received from the SNS. They were unaware of any federal statute that would prohibit states receiving federally provided antivirals from charging a fee for their costs of administration. That being said - project areas should remain cognizant of those populations that are exempt from the fee i.e. recipients of Medicare Part B, those populations that do not have health insurance, vulnerable populations etc.”

Does the state want leftover supplies or the shipping pallets returned?

No.

What do we do about discrepancies in our SNS assets received?

At this time, we will not be sending items that were shorted in the SNS shipments, nor do we want any overages returned. You may email phpr.sns@ncamil.net to notify use of any discrepancies.

Can we give antivirals to physicians to provide in their clinic/office?

The Pharmacy Practice Act says that any physician who “dispenses for a fee or other charge” must be registered with the Board of Pharmacy as a dispensing physician. A physician who dispenses antivirals received from the local health department’s SNS allotment for H1N1 without receiving a fee or other charge need not be registered with the Board of Pharmacy. The physician will need to track the medication so that it is known what Lot # a patient receives and they will need to provide the EUA patient forms found at <http://www.cdc.gov/h1n1flu/eua/pdf/tamiflu-patients.pdf>.

When antivirals are dispensed for H1N1, do we have to provide the patient with EUA information?

Yes. Each patient should be provided with the EUA information when given antivirals from SNS or the state stockpile. We are investigating getting the EUA sheets translated to Spanish. CDC/FDA is not planning to provide those at this time.

Where do I find the Emergency Use Authorization (EUA) information?

<http://www.cdc.gov/h1n1flu/eua/> If you are not familiar with EUA's, the Q&A's at <http://www.cdc.gov/h1n1flu/eua/qa.htm> are very useful.

How do I order additional supplies?

All requests for supplies should be routed through Local Emergency Management to State Emergency Management.

Is there any guidance to share with those the Health Departments give SNS supplies to?

Please see the document at the end of these Q & A's developed by Ashley Stoop. You may consider modifying it for your own use.

When will SNS supplies be shipped to the LRS?

We do not have a definitive timeline. CDC is unable to tell us when all trucks for NC will be received. Once all assets have arrived at the RSS for NC, a member of the RSS team will call to notify of this. At that time, you should notify your LRS staff that a shipment will leave the warehouse in the next 4-6 hours for your county. At the time the truck containing the supplies for your county departs the warehouse, you will be notified the truck is on the road.

How much will my Local Health Department LRS receive?

Counties need to be prepared to receive their full allotment of antivirals and PPE including the allotment for hospitals in the county. For an estimate of the current shipment, you may go to

http://www.epi.state.nc.us/epi/gcdc/pandemic/AppendixD3_2008.pdf and take 25% of that. We estimate the following amount of pallets to each county based on the “C” value assigned in the Antiviral Distribution plan (this is total of pallets for health department and hospital supplies combined:

- “C” value of 1 – 1-3 pallets
- “C” value of 2 – 3-6 pallets
- “C” value of 3 – 6-9 pallets
- “C” value of 4 – 9-12 pallets

Where will shipments be delivered?

All shipments from the RSS will be delivered to the designated Local Receiving Site (LRS). Counties must be able to store antivirals and Personnel Protective Equipment (PPE) and be able to off load all supplies at the LRS.

Must I have DEA signature authority on site at the LRS?

No, but you must have a person (person identified in survey as primary and secondary contact) that is available to sign for receipt of the antivirals at the LRS. A pharmacist is not required to be present to sign or accept delivery.

Do I need to provide Security once the medications delivered to the LRS?

Yes, you must enact the security plans associated with your LRS.

How we should distribute?

Local health departments can distribute to any entity that has the legal authority to dispense pharmaceuticals. Arrangements have been made with the Board of Pharmacy to allow for Health Department Nurses who are certified to dispense, to dispense antivirals. Further information is coming related to this.

How do we track SNS supplies?

There is no federal/state requirement for tracking/reporting antiviral dispensing down to the patient level. However, in the event of a safety recall, you should be able to track lot number to patient. At this time, there is not a NAPH (Name, Age, Patient History Form) form antivirals. LRSs should track their distribution to other entities in any manner they decide, but Lot #'s distributed to each entity must be recorded. Entities receiving antivirals should be able to track the antivirals by Lot # to the patient level. NC is not requiring documentation be submitted to the state. This type of tracking is standard procedure in medication dispensing as part of safety tracking and recalls.

When can Antivirals be used?

- a) Must meet case definition for suspect, probable, confirmed case of swine flu.
- b) Can only be used for treatment

Do we wait to distribute until local supplies are exhausted?

Entities should be encouraged to use normal supply chain. However, you may distribute all or a portion of the supplies and medications once they arrive at the LRS.

When should state supplied antivirals be used?

State supplied antivirals **SHOULD** be used for empiric antiviral treatment of **confirmed, probable or suspected** cases of H1N1 influenza A in patients who cannot or have difficulty obtaining antiviral via normal methods such as local or hospital pharmacies. These medications must be provided free of charge (i.e. dispensing/ handling fee's can not be charged)

When can state supplied antivirals NOT be used?

State supplied antivirals **CANNOT** be used for prophylaxis of any kind including close contacts of probable or confirmed H1N1 cases. State supplied antivirals also cannot be used for treatment of influenza cases NOT related to this novel H1N1 influenza virus.

At what point do we start to order re-supply?

When you have minimum 24 hour supply, an order needs to be placed with local Emergency Management for more antivirals and PPE to be delivered from the RSS.

There is limited Tamiflu Suspension. How can the capsules be used?

The Tamiflu package insert contains directions for a pharmacist to compound the capsules into suspension. In addition, the Patient and Parent Fact Sheet found at <http://www.cdc.gov/h1n1flu/eua/pdf/tamiflu-patients.pdf> provides information about opening the capsules and mixing with sweetened liquids.

Questions: Contact phpr.sns@ncmail.net

Albemarle Regional Health Services
Handling of SNS Assets:
2009 Novel H1N1 Outbreak Response

Assets to be received:

- Personal Protective Equipment
 - N95 Masks
 - Surgical Masks
 - Gloves
 - Shields
 - Gowns
- Anti-virals
 - Relenza Disc
 - Tamiflu 75 mg Blister 10 capsules
 - Tamiflu Oral Suspension 300 mg
 - Tamiflu 45 mg 10 cap/ bottle
 - Tamiflu 30 mg 10 cap/ bottle

Handling of Assets

- Supplies will be distributed to you by ARHS.
- You will be asked to sign the Chain of Custody Form accepting responsibility for all assets.
- Once assets are accepted, they belong to your agency – you will not be returning those assets to ARHS or NCDPH.
- **Any anti-virals distributed to patients must be documented and include the lot # and expiration date.**
- **SNS supply should not be used unless local supply is exhausted.**
- **If local supply is not exhausted, anti-virals in the SNS supply can only be used to meet the needs of indigent individuals.**
- **ANTI-VIRALS DISTRIBUTED TO PATIENTS FROM THE SNS SUPPLY MUST BE PROVIDED FREE OF CHARGE.**
- **You can rotate your stock with these anti-virals to avoid disposal of expiring supplies. HOWEVER, if you rotate stock, please keep the SNS supply rotation separate and follow aforementioned SNS supply guidance.**
- If anti-virals reach their expiration date, please dispose of them according to your agencies pharmaceutical disposal policies and procedures.
- If the expiration date is 06/09, then they are good until 06/30/09, and should be disposed of at that time.

Emergency Use Authorization (<http://www.cdc.gov/h1n1flu/eua/>)

- These assets (specifically the N95 masks and anti-virals) are under Emergency Use Authorization by the FDA.
- N95
 - In order to receive N95 masks, you must sign the attached statement citing compliance with the OSHA Respiratory Protection Standard. If you do not have an OSHA compliant program we cannot issue N95 masks to you.
 - Any employee who receives an N95 mask from the SNS supply must read the N95 EUA Summary Fact Sheet – this is the employer’s responsibility to see this is done. It can be found at <http://www.cdc.gov/h1n1flu/eua/summary-factsheet.htm>.
- Anti-virals
 - Every patient receiving anti-virals from the SNS supply must also receive the respective EUA Fact Sheet found at <http://www.cdc.gov/h1n1flu/eua/>.
 - These fact sheets will be provided by ARHS