

Attachment A-1: ANTIVIRAL MANAGEMENT DURING PANDEMIC INFLUENZA

Assumptions:

- Antivirals would be used almost entirely for treatment. Prophylaxis is limited to CDC recommended uses.
- The drug is much more effective if started within 48 hours after symptom onset; consequently, most patients will need to be started as outpatients.
- Patients who cannot pay will receive medication without charge. Most other doses will be sold for replacement price plus and administration fee¹.
- State cached supplies of antivirals will not be used as long as antivirals can be purchased on the open market.

State Stockpiles of Antivirals

The state expects to have antivirals Tamiflu and Relenza available to use in the event of a pandemic sufficient to cover about a quarter of the population; a small number of courses of amantidine and rimantidine are also available in the cache. Some of the courses were purchased by the state and reside at XXXXXXXXXX where they are rotated; some of the courses were shipped to the state from the federal stockpile at the beginning of the spring outbreak of H1N1; and some of the courses have yet to be shipped to the state from the federal stockpile.

Usage

- Inpatient – During a pandemic, hospitals and any other facilities providing inpatient services (prison infirmaries) could receive antivirals through stockpile deliveries.
- Outpatient – Guidelines for appropriate use will be supplied by NDDoH; the guidelines will be developed in consultation with state infectious disease experts and federal guidance for antiviral use. Recommendations for usage might be adjusted during the pandemic based on epidemiologic evidence of risk of dying (e.g., age groups at greatest risk) and quantities of remaining antiviral supplies. It is expected that influenza clinics will be established early in the course of the illness and that they would process a high percentage of influenza patients seeking care (at least in urban areas); however, physicians in other venues will also be seeing patients with suspected influenza. Usage patterns would be monitored statewide to ensure that level of dispensing is consistent with the population size and numbers of known cases in the area.
- Telephone prescribing – Only as a last resort to unload outpatient care which cannot provide care to all who need it, NDDoH is prepared to standup a telephone-based prescribing system which would make the determination to provide treatment over the phone using non-medical

¹ This may only be possible for drug which was purchased with state money. Policies regarding charging for antivirals purchased with federal dollars will be set by the federal government. NDDoH preference would be for private pharmacies to dispense antivirals provided by the cache charging replacement cost plus a dispensing fee. Insurance or patient may be billed per usual practice. Pharmacies would be asked to supply the drug without cost to those who cannot pay (with either replacement of the drug at no cost or reimbursement from the state). The price paid to [REDACTED] for the antivirals will be used by [REDACTED] to replace the antivirals in the state cache as soon as commercial availability resumes.

staff and protocols. This would be implemented on a county by county basis if all outpatient providers within the county request it. Since this procedure is viewed as a change in the standard of care, it will not be implemented except as a disaster response tool. It would not be used so that clinics in an area could continue seeing non-urgent patients as usual. Telephone-based dispensing would use a protocol to decide whether to dispense to a person requesting the drug. If drug is to be dispensed, the person's identification and a code number will be recorded in Internet-based software. The person would be provided the code at the time of diagnosis and may present the code and identifying information at any designated dispensing site. Dispensing sites will be able to confirm the prescribing information from the Internet database.

Usage Guidelines

In the presence of a pandemic and inability of providers needing antivirals to obtain them through private distribution systems, the North Dakota cache will be made available for use; however, only a small amount of antiviral medications will be pre-positioned prior to the opening of cache use. Any drug which is pre-positioned will be continuously temperature monitored until used or returned to the state cache. Private physicians will be the prescribers (except for telephone-based prescribing above). NDDoH will provide usage guidelines but does not intend to restrict prescribing unless evaluation indicates substantial misuse. Evidence of use which is inconsistent with state guidelines or with the known epidemiology of the disease may result in corrective action

Antiviral Distribution and Dispensing

Federal shipments of antivirals will be received at the cache warehouse which has secure, climate controlled storage.

Shipment of antivirals may follow one of two patterns. Antivirals held in the state cache will be supplied to ██████████ which will become the sole antiviral wholesaler in the state. Shipments leaving the warehouse will be temperature monitored until they are turned over to their destination (e.g., ██████████). ██████████ will receive the drug from NDDoH as needed, and supply it to local pharmacies². Alternatively, NDDoH may elect to ship materials directly from its warehouse to requesting destinations in the same way that it now ships medical supplies. This can be done by commercial carrier if that it still available during a pandemic, or may be included on shipping vehicles operated by NDDoH. If a larger scale breakdown in transportation resources occurs, the local public health units indicated in the table below will become depot sites from which dispensers can pull the drug.

² ██████████ largely depends on contract carriers which may become impaired in a pandemic that damages infrastructure.

Region		Depot Cities	

It is possible that other sites such as influenza clinics could become dispensers if needed. NDDoH would expect to supply antivirals to all populations in the state where the drugs were needed. This includes military bases, Indian reservations, IHS facilities, prisons and other custodial institutions.

Ordering of Antivirals

Antivirals can be ordered by registering and ordering at <http://hanassets.nd.gov>. Orders will be received by the DOC and approved, modified or rejected. During H1N1, each order through this site prompted a phone call back to the requester. This may or may not be possible during a future pandemic depending on the demand place on the system in the DOC. The planning section would take the data from HAN Assets and track usage rates against amounts remaining in the warehouse.

Adverse event tracking

Since physicians and pharmacies are prescribing and dispensing antivirals, the state will allow normal adverse drug tracking mechanisms to function; in addition, providers will be asked to report severe adverse reactions to NDDoH Division of Disease Control. Current federal information systems available to track adverse reactions include the Adverse Event Reporting System (AERS) available on the FDA website. NDDoH will provide guidance, as needed, on what kinds of events to report.