

**State of Louisiana
Department of Health and Hospitals
Office of Public Health**

**Pandemic Influenza Guidance
Annex 4: Antiviral**



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I. Antiviral Overview

The Louisiana Department of Health and Hospitals (DHH) Office of Public Health (OPH) considers the use of antiviral medications as one component of a comprehensive containment and treatment plan to assist in the control of an outbreak of a novel influenza virus. Medications will be used in compliance with international and national recommendations.

DHH OPH has a limited supply of antiviral medication in a state stockpile, referred to as State Antiviral Cache (SAC). This SAC is comprised of purchases made by Louisiana using general funds and purchases made using federal preparedness funds. Additional antiviral medications have been received as a component of the federal Strategic National Stockpile (SNS) for the State of Louisiana on a pro rata basis.

Mission

Since the allocated amount of antiviral medications is small compared to the State population, individuals and entities in need of antiviral medications are encouraged to obtain materials through normal channels in the marketplace as they would have prior to this response. The Centers for Disease Control issues the directive for the mission of stockpiles.

II. Command and Control

National Incident Management

This Antiviral Guidance is compatible with the State of Louisiana Emergency Operations Plan. Further, it is compliant with National Response Framework, which requires the organization of response according to the National Incident Management System (NIMS). Operations are conducted using the Incident Command System (ICS).

During an emergency or disaster, some administrative procedures may be suspended, relaxed, or made optional. Such action will be carefully considered, and the consequences should be projected realistically. Departures from usual guidelines will be stated in the Governor's State of Emergency Order and in emergency plans or guidelines.

Authority to Dispense Medication

Antivirals require a prescription from a Louisiana licensed prescriber. In case of a public health emergency and based on the severity of events, additional authority to dispense medication without a prescription pursuant to an Emergency Use Authorization (EUA) may be given by the State Health Officer (SHO) or designee.

Lead Agency

DHH OPH is the lead agency for Pandemic Influenza Response within Louisiana which includes guidance for antiviral medications. DHH works collaboratively with several State, local, and private agencies to provide trainings and other educational opportunities to ensure preparedness in a pandemic situation. Any meetings and exercises, however, also contribute to the success of State operations and training programs in that they ensure a variety of educational opportunities are available for the Pandemic Influenza Response topics.

Roles and Responsibilities

The Office of Public Health will store, request, distribute, track, administer and provide guidance for antiviral medications during an influenza pandemic. Communication will be coordinated with response partners.

III. Planning Section

Preparedness

Louisiana seeks opportunities to work with local partners and assist with event-specific planning. Various aspects of this Guidance have been exercised or drilled in accordance with the Louisiana SNS Plan requirements, which provides strong community response and cooperation.

The DHH OPH office has identified persons (see the State SNS Plan, Confidential Appendix A) to lead, plan, and oversee the training, exercise, and evaluation components – and there are regional counterparts for each of these positions. The regions coordinate and receive guidance from the Louisiana OPH Center for Community Preparedness. Coordination occurs within regions and parishes to provide guidance of upcoming and future training activities as well as event-specific training and exercise plans (as listed in the State SNS Plan, which is updated annually). The multi-year plan is compliant with federal requirements (such as “HSEEP”, the Homeland Security Exercise and Evaluation Program”), and uses local, parish, and region-wide exercises to test knowledge post-training, and lessons learned are incorporated into the AHF through an ongoing review process.

Prioritizing Antiviral Medications to Prevent Death and Serious Complications

Louisiana will prioritize the use of state antiviral medications for treatment or chemoprophylaxis of patients at higher risk for influenza-related complications. Revisions to these recommendations for antiviral treatment should be expected as the epidemiology and clinical presentation of each novel virus infection is better understood. Evolution of recommendations is evidenced in the progression of 2009 H1N1 Pandemic Influenza. This guidance can be adapted according to local epidemiologic data and antiviral supply considerations.

Assumptions to Determine Antiviral Distribution Mechanisms

- There may be a limited supply of state stock antiviral medication. There may not be enough medication for everyone ill with a novel virus.
- These limited amounts of medication will be used for persons most likely to have severe complications from influenza illness and based on guidance from the CDC.
- Most persons will recover without the need for antiviral medications.
- The number of receiving entities, including end-user pharmacies must be limited to avoid depleting resources with initial allocation.
- DHH OPH Pharmacy will work to provide an option with chain retail pharmacies to serve as many citizens of the State as possible since the chain pharmacies have their own distribution systems. This may minimize the strain on the DHH OPH Receiving, Staging and Storing (RSS) site.

- Per the suggestion of the Louisiana Board of Pharmacy, an open letter will be sent to all pharmacies in the State offering participation in the antiviral campaign; from signed and returned MOUs, the DHH OPH Pharmacy selects appropriate pharmacies throughout the State.
- Once the pharmacies throughout the State have been identified, the listing and all updates will be posted for reference by the public and prescribing providers.
- Louisiana assumes the cost to ship antiviral medications from RSS to the chain pharmacy distribution center or from the RSS to the independent pharmacy store.
- In chain pharmacy, independent pharmacy, and Federally Qualified Health Center settings, healthcare prescribing providers act as the gatekeeper to determine which individuals receive a state stock prescription based on need. Pharmacists will be the backup gatekeeper, for redundancy purposes.
- The antiviral medications that are received from the Strategic National Stockpile are federal assets and as such come with federal guidance for use. It is important to recognize this guidance will continue to evolve as the pandemic progresses.

Documentation

Under NIMS, the appropriate method of tracking operational objectives, logistics movements, and safety issues is through the Incident Action Plan (IAP). Through the assistance of the DHH OPH Documentation Coordinator at the Emergency Operations Center, the DHH OPH Planning Section will be able to complete the appropriate sections of the IAP to track requests for assets, distribution of inventory, and documentation of communications with RSS or regional staff regarding antiviral dispensing sites.

An IAP must be created for every operational period, which may fluctuate as the event and response unfolds. IAPs are typically created for a 12-hour operational period, but may be created for shorter periods of time. IAPs may be created for operational periods up to 24-hours once an event/response has been underway for some time.

While Louisiana and the federal government do not guarantee any reimbursement for the use of the site, in the event that reimbursement becomes available, it will be important that accurate and comprehensive documentation be available. The IAP is a generally accepted mechanism for accurately and adequately tracking situational information.

IV. Operations Section

Concept of Operations

This Antiviral Guidance is created with a cooperative management concept. While the State Health Officer (SHO) is the single point of contact for key medical-related information and the DHH OPH Pharmacy is the single point of contact for retail pharmacies, many of the other requirements of the program are supported by other State agencies at various stages of the pandemic. Planning, emergency management, prevention, preparedness, response, recovery, and mitigation discussions are facilitated by DHH OPH and subject matter experts are utilized for relevant contributions.

Mechanisms for Distributing Antiviral Medications

The State antiviral medication is stored in a secure, climate controlled Receiving, Staging and Storing (RSS) site from which distributions are made. The RSS for this event has been established at a confidential site. The Louisiana OPH CCP will handle the oversight and administration of this warehouse operation, including the inventory tracking and shipping/distribution of the antiviral cache to the identified locales.

Methodology for the distribution of the State assets began with the assumption that it would be most efficacious to distribute a portion of the cache to the chain and independent pharmacies in the State. This allocation to retail pharmacies will be restricted to serve only the uninsured or underinsured. DHH OPH Pharmacy determined allocations in 2009, for instance, for each parish within the State, tiered based on total population total population in poverty, distribution within census tracts and/or zip codes, and influenced by experiences in the State from previous disaster response.

For a location to receive antivirals from the State as part of this antiviral guidance a Memorandum of Understanding must be secured. This document will outline the guidelines for storage, record keeping, and dispensing of the antiviral cache, and an executed agreement will be required prior to distribution to that location.

DHH OPH may provide antivirals directly to the following entities:

Hospitals and Residential Health Care Facilities:

Supplies will be used within the current treatment guidelines for the treatment of hospitalized patients and residents of health care facilities within Louisiana. Allocation was distributed in May 2009 to these facilities in coordination with the Louisiana Hospital Association and the Louisiana Nursing Home Association and pre-event public health disaster planning with additional groups and organizations within the State. Re-supply requests will be executed through the inventory process described in this Guidance by the DHH OPH CCP RSS.

Parish Health Units:

Supplies will be used for outbreak control by the parish health units as directed by the State Epidemiologist. Allocation was distributed in May 2009 to these facilities. Supplies will also be used to meet small needs that may arise due to supplier breakdowns and outbreak control in entities such as hospitals. Re-supply requests will be coordinated through and completed by the DHH OPH CCP RSS.

Federally Qualified Health Center (FQHC):

The RSS provided medications to multiple CHC/FQHC clinic sites in May 2009 to meet the needs of their patient population without utilizing a retail pharmacy. CHC/FQHCs are not expected to serve non-CHC/FQHC patients. Re-supply requests will be coordinated through and completed by the DHH OPH CCP RSS.

Military Installations and Indian Tribes:

The RSS provided medications to these health care facilities with an infirmary in May 2009 to meet the needs of their patient population without the patient needing to go to a retail pharmacy. These facilities are not expected to serve the general public. Re-supply requests will be coordinated through and completed by the DHH OPH CCP RSS.

Chain and Independent Retail Pharmacies:

DHH OPH partnered in 2009 with chain and independent pharmacies to provide antivirals to the uninsured/underinsured across the State. The RSS shipped assets via a contracted courier to a central distribution center of DHH OPH contracted chain pharmacies, which in turn supply all selected stores in their organization. The RSS also shipped directly to selected independent pharmacies via the contracted courier to locations that were determined to be necessary in outreach to the uninsured/underinsured within the State.

Primary Process for Pharmacy Supply

The following is the process the Louisiana DHH OPH used to dispense state antiviral medications through retail pharmacies during novel virus response efforts, based on the actual practice during the 2009 H1N1 Influenza response and best practices.

Primary Initial Supply for Pharmacies

1 DHH determined which pharmacies will be participating based on methodology previously described. These pharmacies signed and returned an MOU to receive antiviral distributions.

2 Pharmacies with a signed MOU to participate in this Antiviral response (based on previously described methodology) were provided login instructions to LINKS with their invitation for the program. A LINKS provider number was generated at that time, which was used for tracking inventory at each location as well as antivirals dispensed from the State antiviral cache.

3 If a pharmacy had a distribution center within the State – or was willing to use an appropriate store as a drop-shipment site – the RSS shipped antivirals for all pharmacies to this one location via the contracted courier. This shipment included a breakdown of supplies to go to specific locations within the state. The subsequent distribution to retailers from this chain or independent pharmacy distribution location was at cost and the responsibility of the retailer if smaller shipments are required from the RSS drop-shipment.

4 Once participating pharmacy received their allocation, the pharmacy entered in their initial allocated inventory totals and subsequent shipments into LINKS. [Dispensing framework is outlined at the end of this section, and the entire workflow for tracking medication is located in the Workflow in the Logistics Section.]

Primary Resupply for Independent Pharmacies

Any resupply requests must follow the resupply request process as outlined and explained in detail – including such forms that are necessary – within in the RSS Operations Manual.

Contingency Process for Pharmacy Supply

The following is the process the Louisiana DHH OPH will use to dispense state antiviral medications as a contingency plan to the RSS process if a contractor is used.

Contingency Initial Supply for Pharmacies

Note: this may be adjusted once contingency contract is executed.

1. Part of the State cache will be picked up by the contractor and held at a secure location.
2. A portion of this amount will be allocated to retail pharmacies per Appendix 1 according to the previously described methodology.
3. The Contractor will distribute this initial allocation to the retail pharmacies as included in Appendix 1.
4. The remainder of the State cache will be held for resupply.

Contingency Resupply for Independent Pharmacies

Note: this may be adjusted once contingency contract is executed.

1. Each retail pharmacy will be assigned a customer number by the contractor, for tracking and ordering purposes. The contractor will notify each retail pharmacy included of their customer number.
2. This customer number will be used to access an online ordering system. The secure system web address will be provided to each retail pharmacy by the contractor, with instructions on how to use online ordering.
3. The contractor has a locked ordering database for this antiviral guidance response. This

online ordering system is limited for these pharmacies with respect to the antiviral guidance, and only those items included in this guidance and response are available for “selection” in the contractor’s system.

4. The pharmacies will be granted order entry privileges only; they are not able to submit a completed order.
5. Once a restricted order has been entered by the retail pharmacy, a member from CCP will be assigned to review each order entered on the closed system for approval. This approval process also includes the ability to adjust an order when reviewing distribution habits of the LINKS reporting systems in conjunction with input from the State Health Officer, ID Epi, and other leadership members in DHH or OPH.
6. When CCP approves the order, the contractor will process the order and distribute the request per terms of the contractual agreement for this response.
7. The contractor will advise CCP of inventory levels on a timeframe as discussed and agreed to by both parties. Additional State cache supplies may be made available from the RSS location to continue filling orders.

Documentation

Reporting Requirements - Inventory

The mechanisms and process required for Inventory Control and reporting are detailed in the RSS Operations Manual as previously cited.

Reporting Requirements – RSS Operations

The mechanisms and process required for Inventory Control and reporting are detailed in the RSS Operations Manual as previously cited.

Reporting Requirements – Patient Dispensing

The mechanisms and process determined for antiviral dispensing may be LINKS, the Louisiana Immunization Network for Kids Statewide. The LINKS system includes an on-line tutorial for users. LINKS had a specific antiviral ‘module’ created and fully tested for the 2009 H1N1 Pandemic Influenza response. While it was not utilized for dispensing due to the low demand for antivirals from the SAC and SNS caches, the system may be activated and utilized on the same day as the State determines it is the required tracking system for patient dispensing. Providers already have use of the system, and those participating entities as previously listed (that received cache supplies) are already coded for this module.

LINKS Data Entry

- 1 As previously stated, pharmacies participating in the State antiviral response will receive notification of the LINKS data entry process. Initial State cache allocation will be

entered by the participating pharmacy into LINKS.

- 2 For each patient to whom medications are dispensed, at the time of dispensing the pharmacy will enter the patient demographic information and dosage dispensed into LINKS. This includes: last name, first name; date of birth; complete address including zip code; phone number; gender; guardian first name (if applicable, as determined by age field), and; date of dispensing.
- 3 This data will allow real-time reporting whenever necessary by CCP staff.

Mechanisms for Destroying Expired/Residual Antiviral Medications

The State antiviral medication is allocated to appropriate statewide entities for dispensing according to the mission and processes outlined in this Guidance. When the time arrives that either medications are expired (and have not received Shelf Life Extension Program instruction from the Centers for Disease Control) or a directive from the State Health Officer explains that the threat is passed, guidance on handling these residual medications will be provided. This may include destroying the medications per usual means.

The State may pick up, receive, destroy, and/or pay for the destruction of these assets when appropriate. However, while Louisiana and the federal government do not guarantee any reimbursement regarding destruction or storage of the antiviral medication, in the event that reimbursement becomes available, it will be important that accurate and comprehensive documentation be available.

V. Logistics Section

Process for Distributing State Antiviral Medications by the RSS

Previous frameworks and plans have been completed, tested, evaluated by the Centers for Disease Control, and are ready for implementation. They address the specific needs of each of the particular outlets listed in the previous section except retail pharmacies, which is addressed in this section. Please refer to the State Strategic National Stockpile and appropriate supporting documentation for logistics around distribution to hospitals, parish health units, and other “points of dispensing” (or PODs).

The mechanisms and process required for dispensing the State cache and reporting processes (including resupply requests) are detailed in the RSS Operations Manual.

Process for Dispensing State Antiviral Medications by Pharmacies

Utilizing the existing pharmacies processes, the workflow below explains pictorially the process for filling antiviral requests. Important notes include:

- The State cache of antivirals will be dispensed based on a prescription written by a Louisiana-prescribing practitioner. However, in case of a public health emergency and based on the severity of events, additional authority to dispense medication without a prescription pursuant to an Emergency Use Authorization (EUA). The prescribing practitioner refers those who verbally state they cannot afford the medication to a participating pharmacy in the Antiviral Program (as posted and updated on the www.fighttheflula.com website). Whenever the SAC or SNS antivirals are used, the administrative fee (sometimes referred to as a “copayment” or “dispensing fee”) must be waived.
- A dispensing fee may be charged unless the patients states they cannot pay.
- A person coming to the pharmacy does not need to show proof of residency – visitors are permitted to receive antivirals from the commercial resources or State cache (if qualified), providing greater protection for Louisianans.
- Even if someone fitting the target group for antivirals (such as a pregnant female) requests medication, the first route for coverage and providing supply should be that person’s insurer. Only if the patient states they cannot pay (the copayment, for example) will the supply be from the State cache.

- No more than two regimens from the SAC are permitted per individual for treatment of a novel virus. By using LINKS at the time of dispensing, this will eliminate abuses of dispensing the State cache.

VI. Security Section

Overview

During a public health emergency requiring dispensing medication or vaccine to the entire local population, security will play an essential role in the efficient operation of the Point of Dispensing, or POD site.

The State SNS Plan, as previously mentioned, lists in detail the processes and mechanisms for maintaining positive control of the antiviral assets. In tandem with the State Plan, Regional OPH plans for inventory control, security, and dispensing are in place and are the reference for security operations, experts, and details. Please refer to the appropriate Regional OPH SNS plans as well as Regional/Local POD plans.

For local crowd control, local law enforcement will be responsible for traffic flow, maintaining perimeter control of the vaccination location, for immunization staff, and protecting antiviral assets.

Each dispensing entity must have plans in place with the appropriate authority to handle potential security issues, including response to events as well as the possibility of enhanced precautionary security measures on-site. The State has determined at this time that the individual entities are responsible for absorbing the costs of any additional requirements they determine are necessary.

Rules of Engagement for Law Enforcement Personnel

The rules of engagement for each officer assigned to the security detail will be consistent with each officer's parent department/agency and will be in compliance with state and federal rules for engagement. Regional law enforcement will be able to request additional resources through their standing procedures and in compliance with the parish Office of Homeland Security and Emergency Preparedness (OHSEP) Emergency Operations Center (EOC) guidelines. Law enforcement will use the continuum of force, as appropriate, per their training and certifications.

VII. Public Information Section

Health Alert Network (HAN)

The LA-HAN is a communication network that, in the event of a public health emergency, vital health information and education about the incident is channeled efficiently around the state to doctors, paramedics, hospitals, laboratories, public safety officials, and the media or representatives for the general public. The HAN messaging is distributed primarily through a fax blast system (a network of faxes integrated into the DHH OPH e-mail system and can be triggered via e-mail and/or web processes). Initiation of the use of this system is primarily through the DHH OPH office. In the case of a Antiviral Program activation, the HAN could be used to distribute accurate and timely information in an efficient manner.

The CCP, in coordination with DHH OPH Pharmacy, will distribute messages appropriate to pharmacies via the HAN.

Messages

Public information materials for influenza have been developed by DHH through the Bureau of Media and Communications (BMAC) in order to hasten response to a pandemic threat. The DHH Public Information Officer (PIO) has the ultimate authority and responsibility for all media communications and content for the Louisiana Department of Health and Hospitals.

Prepared information has been developed and printed by DHH and includes:

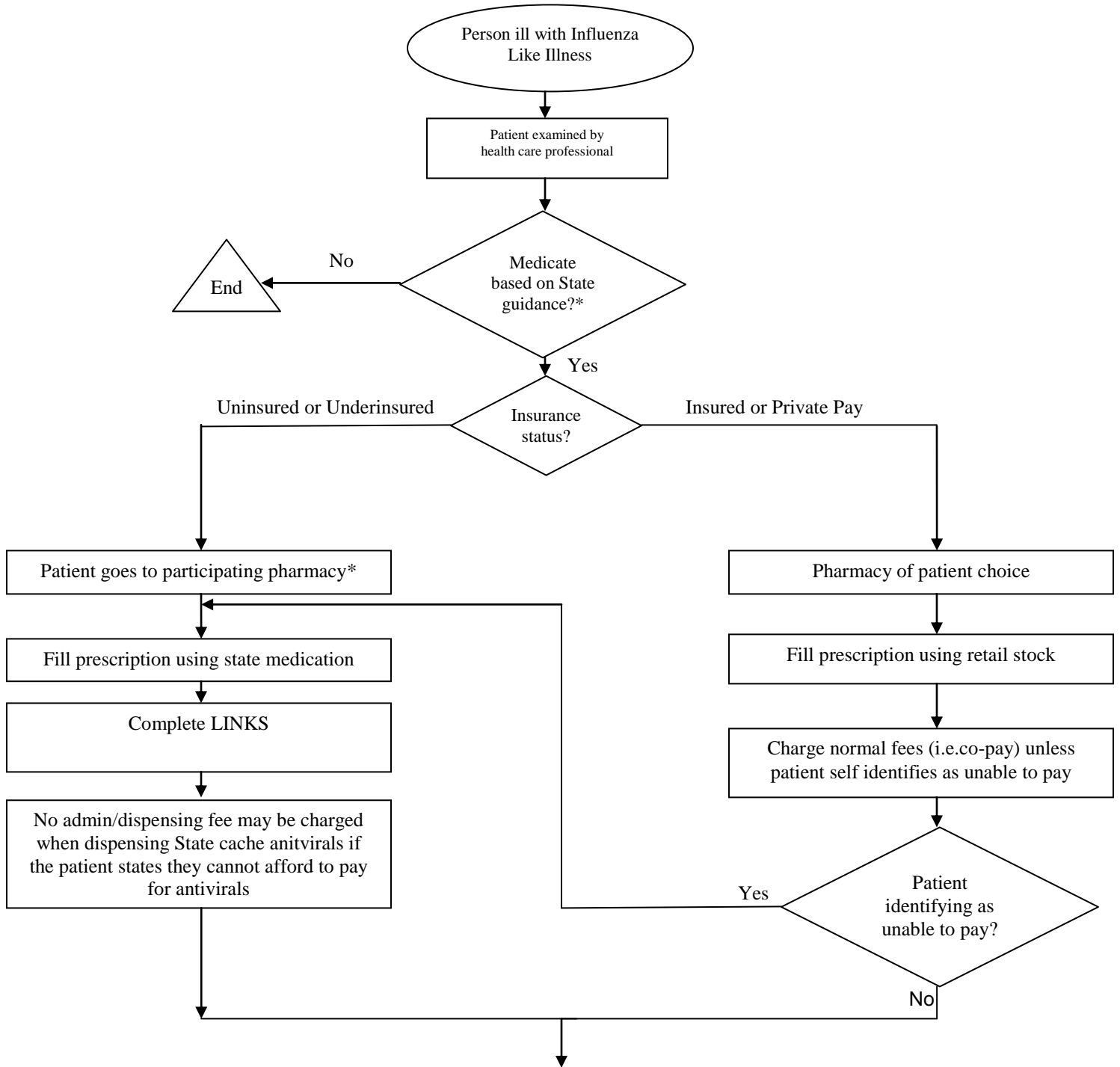
- Sample advertisements, media alerts, and media advisories
- Agent-specific information sheets (utilized for specific events, based on agent)
- Precautionary measures for reduction of viral infection
- Public announcements will not be made that direct the public to the dispensing sites; only campaigns with instruction for seeking medical attention will occur

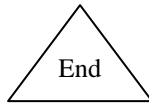
General “Points of Dispensing” Information

A separate Command and Operations Area may be established for managerial, communications, and security staff within a Region if a “Point of Dispensing” site is required. Security should be provided at all entrances and exits, and inside the dispensing site based on the site assessment by local law enforcement or security response personnel. Each public health region in Louisiana has a Strategic National Stockpile Acquisition and Dispensing Plan that includes specific frameworks for activating PODs that may be used in this antiviral deployment.

VIII. Supporting Documentation

Table 1. Pharmacy Workflow for State Antiviral Cache





*Participating pharmacies listed on
www.fighttheflula.com

