

MEMORANDUM OF AGREEMENT

BETWEEN

SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
PUBLIC HEALTH REGION _____

AND

(NAME OF CONTRACTING PARTY)

I. PURPOSE: Pandemic Influenza Antiviral Medication Distribution, Inventory Tracking, and Prescribing

The South Carolina Department of Health and Environmental Control (DHEC) and (Name of Contracting Party) (Contractor) enter into this Memorandum of Agreement (MOA) for the purpose of distributing, inventory tracking, prescribing, and dispensing of antiviral medications during an outbreak of pandemic influenza in South Carolina.

The United States Department of Health and Human Services (USDHHS) requires all states who receive antivirals to: collect and maintain data for inventory management; collect and maintain patient demographic information; and monitor patient adverse events and antiviral resistance.

This Agreement sets forth the terms, conditions, and responsibilities of health care providers, hospitals and pharmacies that are willing to receive antiviral medications from DHEC and prescribe and/or dispense those medications to individuals as indicated by the United States Department of Health and Human Services (USDHHS) and the Centers for Disease Control and Prevention (CDC) during an outbreak of pandemic influenza.

II. SCOPE OF SERVICES:

A. Responsibilities of DHEC.

Under the terms of this MOA, DHEC will be responsible for:

1. Providing an inventory request form (DHEC Form 1297, "Provider Influenza Countermeasure Order Sheet") to be used to request influenza antiviral medication from DHEC, and an inventory and dose tracking form (DHEC Form 950, "Legend and Non-Legend Drugs Record Sheet").
2. Arranging for distribution of antiviral medication to Contractor upon receipt of DHEC Form 1297 and a copy of a completed DHEC Form 950 or other prescription dispensing record.
3. Providing antiviral information and updates through the ReachSC Health Alert Network and the DHEC Website including, but not limited to, information from USDHHS and CDC, information on case definitions, medical risk factors, prescribing, dispensing, adverse event reporting, patient education information, procedures for influenza antiviral use, treatment and prescribing recommendations, and medical practice standards.

4. Collecting and tabulating the inventory status information received from the contractors and maintaining DHEC antiviral inventories utilizing the DHEC Form 1285 SNS Perpetual Inventory form within the DHEC Health Regions.
5. Providing guidance and training, as necessary, to the Contractor on the applicable influenza antiviral medication inventory tracking systems and the Food and Drug Administration's Medwatch program. (<http://www.fda.gov/medwatch/getforms.htm>) Providing FDA approved patient education materials consistent with the Emergency Use Authorization.

B. Responsibilities of Contractor.

Under the terms of this MOA, Contractor shall be responsible for:

1. Maintaining the supply of influenza antiviral medications consistent with standard pharmaceutical practices in a secure location.
2. Maintaining an up to date inventory of antiviral medications using its internal pharmaceutical tracking system and submit to the Public Health Region when requesting additional medications. If the Contractor does not have an existing pharmaceutical tracking system, the Contractor must use DHEC Form 950 to track inventory.
3. Submitting to DHEC a completed DHEC Form 1297 and DHEC Form 950 or other prescription dispensing record by facsimile to the Public Health Region at least 48 hours before Contractor needs its order to be filled.
4. Registering with the ReachSC Health Alert Network or verifying the information currently in ReachSC and updating the contact information if necessary.
5. Reporting the inventory of antiviral medications to the Public Health Region on a schedule to be established by DHEC:
 - i. Hospitals will report inventory using DHEC Form 1297 or by using the SC SMARTT system, if requested by DHEC.
 - ii. Non-hospital health care providers will report inventory using DHEC Form 1297.
6. Prescribing and/or dispensing to the patient or recipient, DHEC provided influenza antiviral medications as indicated by DHEC, DHHS, and the CDC, and based on the case definition for the illness and medical prescribing standards in place at the time.
7. Dispensing the DHEC provided antivirals only to patients or recipients who would otherwise be unable to afford the medications due to cost or are unable to obtain the medications because the commercial supply is unavailable in the community. The Contractor may charge a dispensing fee of \$5.00 unless the patient or recipient cannot afford to pay the fee, in which case the contractor must dispense the medications without charging the fee.
8. Providing appropriate Food and Drug Administration Emergency Use Authorization patient drug information sheets to individuals receiving antivirals.
9. Reporting influenza antiviral medication adverse events to the Food and Drug Administration's Medwatch program, (<http://www.fda.gov/medwatch/getforms.htm>), and insure medication is labeled to proper dosing instructions and that each prescription will be labeled with the following statement: "Call your doctor for medical

advice about side effects. You may report side effects to Food & Drug Administration at 1-800-FDA-1088”.

10. Participating in surveillance and reporting for antiviral resistance according to guidelines provided by DHEC at the time of antiviral distribution.

III. TERMS AND CONDITIONS:

A. Effective Dates.

This agreement shall be effective for the period of one year, effective ____ [DATE] ____ and will terminate ____ [DATE] _____. This MOA is renewable for four additional one year periods based on an annual review of criteria listed under Evaluation of MOA and agreement by both parties.

B. Termination.

1. Subject to the provisions contained below, this MOA may be terminated by either party providing thirty (30) days advance written notice of termination.
2. DHEC may terminate this MOA for cause, default or negligence on the part of (the Contracting Party) at any time without thirty days advance written notice.

C. Amendment.

Any changes to this MOA, which are mutually agreed upon between DHEC and the Contractor, shall be incorporated in written amendment to this MOA and will not become effective until the amendment is signed by each party.

D. Nondisclosure

To the extent permitted by law, the parties agree that neither will disclose the location of the drug distribution warehouse site or dispensing site or the nature of this effort except as is necessary to fulfill its mission, and pursuant to statutory and regulatory responsibilities.

E. Ownership of Antiviral Medications

Pursuant to federal guidance, once the antiviral medications are provided to the South Carolina Department of Health and Environmental Control through the Strategic National Stockpile, they are no longer federal property. Upon receipt of the antiviral medications by the Contractor, they are no longer state property and the Contractor becomes the owner of the antiviral medications.

F. Liability.

Neither party shall be liable for any claims, demands, expenses, liabilities and losses (including reasonable attorney's fees) which may arise out of any acts or failures to act by the other party, its employee or agents, in connection with the performance of services pursuant to this MOA.

G. Non-Discrimination.

No person shall be excluded from participation in, be denied the benefits of, or be subjected to discrimination in relation to any activities carried out under this MOA on the grounds of race, handicap, color, sex, religion, age, health status or national origin.

H. Evaluation of MOA.

Appropriate staff of the Contractor and DHEC can meet on an as needed basis to evaluate this MOA based on the responsibilities for each party listed under Sections II and III, Scope of Services, of this agreement.

I. Governing Law.

The Agreement, any dispute, claim, or controversy relating to the agreement and all the rights and obligations of the parties shall, in all respects, be interpreted, construed, enforced and governed by and under the laws of the State of South Carolina, except its choice of law rules. All disputes, claims, or controversies relating to the Agreement shall be resolved in accordance with the South Carolina Procurement Code, Section 11-35-10 et. seq., or in the absence of jurisdiction, only in the Court of Common Pleas for, or a federal court located in Richland County, South Carolina.

J. Insurance.

Each of the parties agrees to maintain professional, malpractice and general liability insurance, and may be required to provide the other party with satisfactory evidence of such coverage. Neither party will provide individual coverage for the other party's employees and each party shall be responsible for coverage of its respective employees.

K. Applicability of the Public Readiness and Emergency Preparedness Act.

The parties intend and agree that the activities to be conducted under this MOA are emergency response activities consistent with South Carolina emergency response plans and that the targeted liability protections of the Public Readiness and Emergency Preparedness Act, 42 U.S.C. §§ 247d-6d and 247d-6e, are applicable to the parties, the officials, employees, agents, and contractors of the parties, the purposes of this MOA, the antivirals to be dispensed under this MOA, and the activities listed under Section II, Scope of Services.

L. Licenses.

The parties agree that during the term of this MOA, each party shall maintain its respective federal and state licenses, certifications, and accreditations required for the provision of services herein.

M. Expenses

With the exception of the antiviral medications, for which DHEC will not charge the Contractor, each party shall bear and be responsible solely for its own costs and expenses necessary to comply with this MOA, including Contractor's travel costs if it is necessary for Contractor to pick up the antiviral medications at a DHEC or other location.

N. Severability

Should a court of competent jurisdiction rule any portion of this agreement invalid, null, or void, that fact shall not affect or invalidate any other portion or section of the agreement and all remaining portions and sections of the agreement remain in full force and effect.

O. PREVENTING AND REPORTING FRAUD, WASTE AND ABUSE.

SCDHEC has procedures and policies concerning the prevention and reporting of fraud, waste and abuse (FWA) in agency-funded programs, including but not limited to those funded by federal grants such as Medicaid. No agency employee, agent, or contractor shall direct, participate in, approve, or tolerate any violation of federal or state laws regarding FWA in government programs.

Federal law prohibits any person or company from knowingly submitting false or fraudulent claims or statements to a federally funded program, including false claims for payment or conspiracy to get such a claim approved or paid. The False Claims Act includes "whistleblower" remedies for employees who are retaliated against in their employment for reporting violations of the Act. Under State law, persons may be criminally prosecuted for false claims made for health care benefits, for Medicaid fraud, for insurance fraud, or for using a computer in a fraud scheme or to obtain money or services by false representations. Additional information regarding the federal and state laws prohibiting false claims and SCDHEC's policies and procedures regarding false claims may be obtained from the agency's Contract Officer or Bureau of Business Management.

Any employee, agent, or contractor of SCDHEC who submits a false claim in violation of federal or state laws will be reported to appropriate authorities.

If the Contractor, Contractor's agents or employees have reason to suspect FWA in agency programs, this information should be reported in confidence to the agency. A report may be made by writing to the Office of Internal Audits, SCDHEC, 2600 Bull Street, Columbia, South Carolina 29201; or by calling the Agency Fraud, Waste and Abuse Hotline at 803-896-0650 or toll-free at 1-866-206-5202. The Contractor is required to inform Contractor's employees of the existence of DHEC's policy prohibiting FWA and the procedures for reporting FWA to the agency.

AS TO DHEC

BY: _____
(REGION HEALTH DIRECTOR)

DATE: _____

AS TO THE CONTRACTING PARTY

BY: _____
(NAME)

ITS: _____
(TITLE)

DATE: _____

MAILING ADDRESS: _____
