Protocol for Testing and Initiation of Therapy for Suspected Influenza in Adult Patients

1. Authorization

This protocol is issued pursuant to K.S.A. 65-16,131, which allows a pharmacist to initiate therapy for influenza pursuant to a statewide protocol adopted by the Kansas Collaborative Drug Therapy Management Advisory Committee. A pharmacist shall engage in this protocol only when the pharmacist has complied with the Kansas Pharmacy Practice Act and all rules and regulations promulgated thereunder.

This authorizes the Kansas-licensed pharmacist who has signed and dated this Protocol to initiate CLIA-waived point-of-care testing for influenza and, when diagnostically confirmed, initiate the dispensing of antiviral therapies to treat the infection.

A pharmacist may not initiate assessment or testing unless sufficient antiviral therapy is readily available to treat acute influenza infection pursuant to this Protocol.

A pharmacist shall ensure that sufficient space is available in or around the pharmacy for safe and confidential assessment and treatment of patients under this Protocol.

Terms identified in this Protocol shall have the meaning set forth in K.S.A. 65-1626, and amendments thereto.

A pharmacist shall exercise clinical judgement in assessing patients pursuant to this Protocol outside of the standard influenza season (approximately October 1 – April 30). Resource: https://www.cdc.gov/flu/weekly/

2. Evaluation Criteria

Pharmacist(s) authorized to initiate the dispensing of antiviral therapy to treat acute influenza infection shall treat patients according to current CDC guidelines.

Pharmacists shall assess a patient based on the inclusion and exclusion criteria below based on the sample Pharmacist Assessment, Evaluation, and Prescribing Form in Appendix A.

Inclusion criteria:

Any patient who presents to the pharmacy and meets **all** the following criteria:

- Age 18 years or older and able to give informed consent;
- Complaint of any sign or symptom consistent with influenza (fever, myalgia, headache, malaise, nonproductive cough, sore throat, rhinitis);
- Reported symptom onset < 48 hours before time of presentation; and
- If testing positive, the patient must be willing to wait at the pharmacy until antiviral therapy is dispensed.

Exclusion criteria:

Any individual who meets **any** of the following criteria:

- Under 18 years old;
- Pregnant or breastfeeding;
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS);

- A positive influenza test within the previous four weeks;
- Any condition requiring supplemental oxygen therapy;
- Known hypersensitivity to all antiviral therapies for influenza or to any common component of the products;
- Administration of FluMist or generic equivalent within the previous two weeks;
- Residents of a nursing home or long-term care facility;
- A patient being treated in a medical care facility or emergency department;
- A patient receiving hospice or home health services;
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or
        - Temperature > 100.4 degrees Fahrenheit; or
    - Any one of the following criteria:
        - Acute altered mental status;
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >125 beats/min;
        - Respiratory rate >30 breaths/min;
        - Oxygen saturation (SpO_2) < 90% via pulse oximetry; or
        - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

The pharmacist shall provide counseling to any patient being assessed, tested, and/or treated pursuant to this Protocol on all the following:

- Influenza vaccination;
- Appropriate self-care, including symptom control, hygiene, and infection control measures;
- CDC guidelines that a patient with a confirmed diagnosis of influenza should stay home from work, school, or daycare until they are afebrile (100°F) for at least 24 hours without the use of a fever-reducing medication and at least 24 hours after starting antiviral therapy;
- Medication counseling pursuant to K.A.R. 68-2-20; and
- Signs and symptoms that warrant emergency medical care.

3. Initiation of Therapy and Procedures

The pharmacist shall assess the patient's relevant medical and social history:

- Patient demographics
- Medical history

- Relevant social history
- Current clinical comorbidities or disease states, including current mental status
- Current blood pressure, pulse, oxygen saturation, respiratory rate, temperature, and weight
- For females of child-bearing potential, pregnancy, or breastfeeding status
- Current Medications
- Medication allergies and hypersensitivities (pharmacist shall assess reported allergies for validity by reviewing the patient's pharmacy record, if applicable, and documenting the reported reaction)
- Onset and duration of flu-like signs and symptoms

If the patient qualifies for CLIA-waived testing under this Protocol, then the pharmacist shall perform a CLIA-waived point-of-care test to determine the patient's influenza status.

- If positive, the pharmacist may proceed to consideration for immediate antiviral therapy treatment.
- If negative, the pharmacist shall counsel the patient or caregiver on the risk of a false-negative test result and on appropriate self-care (stay home for at least 24 hours after fever subsides, drink plenty of fluids, treat symptoms as needed, and consider influenza immunization) or shall refer the patient to a primary care provider or urgent/emergency treatment facility as clinically appropriate.

The pharmacist shall evaluate for contraindications and precautions.

The pharmacist may immediately initiate antiviral therapy only in carefully selected individuals based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening.

Antiviral Therapy

The pharmacist is authorized to order and dispense the following antiviral agents to a patient that meets the evaluation inclusion criteria unless an identified contraindication applies for the patient.

A. Oral oseltamivir (Tamiflu)
    a. Contraindications
        i. Known hypersensitivity to oseltamivir or any component
        ii. Patients 18 years and older with CrCl < 10 ml/min. If the pharmacist is unable to obtain a current CrCl for a patient with a history of chronic kidney disease (i.e., creatinine clearance (CrCl) < 60 ml/min, reduced kidney function, etc.), then the patient should be excluded from receiving Tamiflu. For purposes of this Protocol, current CrCl means a lab value obtained within the past six months and documented by a physician's office, laboratory, or patient electronic health record, or reported by the patient and the pharmacist determines in their clinical judgment the patient report is accurate. The pharmacist shall document this information in the patient record.
    b. Dosing – all doses to be administered x 5 days
        i. Patients 18 years and older: 75 mg twice daily
        ii. Patients 18 years and older with renal impairment
            1. CrCl > 60 ml/min: no dosage adjustment necessary
            2. CrCl > 30 to 60 ml/min: 30mg twice daily
            3. CrCl > 10 to 30 ml/min: 30mg once daily

B. Oral baloxavir marboxil (Xofluza)
    a. Contraindications
        i. Known hypersensitivity to baloxavir or any component
        ii. Weight < 40 kg
    b. Dosing – all doses to be administered as a single dose
        i. Weight-based
            1. 40 kg to < 80 kg: 40 mg
            2. 80 kg and above: 80 mg
C. Inhaled zanamivir (Relenza Diskhaler)
    a. Contraindications
        i. Known hypersensitivity to zanamivir or any component
        ii. Underlying respiratory disease or asthma
    b. Dosing – all doses to be administered twice daily x 5 days
        i. 10 mg (two 5 mg inhalations)

If the patient qualifies for multiple therapies above, the pharmacist shall document the rationale for selecting the antiviral therapy dispensed. Documentation may include patient preference, cost, and shared clinical decision-making.

The pharmacy shall ensure that a pharmacist that has entered the Protocol shall monitor the patient for continuation or adjustment of therapy, including the following:

- As clinically appropriate, initiate telephone follow-up within 72 hours of dispensing to assess the clinical stability, onset of new symptoms, and medication adverse effects.
- If the patient is 65 years of age or older, telephone follow-up is mandatory within 72 hours of dispensing to assess the above patient status. If an initial follow-up does not result in direct patient contact, a second telephone follow-up attempt shall be made. Follow-up attempts must be documented by the pharmacist.
- Refer to a primary care provider or urgent/emergent treatment facility if any of the following are reported:
    - Significant deterioration in condition or new evidence of clinical instability;
    - Onset of symptoms inconsistent with influenza or indicative of serious complications of influenza; or
    - Medication adverse effects severe enough to warrant discontinuation.

4. Documentation and Recordkeeping

The pharmacist shall create a medication profile record for each patient who is assessed, tested, and/or treated for influenza pursuant to this Protocol and shall document the results and dispensing of any antiviral therapy in the prescription record, including documentation of the following:

- Elements required by K.S.A. 65-1642 and K.A.R.68-7-14;
- Presenting signs and symptoms of the patient that warranted testing;
- The manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used;
- Patient informed consent and counseling provided, including any patient referral;
- Rationale for the antiviral therapy selected, if any, and/or OTC medications recommended for symptom management;
- Appropriate clinical follow-up, if any; and
- Notifications to other healthcare providers.

Each pharmacist dispensing medication pursuant to this Protocol shall record themselves as the prescriber. The record shall be maintained such that the required information is readily retrievable and shall be securely stored within the pharmacy or electronic pharmacy management system for a period of 10 years from the date of assessment, testing, and/or dispensing. Records may be required to be stored (and may be off-site) for longer periods to comply with other state and federal laws.

5. Training and Counseling

Prior to initiating testing and dispensing antiviral therapies under this protocol, a pharmacist shall receive and document education and training in point-of-care CLIA-waived testing techniques appropriate to the test employed by the pharmacy from a provider accredited by the Accreditation Council for Pharmacy Education (ACPE). Additionally, the pharmacist shall maintain knowledge of the Centers for Disease Control's (CDC) current recommendations for the use of antiviral drugs in the treatment of influenza. Individuals who will be involved with patient specimen collection shall have documented hands-on training for specimen collection which includes infection control measures.

6. Notification

The pharmacist shall ask the patient tested under this Protocol for the name and contact information of a primary care provider. If the patient identifies a primary care provider, the pharmacist shall provide a summary of the patient encounter to the provider within seven days, including at least the patient's name, date of birth, influenza test results, any medication dispensed, and follow-up plan.

Each pharmacist that conducts a CLIA-waived point-of-care test shall provide the patient with a copy of the test result.

7. Signed Protocol

Each pharmacist utilizing this Protocol shall maintain a copy of the signed and dated Protocol for ten years from the date of last assessment, testing, or dispensing at each Kansas Board of Pharmacy registered facility where the pharmacist has provided services.

PHARMACIST AUTHORIZATION*

Printed Name	Kansas License Number

SIGNATURE

DATE SIGNED

Kansas	**STATE BOARD OF PHARMACY** 800 SW Jackson, Suite 1414 Topeka, Kansas 66612-1244 www.pharmacy.ks.gov (785)296-4056 pharmacy@ks.gov Fax (785) 296-8420	**STATEWIDE PROTOCOL:** **Influenza - Adult** Appendix A

Pharmacist Assessment, Evaluation and Prescribing Protocol Form: Influenza, Adult

PATIENT INFORMATION

Name		Date of Birth	Age
		Phone	Email
Address			
City	State	Zip	County
Primary Care Provider			
Medication Allergies			
Current Medications (Rx, OTC, herbal, topical, pain or allergy, supplements, vitamins, etc.):			
Treatments tried for current condition (if none, indicate N/A):			

PATIENT ELIGIBILITY

☐ Yes ☐ No Are you 18 years of age or older?
☐ Yes ☐ No Are you pregnant or breastfeeding?
☐ Yes ☐ No Have you ever been diagnosed with a weakened immune system (e.g., cancer, HIV/AIDS, transplant, long-term steroids, etc.)? If yes, explain:
☐ Yes ☐ No Do you require supplemental oxygen therapy?
☐ Yes ☐ No Are you a resident of a nursing home or long-term care facility, in hospice, or receiving home health services?
☐ Yes ☐ No Do you have a pending test for your flu-like symptoms (COVID, strep, flu)?
☐ Yes ☐ No Have you tested positive for influenza in the previous four weeks?
When did your flu-like symptoms start? ☐ More than two days ago. ☐ 2 days ago, yesterday, or today.
Do you have any of the following symptoms (check all that apply)? ☐ Fever ☐ Nasal congestion ☐ Muscle/body aches ☐ Cough ☐ Sore Throat ☐ Other:
Do you have any of the following? ☐ History of allergic reactions to influenza treatment ☐ History of physiologic side effects from any previous influenza treatment ☐ Received FluMist or a generic equivalent within the past two weeks

– PHARMACY STAFF ONLY –

PATIENT ASSESSMENT

Physical Assessment (please record values)	**Refer to PCP** if determined clinically unstable in pharmacist professional judgment or **any** of the following criteria:
Blood Pressure	Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
Respiratory Rate	Respiratory rate >30 breaths/min (single criteria); Respiratory rate >20 breaths/min (dual criteria)
Oxygen Saturation	Oxygen saturation (SpO_2) < 90% via pulse oximetry
Pulse	Pulse >125 beats/min (single criteria); Pulse >90 beats/min (dual criteria)
Temperature	Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit (single criteria); Temperature < 96.8 degrees Fahrenheit (single criteria); Temperature > 100.4 degrees Fahrenheit (dual criteria)
☐ Yes ☐ No Acute altered mental status	Yes

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

Treat using protocol if:

- Age 18 years or older and able to give informed consent;
- Complaint of any sign or symptom consistent with influenza (fever, myalgia, headache, malaise, nonproductive cough, sore throat, rhinitis);
- Reported symptom onset < 48 hours before time of presentation; and
- If testing positive, the patient must be willing to wait at the pharmacy until antiviral therapy is dispensed.

Refer to PCP and exclude from testing if:

- Under 18 years old;
- Pregnant or breastfeeding;
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS);
- A positive influenza test within the previous four weeks;
- Any condition requiring supplemental oxygen therapy;
- Known hypersensitivity to all antiviral therapies for influenza or to any common component of the products;
- Administration of FluMist or generic equivalent within the previous two weeks;
- Residents of a nursing home or long-term care facility;
- A patient being treated in a medical care facility or emergency department;
- A patient receiving hospice or home health services;
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or

- Temperature > 100.4 degrees Fahrenheit; or
- Any one of the following criteria:
  - Acute altered mental status;
  - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
  - Pulse >125 beats/min;
  - Respiratory rate >30 breaths/min;
  - Oxygen saturation (SpO_2) < 90% via pulse oximetry; or
  - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

CLIA-WAIVED POC TEST RESULT

☐ Positive for influenza (continue)

☐ Negative for influenza (refer to PCP + symptomatic treatment)

PATIENT ACTION

☐ Yes ☐ No Influenza Diagnosed

☐ Yes ☐ No Antiviral Treatment Prescribed

☐ Yes ☐ No Refer to PCP

Therapy Options		
Influenza Adult **Treatment**		
❑ Oral Oseltamivir (Tamiflu)	Dispense: ❑ 75mg #10 ❑ Renal impairment CrCl > 30 to 60 ml/min: 30mg twice daily CrCl > 10 to 30 ml/min: 30mg once daily No refills	Sig: Take 1 (one) (75mg) by mouth twice daily for 5 days
❑ Inhaled Zanamivir (Relenza Diskhaler)	Dispense: ❑ 1 inhaler No refills	2 inhalations by mouth twice daily for 5 days
❑ Oral Baloxavir Marboxil (Xofluza)	Dispense: ❑ 40mg x 1 ❑ 80mg x 1 No refills	Take 1 tablet by mouth now

PHARMACIST PRESCRIBER CERTIFICATION

Printed Name	License Number

SIGNATURE _____ DATE _____

PATIENT FOLLOW-UP

Assessment	**Refer to PCP (**if symptoms persist) ☐ Yes ☐ No

PHARMACIST FOLLOW-UP CERTIFICATION

Printed Name	License Number

SIGNATURE

DATE