ALABAMA BOARD OF MEDICAL EXAMINERS &
ALABAMA BOARD OF PHARMACY

Collaborative Practice Agreement Submission: Test to Treat Protocol

For Board Use Only:
Effective Date: _____
Expiration Date: _____

SECTION I. INTRODUCTION

A. Date Originally Created: _____
B. Office hours and location(s) of practice site(s)
C. Team members *(If requesting to include more pharmacists and/or physicians as part of the Agreement, please complete Section IV and attach list of additional providers).*

	Collaborating Physician	Collaborating Pharmacist	Covering Physician	Covering Pharmacist
Name & Title				
License #				
Practice Location				
Mileage between Pharmacy and Physician*				
Email				
Phone				
Fax				

***Distance should not exceed 20 miles.** **If distance exceeds 20 miles, please include an addendum justifying expansion. The committee will evaluate factors including, but not limited to, physician scarcity, geographical location, patients' prior-existing relationships with the physician, and similar factors illustrating patient need. Any additional information you provide will help the committee in making their decision.**

SECTION II. AUTHORIZED CARE AND SERVICES
List the scope of practice being co-managed under the CDTM.

Disease State	Scope of Practice*
Test to Treat (must include documentation of POCT training)	☐ Initiate influenza treatment ☐ Initiate streptococcus treatment

A. Provider Communication
Describe, with specificity, how communication between the collaborating physician and collaborating pharmacist will be accomplished, including the frequency of communication and arrangements for exchanging information about test results, copies of prescriptions, other patient information, and for the identification and transmission of urgent information. Please also describe each computer system used and if the collaborating pharmacist will have immediate access to the collaborating physician's electronic medical records. Please also describe your plan to keep this form of communication (tablet, laptop, etc.) locked and secure in the facility where services are being provided. See ALBME Chapter 540-X-26-.04(1c) or ALBOP Rule 680-X-2-.44 (4)(3) for full communication requirements.

SECTION III. PROCEDURES FOR INITIATION OF TESTING & TREATMENT
A. Patient visit procedure
   a. Circumstances warranting referral to PCP and/or collaborating physician
   b. Screening questionnaire
   c. Patient consent form
B. Testing protocol
   a. Test type
   b. Specimen collection technique
   c. Evaluation of test result
C. Monitoring and Follow-up
   a. Plan for monitoring and continuation or adjustment of therapies
   b. Plan for follow-up with patient, pursuant to ALBOP Rule 680-X-2-.44(4)(3)

SECTION IV. GOLD STANDARD FOR GROUP A STREPTOCOCCUS
CRITERIA
Pharmacist authorized to initiate the dispensing of antibiotics to treat acute GAS infection will treat individuals according to current IDSA guidelines.

Inclusion criteria:
Any individual who presents to the pharmacy and meets ALL of the following inclusion criteria:

- Age 5 years or older (with consent of a parent/guardian if <18 years old)
- Complaint of any sign or symptom consistent with GAS pharyngitis (sore throat, pain on swallowing, fever, headache, swollen or tender cervical lymph nodes, inflamed or swollen tonsils or uvula)
- Positive GAS result via CLIA-waived point-of-care RADT

Exclusion criteria:
Any individual who meets ANY of the following criteria:

- Age <5 years
- Pregnant or breastfeeding
- Renal dysfunction (based on individual's report or pharmacy records)
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS)
- History of rheumatic fever, rheumatic heart disease, scarlet fever, or GAS-induced glomerulonephritis
- Other antibiotic therapy prescribed for sore throat or upper respiratory infection within the previous 30 days
- Clinically unstable based on the clinical judgement of the pharmacist or any of the following criteria:
    - Acute altered mental status
    - Systolic blood pressure <90 mmHg or diastolic blood pressure <60 mmHg
    - Heart rate >125 bpm
    - Respiratory rate >30 breaths/min
    - Temperature >103 °F
    - Presenting with overt viral features (rhinorrhea, cough, oral ulcers, and/or hoarseness)

Individuals who do not qualify for RADT under this protocol will be referred to a primary care provider or urgent/emergent treatment facility as clinically appropriate. Individuals who do not qualify for antibiotic dispensing following RADT will be referred for additional evaluation when the pharmacist has high suspicion of a false-negative result, determines that the individual is at high risk for complications, or otherwise considers additional care to be in the best interest of the individual.

<u>MEDICATIONS</u>
The pharmacist may initiate the dispensing of one of the following medication regimens to an individual meeting criteria:
First line treatment (unless contraindicated due to history of penicillin allergy):

- Amoxicillin PO 25 mg/kg (max=500 mg) twice daily for 10 days or 50 mg/kg (max 1,000 mg) once daily for 10 days

Second line treatment (for those with mild allergic reactions [e.g., rash] to penicillin)

- Cephalexin PO 20 mg/kg/dose (max 500 mg/dose) twice daily for 10 days

Third line treatment (for those with mild allergic to penicillin and cephalosporins or severe reactions [e.g., anaphylaxis] to penicillin)

- Azithromycin PO 12 mg/kg (max 500 mg) once daily for 5 days
- Clindamycin PO 7 mg/kg/dose (max 300 mg/dose) three times daily for 10 days
- Clarithromycin PO 7.5 mg/kg/dose (max 250 mg/dose) twice daily for 10 days

PROCEDURES FOR INITIATION OF THERAPY

Perform RADT to determine between acute GAS and viral pharyngitis

- If positive: continue to evaluate with protocol
- If negative:
    - >18 yo: no backup throat culture needed
    - <18 yo: backup throat culture required—refer to PCP, collaborating physician, or urgent care

Assess for Relevant Medical and Social History:

- Patient demographics and weight if <18 yo using scale in pharmacy
- Medical history
- Relevant social history
- Current medications
- Medication allergies and hypersensitivities

Evaluate for Contraindications and Precautions

- Mild allergic reactions to penicillin (amoxicillin)
- Mild allergic reactions to cephalosporins (cephalexin)
- Severe allergic reactions to penicillin (amoxicillin and cephalexin)
- Allergic reactions to macrolides (azithromycin and clarithromycin)
- Allergic reactions to clindamycin

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

Telephone follow-up within 24 to 48 hours of dispensing to assess the need for additional medical intervention. Follow-up will assess for clinical stability, symptom burden, and medication adverse effects. Referral to a primary care provider or urgent/emergent treatment facility will occur if any of the following are reported:

- Significant deterioration in condition or new evidence of clinical instability
- Lack of improvement in symptoms or onset of symptoms indicative of serious complications
- Medication adverse effects severe enough to warrant discontinuation

COUNSELING REQUIREMENTS

All individuals tested under this protocol will receive counseling on:

- Appropriate self-care, including symptom control, hygiene, and infection control measures.
- Per CDC guidelines, patients with acute GAS pharyngitis should stay home from work, school, or daycare until afebrile and until 24 hours after starting appropriate antibiotic therapy

Individuals receiving antibiotics under this protocol will also receive the following:

- Medication counseling consistent with state and federal requirements for prescription drug products
- Instructions on signs or symptoms that warrant emergent medical care
- Follow-up details

DOCUMENTATION

Pharmacist will document via prescription record each person who is tested for GAS under this protocol, including:

- Documentation of the presenting signs and symptoms that warranted testing
- Vitals pursuant to attached patient screening form
- Documentation of test results and any clinical/referral notes when applicable will be scanned into the patients record

NOTIFICATION

Pharmacist shall ask all persons tested under this protocol for the name and contact information of a primary care provider. If an individual (or caregiver) identifies a primary care provider, the pharmacist will provide that provider with a summary of the encounter, including at least the individual's name, date of birth, GAS test results, medication dispensed, and follow-up plan, within 24 hours.

SECTION V. GOLD STANDARD FOR INFLUENZA

CRITERIA

Pharmacist authorized to initiate the dispensing of antiviral therapy to treat acute influenza will treat individuals according to current guidance from CDC.

Inclusion criteria:

Any individual who presents to the pharmacy during influenza season, when known influenza viruses are circulating in the community, and meets ALL of the following criteria:

- Age 5 years or older (with consent of a parent/guardian if <18 yo)
- Complaint of ANY sign/symptom consistent with influenza (fever, myalgia, headache, malaise, nonproductive cough, sore throat, rhinitis)
- Reported symptom onset < 48 hours before time of presentation
- Positive influenza virus result via CLIA-waived point-of-care RIDT

Exclusion criteria:

- Age < 5 years
- Pregnant or breastfeeding
- Renal dysfunction (based on individual's report or pharmacy records)
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS)
- Long-term aspirin therapy in individuals younger than 19 years of age
- Antiviral agent prescribed currently or within the previous 2 weeks
- Any condition requiring home oxygen therapy
- Known hypersensitivity to oseltamivir or other antiviral therapy or any component of the products
- Receipt of FluMist within past 2 weeks
- Clinically unstable based on the clinical judgment of the pharmacist or any of the following:
    - Acutely altered mental status
    - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
    - HR >125 bpm

- Respiratory rate >30 breaths/min
- Temperature >103 °F taken orally

Individuals who do not qualify under this protocol will be referred to a primary care provider or urgent/ emergent treatment facility as clinically appropriate. Individuals who do not qualify for antiviral dispensing will be referred for additional evaluation when the pharmacist has a high suspicion of a false-negative result, determines that the individual is at high risk for complications, or otherwise considers additional care to be in the best interest of the individual.

MEDICATIONS

This protocol authorizes the pharmacist to initiate the dispensing of the following antiviral agents. The pharmacist may dispense any dosage form deemed appropriate for the individual.

Oral oseltamivir dosing:

- Adults: 75 mg twice a day x 5 days
- Children (current weight determined using pharmacy's scale) x 5 days:
  - 15 kg or less: 30 mg twice a day
  - 15 kg to 23 kg: 45 mg twice a day
  - 23 kg to 40 kg: 60 mg twice a day
  - >40 kg: 75 mg twice a day

Oral baloxavir dosing:

- Adults and Children 12 and older:
  - 40 to less than 80 kg: single dose of 40 mg
  - 80 kg or more: single dose of 80 mg

Inhaled zanamivir dosing:

- Children 7 years or older and adults: 10 mg (two 5mg inhalations) twice daily x 5 days

PROCEDURES FOR INITIATION OF THERAPY

Antiviral therapy will be initiated only in carefully selected individuals based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening.

Relevant Medical and Social History

- Past medical history
- Current medications
- Allergies and hypersensitivities
- Onset and duration of flu-like symptoms
- Positive RIDT

Contraindications and Precautions

- Known hypersensitivity to oseltamivir, zanamivir
- Underlying respiratory disease or asthma (zanamivir)
- Severe renal dysfunction (est. CrCl < 30 ml/min, oseltamavir)

- Fructose/sorbitol intolerance (oseltamivir)
- Weight under 40kg (baloxavir)
- Under 12 years of age (baloxavir)
- Under five years of age

PROCEDURES FOR MONITORING AND CONTINUATION OR ADJUSTMENT OF THERAPIES

Telephone follow-up within 24 to 48 hours of dispensing to assess the need for additional medical intervention. Follow-up will assess for clinical stability, symptom burden, and medication adverse effects. Referral to a primary care provider or urgent/ emergent treatment facility will occur if any of the following are reported:

- Significant deterioration in condition or new evidence of clinical instability
- Lack of improvement in symptoms or onset of symptoms indicative of serious complications
- Medication adverse effects severe enough to warrant discontinuation

COUNSELING REQUIREMENTS

All individuals tested under this protocol will receive counseling on influenza vaccination and education on appropriate self-care, including symptom control, hygiene, and infection control measures.

Individuals receiving antiviral therapies under this protocol will also receive the following:

- Medication counseling consistent with state and federal requirements for prescription drug products
- Instructions on signs or symptoms that warrant emergent medical care

Individuals who test negative for influenza via point-of-care testing will be counseled on the risk of a false-negative test result and will be counseled on selfcare or referred to a primary care physician or urgent/emergent treatment facility as clinically appropriate.

DOCUMENTATION

The pharmacist will document via prescription record each individual who is tested for influenza under this protocol, including:

- Documentation of the presenting signs and symptoms that warranted influenza testing via triage form
- Vitals pursuant to attached patient screening form
- Documentation of test results and any clinical/referral notes when applicable will be scanned into the patient's record

NOTIFICATION

Pharmacist shall ask all persons tested under this protocol for the name and contact information of a primary care provider. If an individual (or caregiver) identifies a primary care provider, the pharmacist will provide that provider with a summary of the encounter, including at least the individual's name, date of birth, influenza test results, medication dispensed, and follow-up plan, within 24 hours.

SECTION VI. RESPONSIBILITIES AND AGREEMENTS OF THE PARTIES TO THIS AGREEMENT

A. Responsibilities of the Collaborating Pharmacist:

- ☐ I shall have signed, and obtained a copy of, a fully executed written CDTM agreement which complies with the requirements of the Alabama Board of Pharmacy (680-X-2-.44) and the Board of Medical Examiners (540-X-26) before rendering or advertising any CDTM services.
- ☐ I shall maintain contact with and document communication with the collaborating physician with whom I have entered into this CDTM Agreement, as described in Part II above.
- ☐ I shall practice in accordance with Board of Pharmacy rules and regulations
- ☐ I shall maintain a written record of the patient's written informed consent to the collaboration in the patient's record which the collaborating physician and I will maintain in accordance with responsibilities and protocols noted above and required by 680-X-2-.44 and 540-X-26.
- ☐ I shall communicate modification or discontinuation of a prescription to the collaborating physician within 24 hours of issuance unless more urgent notification is required under the circumstances.
- ☐ If applicable, I shall order and evaluate the results of laboratory tests directly related to drug therapy in accordance with approved protocols under the supervision of, or in direct consultation with the collaborating physician.
- ☐ If applicable, I shall receive the most current and up-to-date training on the equipment necessary to provide the authorized care and services listed in Section II above.
- ☐ I shall use an area for in-person or other approved consultations with patients that ensures the confidentiality of the communication and complies with the requirements and standards set forth by the Board of Pharmacy in Board Rule 680-X-2-.27.
- ☐ I shall maintain a current CDTM agreement at the primary practice setting and will ensure that these documents are readily retrievable at the request of the Board of Pharmacy and/or Board of Medical Examiners.
- ☐ I affirm and acknowledge that I am limited to collaborating with not more than three (3) physicians.

B. Responsibilities of the Collaborating Physician:

- ☐ I shall have signed, and obtained a copy of, a fully executed written CDTM agreement which complies with the requirements of the Board of Medical Examiners (540-X-26) and Board of Pharmacy (680-X-2-.44) before rendering or advertising any CDTM services.
- ☐ I shall provide sufficient communication as agreed upon by both parties of an initial prescription or modification or discontinuation of a prescription related to the CDTM Agreement to the collaborating pharmacist within 24 hours of issuance, unless more urgent notification is required.
- ☐ I shall maintain the original copy of the current CDTM Agreement, in the patient's medical record and will ensure that these documents are readily retrievable at the request of the Board of Pharmacy and/or Board of Medical Examiners.
- ☐ I shall engage in a quality assurance review of the care provided for patients pursuant to the agreement on a quarterly basis of a meaningful sample of patient records. A "meaningful sample" shall consist of not less than 25% of the patients treated pursuant to the Agreement for the first two years of the Agreement, not less than 10% of the patients treated pursuant to the Agreement after the Agreement has been in effect for two years, and all adverse outcomes of the patients treated pursuant to the Agreement.

☐ I affirm and acknowledge that I am limited to collaborating with not more than three (3) pharmacists.

C. Agreements of the Parties

We, the undersigned pharmacist(s) and physician(s), do hereby agree/understand:

☐ The providers listed in the Agreement have an active unrestricted license in Alabama, and if that status changes, Agreements shall be administratively terminated by operation of law.

☐ The providers listed in the Agreement have an active unrestricted Alabama Controlled Substances Certificate issued by the Board of Medical Examiners and the Board of Pharmacy, and if that status changes, Agreements shall be administratively terminated by operation of law.

☐ If applicable, the pharmacists listed in the Agreement have an active unrestricted pharmacy permit and DEA registration.

☐ All care and services provided shall be within the routine scope of practice and services delivered by the collaborating physician; provided, however, that the authorized care and services may not be broader in scope than the permissible functions and activities authorized under Collaborating Pharmacist's license, training, experience, and Board of Pharmacy's laws, rules, policies, and procedures.

☐ All such records shall be maintained by the Collaborating Physician for a period of not less than six (6) years from the date of the last patient contact, or if the patient is a minor, the record shall be maintained for a period of not less than eight (8) years from the date of the last patient contact.

☐ If applicable, all such records shall be maintained by the Collaborating Pharmacist within the employing pharmacy for a period of not less than two (2) years from the date of the last patient contact.

☐ Immediate written notice to all parties is required if any provider is disciplined by the respective professional licensing board, by agreement or Board order, or if either is otherwise subject to any practice restrictions.

☐ Amendments to the Authorized Care and Services section which establish substantive additions or reductions to the scope of patient care services provided under the Agreement, including new therapeutic classes of drugs added to the authorized Formulary, must be provided to the Board of Pharmacy and Board of Medical Examiners no later than ten (10) days from the date the amendment is signed by the parties.

☐ If the Agreement is terminated or not renewed, that prior to termination or nonrenewal of this Agreement, providers will arrange for an uninterrupted continuation of patient drug therapy and inform each patient of the termination or nonrenewal of the Agreement and of the procedures in place for the continuation of the patient's drug therapy.

☐ If an Agreement is voluntarily suspended, providers must notify their respective Board.

☐ Controlled substances shall not be included in the scope of the Agreement.

☐ Each Agreement will contain a provision stating which parties shall bear the costs and responsibility of promptly notifying affected individuals in the event that an Agreement expires or is terminated.

☐ Each Agreement will contain a provision stating the process for modification or termination of the Agreement by any of the parties.

- ☐ Each Agreement will contain a provision that identifies any terms under which a provider will be automatically excluded from participation in the Agreement.
- ☐ All providers are required to read and understand the acts that shall constitute violations of this Chapter/Rule as listed in 680-X-2-.44 and 540-X-26.
- ☐ The information provided in this CDTM Agreement is complete and accurate, and we will abide by the terms of the Agreement.

Signed by:

Collaborating Pharmacist	AL License No.	Date
Collaborating Physician	AL License No.	Date
Covering Pharmacist	AL License No.	Date
Covering Physician	AL License No.	Date

Submission Process

For ALBOP:
Please mail your $100 payment PLUS your completed application (checklist, protocol, and formulary) to the following address:

Collaborative Practice Manager
111 Village Street
Birmingham, AL 35242

For BME:
Once BME receives the application from ALBOP, BME will send the physician a link to pay online.