PROTOCOL FOR PHARMACIST PRESCRIBING OF DANGEROUS DRUGS IN CONJUNCTION WITH POINT-OF-CARE TESTING (POCT)

I. TITLE: New Mexico Pharmacist prescribing of dangerous drugs in conjunction with point-of-care testing (POCT) is intended to support and pursuant to, New Mexico Board of Pharmacy ("Board") Regulation (16.19.26 NMAC).

II. PURPOSE: To assist pharmacists in providing safe and effective prescribing of dangerous drugs in conjunction with CLIA-Waived point-of-care testing (POCT) in New Mexico. Additionally, to set criteria for properly trained and certified pharmacists to prescribe in a safe manner for all eligible and appropriately screened patients in New Mexico who would benefit from testing and therapy.[1-5]

a. COVID-19 FDA-authorized or FDA-approved therapy;
b. Group A Beta-Hemolytic Streptococcus (GAS) Pharyngitis antimicrobial therapy;
c. Influenza antiviral therapy.

III. BACKGROUND: Studies have shown that pharmacist prescribing of dangerous drugs in conjunction with POCT can be beneficial, safe, and effective - see **References, Section XVIII**.[12-32]

IV. GUIDELINES: All pharmacists participating in prescriptive authority for dangerous drugs in conjunction with POCT will:

a. Follow the current prevailing evidence-based guidelines and recognized standards of practice,
b. Follow the current Board-approved pharmacist prescriptive authority training and protocol, including appropriate screening, history, assessment, patient education, and referrals.
c. Follow the applicable **Pharmacist Procedures Section XII and Formulary Section XIII**, as detailed in the Board approved protocol.
d. Assess the need for referral to the patient's primary care provider, urgent care, emergency care, local clinic, or specialty clinic for other recommended testing and follow-up, including patients not eligible for POCT, as appropriate.

V. PHARMACIST MANDATES: All pharmacists participating in prescriptive authority for dangerous drugs in conjunction with POCT must:

a. Follow the current Board approved protocol and have on-site access to the protocol.
b. Possess the knowledge, skills and abilities to appropriately engage in dangerous drug prescribing in conjunction with POCT, and complete the Board approved required training course.
c. Maintain required documentation, including patient records, prescriptions and POCT results.
d. Keep patient specific documents securely stored, electronically or in a locked cabinet in the pharmacy, and HIPAA policies must be followed, as with other pharmacy related materials. These documents will include informed consent, screening documents, and other relevant information, as appropriate.

e. Follow-up with patients, according to prevailing evidence-based guidelines, and clinical studies, as appropriate.
f. Satisfactorily complete the Board approved pharmacist prescriptive authority training course(s).
g. Provide proper notification to the patient's primary care provider of the prescription and POCT results, with patient approval, as stated in the informed consent.
h. Provide proper notification to the New Mexico Department of Health (NMDOH), as required.
i. Follow CLIA-waived requirements for utilized FDA or Emergency Use Authorization (EUA) tests.
j. Complete 2 hours of live ACPE accredited continuing education credits in POCT per category of testing and treatment, every 2 years, to maintain active certification.
k. Documentation of POCT results must:
    i. Be maintained by the certified prescribing pharmacist, and POCT results must be provided to the patient.
    ii. Be sent to the NMDOH as required by New Mexico law.
    iii. Be provided to others (i.e. primary care providers, employers, etc.), upon patient request.

VI. HEALTH ASSESSMENT: Proper assessment of the patient presenting for POCT may include the following:

a. Patient history
b. Family history
c. Social history
d. Current living environment
e. Concurrent illness
f. Allergies and hypersensitivities
g. Medication history
h. Risk factors
i. Additional exposures
j. Physical assessment
k. Other information, as appropriate

VII. CONTRAINDICATIONS AND PRECAUTIONS:

a. Pharmacists with prescriptive authority will follow current prevailing evidence-based guidelines, recognized standards of practice, and professional prescribing information.

VIII. PATIENT EDUCATION: Patient materials can include:

a. General medical condition(s)
b. Drug information
c. Adherence
d. Side effects
e. Referral/follow-up information
f. Other education, as appropriate

IX. REFERRALS:

The pharmacist will provide timely and appropriate referrals as indicated. Referrals may include the patient's primary care provider, urgent care, emergency care, licensed telemedicine provider, specialty clinic, or NMDOH for complete evaluation. The pharmacist will refer under the following circumstances:

i. a patient with a known allergy that interacts or may interact with the dangerous drug(s) in conjunction with POCT, and wishing intervention;
ii. a patient experiencing intolerable side effects or sign/symptoms, and wishing intervention;
iii. if the certified prescribing pharmacist is unable to prescribe indicated dangerous drug(s) in conjunction with POCT for a patient. The pharmacist will communicate timely with the patient regarding the pharmacist's inability and referral.
iv. all patients exhibiting any of the exclusion criteria.

X. INFORMED CONSENT: The informed consent form and process will be provided during the pharmacist training course(s). Informed consent must be obtained from the patient prior to POCT and prescribing of dangerous drugs.

XI. RECORDS:

a. Consent form
b. Patient documentation, including medical history
c. Records of notification and reporting
d. Records of patient education provided
e. Billing
f. Prescription(s)
g. Additional records

XII. PHARMACIST PRESCRIBING OF DANGEROUS DRUGS IN CONJUNCTION WITH POINT-OF-CARE TESTING (POCT) PROCEDURES:

a. **COVID-19 FDA-Authorized or FDA-Approved Therapy:**

i. This service shall be available to all eligible, appropriately screened patients in New Mexico. Proper personal protective equipment (PPE) will be worn when performing the COVID-19 POCT, for the protection of the patient and the certified prescribing pharmacist.[7] A quarantine area of the pharmacy must be separate and apart from other areas of the pharmacy, for the protection of the general public.
   (a) The patient's current signs/symptoms, age, weight, temperature, medical history, current medications, and known drug allergies, will be evaluated by the certified prescribing pharmacist. The certified prescribing pharmacist will obtain a full set of vitals in high-risk patients if deemed necessary and appropriate.
ii. All patients who wish to start COVID-19 FDA-authorized or FDA-approved therapy, must meet the eligibility criteria, based on and consistent with the recommended and prevailing evidence-based guidelines or clinical studies.[3]
iii. The prescription will be written for an appropriate supply of COVID-19 FDA-authorized or FDA-approved therapy, consistent with the

recommended and prevailing evidence-based guidelines or clinical studies, with no additional refills, as authorized by the certified prescribing pharmacist and in the approved **Formulary, Section XIII**.[3]

iv. All patients who are eligible for COVID-19 FDA-authorized or FDA-approved therapy, will receive patient education and counseling on drug information, adherence, side effects, and other patient education materials, as appropriate.

v. All patients who are eligible for COVID-19 FDA-authorized or FDA-approved therapy, but have contraindications to the therapy, or do not wish to use the therapy, must be referred to their primary care provider, local clinic, or the NMDOH, for further evaluation.

vi. All patients, who are experiencing emergency signs/symptoms of possible COVID-19, will be given a referral to the local hospital for further evaluation.

b. **Group A Beta-Hemolytic Streptococcus (GAS) Pharyngitis Antimicrobial Therapy:**

ii. This service shall be available to all eligible, appropriately screened patients in New Mexico, demonstrating inclusion criteria and without any exclusion criteria, and who wish to receive POCT and therapy, if appropriate. Proper personal protective equipment (PPE) will be worn when performing the GAS POCT, for the protection of the patient and the certified prescribing pharmacist. A quarantine area of the pharmacy must be separate and apart from other areas of the pharmacy, for the protection of the general public.

iii. The patient's current inclusion and exclusion will be evaluated by the certified prescribing pharmacist performing POCT, using the appropriate FDA-approved POCT.

iv. The following patient information will be obtained: assessment for swollen or tender lymph nodes and tonsillar exudates, temperature, weight (for patients <18 years of age), medical history, current medications, and known drug allergies, by the certified prescribing pharmacy performing POCT.

(a) The certified prescribing pharmacist will obtain a full set of vitals in high-risk patients if deemed necessary and appropriate.

Patient Inclusion Criteria: Must meet **ALL** of the following:	Patient Exclusion Criteria: Excluded for **ANY** of the following:
1. Positive GAS POCT 2. Presence of signs/symptoms consistent with GAS pharyngitis (i.e., fever, sore throat, painful swallowing, fever, headache, red and swollen tonsils, white patches or pus on tonsils, small red spots	1. Patients $\leq$ 3 years of age 2. Negative GAS POCT 3. Symptoms not consistent with GAS pharyngitis

on the back roof of the mouth, swollen or tender cervical lymph nodes) 3. Centor score $\geq$1	3. History of rheumatic fever, rheumatic heart disease, scarlet fever, or GAS-induced glomerulonephritis 5. Immunocompromised state (malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS 6. Clinically unstable, based on the judgement of the certified prescribing pharmacist 7. Centor Score of <1

v. The prescription will be written for an appropriate supply of GAS pharyngitis antimicrobial therapy, consistent with the recommended and prevailing evidence-based guidelines, with no additional refills.[4]

vi. All patients eligible to receive GAS pharyngitis antimicrobial therapy, will receive patient education and counseling on drug information, adherence, side effects, and other patient education materials, as appropriate.

vii. All patients who have a positive POCT result and eligible for GAS pharyngitis antimicrobial therapy, but have contraindications to the therapy, or do not wish to use the therapy, must be referred to their primary care provider, local provider, or local clinic, for further evaluation.

viii. If it is determined that the POCT is negative, and there is a high index of suspicion for GAS, the certified prescribing pharmacist will refer the patient to their primary care provider, provider, or clinic for further medical assessment, throat culture, and follow-up, if appropriate.

e. Influenza Antiviral Therapy:

i. This service shall be available to all eligible, appropriately screened patients in New Mexico, who wish to receive POCT, influenza antiviral prophylaxis or influenza antiviral therapy, if appropriate. Proper personal protective equipment (PPE) will be worn when performing the GAS POCT, for the protection of the patient and the certified prescribing pharmacist. A quarantine area of the pharmacy must be separate and apart from other areas of the pharmacy, for the protection of the general public.

ii. The patient will be evaluated by the certified prescribing pharmacist performing POCT, using the appropriate FDA-approved POCT. This service shall be available to all eligible, appropriately screened patients in New Mexico, demonstrating inclusion criteria and without any exclusion criteria, and who wish to receive POCT and therapy, if appropriate.

iii. The patient's current signs/symptoms, age (patients must be >3 years of age), weight, temperature, oxygen saturation level, medical history, current

medications, and known drug allergies will be evaluated by the certified prescribing pharmacist.

iv. If it is determined that influenza is present based on a positive POCT result, the certified prescribing pharmacist will prescribe an influenza antiviral therapy, consistent with the recommended and prevailing evidence-based guidelines, with no additional refills, will follow-up with the patient in 24 to 48 hours for evaluation of signs/symptoms, and will refer the patient to their primary care provider, local provider, or local clinic for recommended laboratory testing and follow-up, if appropriate.[8,9]

v. All patients, eligible to receive influenza antiviral therapy, will receive patient education and counseling on drug information, adherence, side effects, and other patient education materials, as appropriate.

vi. All patients eligible for influenza antiviral therapy, but have contraindications to the therapy, or do not wish to use the therapy, must be referred to their primary care provider, local provider, or local clinic, for further evaluation.

vii. If it is determined that the POCT is negative, and there is a high index of suspicion for influenza, the certified prescribing pharmacist will refer the patient to their primary care provider, local provider, or local clinic for further medical assessment and follow-up, if appropriate.

XIII. FORMULARY:

a. **COVID-19 FDA-Authorized or FDA-Approved Therapy:**

i. FDA-authorized or FDA-approved COVID-19 therapy

ii. Intravenous medications are excluded

iii. CDC preventable disease vaccinations are not covered in this protocol, and can be found in the **PROTOCOL FOR PHARMACIST PRESCRIBING OF VACCINES, New Mexico Board of Pharmacy Regulation (16.19.26)**[12]

a. **Group A Beta-Hemolytic Streptococcus (GAS) Pharyngitis Antimicrobial Therapy:**

i. Penicillin VK

ii. Amoxicillin

iii. Cephalexin

iv. Clindamycin

v. Azithromycin

vi. Clarithromycin

vii. Antibiotic regimens recommended for Group A Streptococcal Pharyngitis as stated by IDSA Clinical Practice Guideline for the Diagnosis and Management of Group A Streptococcal Pharyngitis

viii. Referral required in a patient with a known allergy that interacts or may interact with the dangerous drug(s) in conjunction with the GAS POCT as outlined in the above **Referrals, Section IX**.

b. **Influenza Antiviral Prophylaxis Therapy, and Influenza Antiviral Therapy:**

i. Oseltamivir phosphate
ii. Baloxavir marboxil (excluded for use in influenza antiviral prophylaxis therapy)
iii. Zanamivir
iv. Other FDA-approved antivirals for influenza (with the exclusion of intravenous medications)

XIV. SIDE EFFECTS/SYMPTOMS:

a. **COVID-19 FDA-Authorized or FDA-Approved Therapy:**

i. Refer to the package insert of authorized or approved therapy or primary literature.
ii. Other side effects: may require referral to primary care provider or local clinic

b. **Group A Beta-Hemolytic Streptococcus (GAS) Pharyngitis Antimicrobial Therapy:**

i. Diarrhea
ii. Nausea
iii. Vomiting
iv. Other side effects: may require referral to primary care provider or local clinic

c. **Influenza Antiviral Prophylaxis Therapy, and Influenza Antiviral Therapy:**

i. Oseltamivir phosphate and baloxavir marboxil: abdominal pain, nausea, vomiting, diarrhea, and headache
ii. Zanamivir: sore throat, cough, nasal symptoms, nausea, and diarrhea
iii. Other side effects: may require referral to primary care provider or local clinic

XVII. RECORDS:

a. Consent form
b. Records of notification
c. Billing
d. Prescription order

XVIII. REFERENCES:

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