

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. HIV Post-Exposure Prophylaxis (PEP) therapy for patients who have potentially been exposed to HIV within the past 72 hours, in a manner that puts them at risk for HIV infection;
- b. COVID-19 FDA-approved therapy including any FDA-approved Emergency Use Authorization (EUA) COVID-19 therapy; (COVID Prophylaxis Therapy Removed)
- c. Group A Beta-Hemolytic Streptococcus (GAS) Pharyngitis antimicrobial therapy;
- d. 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, local provider, local 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. HIV PEP Therapy:

- i. This service shall be available to all appropriately screened patients in New Mexico, who have potentially been exposed to HIV, within the past 72 hours, in a manner that puts them at risk of HIV infection. Eligibility will be consistent with the recommended and prevailing evidence-based guidelines.^{1,2} Screening information will include:
 - 1. HIV status of source, if known
 - 2. Type of exposure
 - 3. Timing of exposure
 - 4. Reported history of renal dysfunction
 - 5. Other information, as appropriate
- ii. The patient's current HIV status will be evaluated by the certified prescribing pharmacist performing POCT, using the rapid HIV Ab/Ag test, as deemed appropriate by the device manufacturer.

1. If the result of the HIV testing is positive, the patient will **NOT** be prescribed HIV PEP therapy and will be immediately referred to their primary care provider, local HIV clinic, or NMDOH for complete evaluation, along with completion of NMDOH reporting requirements.
 2. If the patient refuses POCT, HIV PEP therapy should not be withheld, if the patient is otherwise eligible, and refusal should be documented.
- iii. All patients who are eligible for HIV PEP therapy, will receive a prescription written for a 1-month supply, consistent with the recommended and prevailing evidence-based guidelines or NMDOH HIV PEP therapy recommendations, with no additional refills.^{1,2,6}
 - iv. All patients who are eligible to receive HIV PEP therapy, will receive patient education and counseling on drug information, adherence, side effects, and other education materials, as appropriate.
 - v. All patients prescribed HIV PEP therapy, must also be referred to their primary care provider, local HIV clinic, or NMDOH, for other recommended laboratory tests and follow-up within 7 days.
 - vi. All patients who are eligible for HIV PEP therapy, but have reported history of renal dysfunction, are ≤ 12 years of age, or have other contraindications to the therapy, will not be prescribed therapy by the certified pharmacist and must be referred to their primary care provider, local HIV clinic, or NMDOH, for complete evaluation.
 - vii. All referrals in which HIV PEP therapy is potentially indicated, but unable to be prescribed by the certified prescribing pharmacist, should include timely and immediate pharmacist communication with the patient's primary care provider, local HIV clinic, or NMDOH, to ensure initiation of HIV PEP therapy within 72 hours of having potentially been exposed to HIV.

b. COVID-19 FDA-Approved Therapy Including any FDA-Approved Emergency Use Authorization COVID-19 Therapy: COVID Prophylaxis Removed

- 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.
 1. The patient's current signs/symptoms, age (patients must be >3 years of age), weight, temperature, medical history, current medications, and known drug allergies, will be evaluated by the certified prescribing pharmacist.
- ii. All patients who wish to start COVID-19 FDA-approved therapy including any FDA-approved Emergency Use Authorization (EUA) COVID-19 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-approved therapy including any FDA-approved Emergency Use Authorization (EUA) COVID-19 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 to COVID-19 FDA-approved therapy including any FDA-approved Emergency Use Authorization (EUA) COVID-19 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-approved therapy including any FDA-approved Emergency Use Authorization (EUA) COVID-19 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.

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

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

Patient Inclusion Criteria: Must meet ALL of the following:	Patient Exclusion Criteria: Excluded for ANY of the following:
1. Positive GAS POCT	1. Patients ≤ 3 years of age 2. Negative GAS POCT

<p>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 on the back roof of the mouth, swollen or tender cervical lymph nodes)</p> <p>3. Centor score ≥ 1</p>	<p>3. Symptoms not consistent with GAS pharyngitis</p> <p>3. History of rheumatic fever, rheumatic heart disease, scarlet fever, or GAS-induced glomerulonephritis</p> <p>5. Immunocompromised state (malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS)</p> <p>6. Clinically unstable, based on the judgement of the certified prescribing pharmacist</p> <p>7. Centor Score of < 1</p>
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- 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.

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. HIV PEP Therapy:

- i. nPEP: Tenofovir disoproxil fumarate 300mg once daily + Emtricitabine 200mg once daily + either Raltegravir 400mg twice daily or Dolutegravir 50mg once daily^{2,10}
- ii. oPEP: Tenofovir disoproxil fumarate 300mg once daily + Emtricitabine 200mg once daily + Raltegravir 400mg twice daily^{2,10,11}
- iii. Any preferred FDA-approved, CDC-recommended PEP regimens^{1,2}
- iv. Any NMDOH recommended PEP regimen²

b. COVID-19 FDA-Approved Emergency Use Authorization COVID-19 Therapy:

- i. FDA-approved COVID-19 or EUA therapy, yet to be determined and upon Board of Pharmacy, Medicine, and Nursing, approval and availability.
- 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. 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. HIV PEP Therapy:

- i. Tenofovir disoproxil fumarate: asthenia, headache, diarrhea, nausea, vomiting, nephrotoxicity
- ii. Emtricitabine: rash, hyperpigmentation/skin discoloration
- iii. Raltegravir: insomnia, nausea, fatigue, headache, skin and hypersensitivity reactions
- iv. Dolutegravir: insomnia, headache
- v. Other side effects: may require referral to primary care provider or local HIV clinic

b. COVID-19 FDA-Approved Therapy Including any FDA-Approved Emergency Use Authorization COVID-19 Therapy:

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

c. 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

d. 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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