**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.[1-6]

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. Statin therapy;
c. SARS-CoV-2 ("COVID-19") FDA-approved prophylaxis therapy, and COVID-19 FDA-approved therapy including any FDA-approved Emergency Use Authorization (EUA) COVID-19 therapy;
d. Group A Beta-Hemolytic Streptococcus (GAS) Pharyngitis antimicrobial therapy;
e. Influenza antiviral therapy, and influenza antiviral prophylaxis 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** of this document.[14-35]

**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.
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 experiencing intolerable side effects or sign/symptoms, and wishing intervention;
ii. if the certified prescribing pharmacist is unable to prescribe indicated dangerous drug(s) in conjunction with POCT for a patient. The patient will timely communicate with the patient regarding the pharmacist's inability and referral.
iii. 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.[1,2,7]

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. **Statin Therapy:**

i. This service shall be available to all eligible, appropriately screened, statin naïve patients in New Mexico, as primary prevention, who are at elevated risk for atherosclerotic cardiovascular disease (ASCVD) based on prevailing evidence-based guidelines and clinical studies.[3, 8]

ii. The patient's current cholesterol levels will be evaluated by the certified prescribing pharmacist performing POCT, using an FDA-approved POCT.

iii. The statin prescription may be written with refills for up to 12 weeks, for moderate-intensity therapy, consistent with the prevailing evidence-based guidelines and clinical studies.

iv. Patient response to statin therapy, adherence, and tolerability will be evaluated 4-12 weeks after initiation of statin therapy. If the statin therapy achieves desired LDL-C reduction (30-49% reduction) and the patient is tolerating the statin therapy without adverse effects, the statin therapy may be refilled for the remainder of the year, from when initial POCT was performed. If the statin therapy does not achieve the desired LDL-C reduction, the statin therapy may be intensified, as long as the dose is

within the moderate intensity range. After reassessment at one year, additional refills of the moderate intensity statin may be provided.

v. All statin naive patients at high-risk for ASCVD events, who wish to start primary prevention with statin therapy, must meet eligibility criteria based on and consistent with the prevailing evidence-based guidelines and clinical studies.

| Patient Inclusion Criteria |
|---|
| Age 40-75 years **AND** LDL-C between 70-189 mg/dL **AND** ASCVD risk ≥10%<br>**OR**<br>Age 40-75 years **AND** diagnosed with diabetes mellitus, as per AHA/ACC guidelines and USPSTF Recommendations.[3,8] |
| *Women of child-bearing age must be using a reliable form of birth control (hormonal contraception, IUD, etc.) |

vi. Patients at elevated risk, and not meeting the inclusion criteria for eligibility, may not receive statin therapy and must be referred to their primary care provider, local provider, or local clinic for complete evaluation.

vii. All patients who are eligible based on ASCVD risk for primary prevention with statin therapy, but have contraindications to the therapy, or do not wish to use statin therapy, must be referred to their primary care provider, local provider, or local clinic for complete evaluation.

viii. All patients who are eligible to receive statin therapy, will receive patient education and counseling on drug information, adherence, side effects, ASCVD risk, and other patient education materials, as appropriate.

c. **COVID-19 FDA-Approved Prophylaxis Therapy, and COVID-19 FDA-Approved Therapy Including any FDA-Approved Emergency Use Authorization COVID-19 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.[9]

1. 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.

ii. All patients who wish to start COVID-19 FDA-approved prophylaxis therapy or 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.[4]

iii. The prescription will be written for an appropriate supply of COVID-19 FDA-approved prophylaxis therapy or 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.[4]

iv. All patients who are eligible to receive COVID-19 FDA-approved prophylaxis therapy or 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 prophylaxis therapy or 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.

d. **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.

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. Presence of signs/symptoms consistent with GAS pharyngitis (i.e., fever, sore throat, painful swallowing, fever, | 1. Patients < 3 years of age<br>2. Symptoms not consistent with GAS pharyngitis |

| | |
|---|---|
| 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)<br>2. Centor score ≥1 | 3. History of rheumatic fever, rheumatic heart disease, scarlet fever, or GAS-induced glomerulonephritis<br>4. Immunocompromised state (malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS<br>5. Clinically unstable, based on the judgement of the certified prescribing pharmacist<br>6. 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.[5]

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 Prophylaxis Therapy, and 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.

ii. The patient will be evaluated by the certified prescribing pharmacist performing POCT, using the appropriate FDA-approved POCT.

iii. 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.

vii. If it is determined that the patient is eligible to receive influenza antiviral prophylaxis therapy, the prescription will be written for an appropriate supply, consistent with the recommended and prevailing evidence-based guidelines or clinical studies, with no additional refills, as authorized 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.[10,11]

v. All patients, eligible to receive influenza antiviral prophylaxis or 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 prophylaxis or 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[2,12]

ii. oPEP: Tenofovir disoproxil fumarate 300mg once daily + Emtricitabine 200mg once daily + Raltegravir 400mg twice daily[2,12,13]

iii. Any preferred FDA-approved, CDC-recommended PEP regimens [1,2]

iv. Any NMDOH recommended PEP regimen [3]

b. **Statin Therapy:**

i. Atorvastatin 10-20mg

ii. Fluvastatin 20-40mg

iii. Lovastatin 20-40mg

iv. Pravastatin 10-80mg

v. Rosuvastatin 5-10mg

vi. Simvastatin 10-40mg

vii. Other FDA approved statin therapy, within low to moderate intensity dose ranges

c. **COVID-19 FDA-Approved Prophylaxis Therapy, and COVID-19 FDA-Approved Therapy Including any FDA-Approved Emergency Use Authorization COVID-19 Therapy:**

i. FDA-approved COVID-19 or EUA therapy,

ii. FDA-approved COVID-19 or EUA prophylaxis

iii. Intravenous medications are excluded

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

i. Penicillin VK
ii. Amoxicillin
iii. Cephalexin
iv. Clindamycin
v. Azithromycin
vi. Clarithromycin

e. **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. **Statin Therapy:**

i. Common: abdominal pain, constipation, headache
ii. Rare but potentially serious: diabetes mellitus, increased serum transaminases, hepatotoxicity, myalgia, myositis, rhabdomyolysis
iii. Other side effects: may require referral to primary care provider or local clinic

c. **COVID-19 FDA-Approved Prophylaxis Therapy, and 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

d. **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

e. **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

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**Figure : Centor Score for Group A Streptococcus**[5]