PROTOCOL FOR PHARMACIST PRESCRIBING HIV POST-EXPOSURE PROPHYLAXIS (PEP) THERAPY IN CONJUNCTION WITH POINT-OF-CARE TESTING (POCT)

I. TITLE: New Mexico Pharmacist prescribing of HIV Post-Exposure Prophylaxis (PEP) therapy 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 HIV Post-Exposure Prophylaxis (PEP) therapy 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 the testing and therapy.[1,2]

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.

III. BACKGROUND: Studies have shown that pharmacist prescribing of HIV Post-Exposure Prophylaxis (PEP) therapy in conjunction with POCT can be beneficial, safe, and effective.

a. In 2010, the White House released a National HIV/AIDS Strategy to prevent HIV infection and infection related deaths with three main strategies: (1) reducing new infections, (2) increasing access to care and improving health outcomes, and (3) reducing health disparities and inequalities.[3] In New Mexico, there were 3,283 people living with diagnosed HIV as of 2016, and an average of 143 new cases of HIV are discovered each year.[4,5] By expanding availability and accessibility of PEP, we can work towards eliminating new HIV cases. Pharmacists are the most accessible healthcare providers who can be seen without an appointment, are available for extended hours, and can be found in most rural communities. Rapid HIV testing and clinical evaluation of patients are well within the skills of a pharmacist. By making PEP available by pharmacists, there will be an increase in timely access to care and a reduction in disparities.

b. Post-exposure prophylaxis, both occupational (oPEP) and non-occupational (nPEP), has been recognized as a strategy to successfully prevent HIV infection in individuals who may have been exposed to HIV contaminated blood or body fluids. The risk for HIV transmission after a percutaneous exposure to HIV-infected blood is estimated to be approximately 0.3%.[6] Prospective human trials of PEP are limited, however available evidence shows safety and efficacy. A case control study conducted in 1997 showed an 81% reduction in risk of acquiring HIV in healthcare workers who received oPEP consisting of a single-drug.[7] More recently, a study looked at two community based clinics in Los Angeles who administered PEP to 282 individuals over 18 months. Results showed that 97.5% of patients remained HIV-negative at

follow-up, and of the 7 with a positive test, 6 reported engaging in high risk behaviors after baseline.[7]

c. The CDC published guidelines for both oPEP and nPEP in 2013 and 2016, respectively.[8,9] These guidelines recommend PEP should be initiated as soon as possible, within no more than 72 hours post-exposure in any individual with high risk exposure to HIV-positive blood or body fluids from a person known to be infected. If the status of the source individual is unknown, the decision for PEP is assessed on a case-by-case basis. When evaluating patients to determine if PEP is appropriate, HIV testing and baseline laboratory values are recommended in order to manage comorbid conditions and identify those that might affect the drug regimen. The CDC recommends that when results are not immediately available, initiation of PEP should not be delayed because it has shown to be less effective with increased time since exposure.[8,9]

d. The CDC recommends that evaluation for PEP includes an HIV test. If possible, this should be done with an FDA-approved rapid antibody or Ag/Ab blood test kit with results available within an hour.[10] The Ag/Ab combination, also known as a 4th generation HIV test, is preferred because it detects both HIV-1/2 antibodies and free HIV-1 p24 antigen, allowing detection of HIV earlier in the infection course than antibody-only tests. There is currently one CLIA-waived, 4th generation rapid HIV point-of-care blood test available in the U.S., which is the Alere Determine™ HIV-1/2 Ag/Ab Combo.[11] This test offers results in 20 minutes, with a sensitivity of 99.4-100% and a specificity of 98.9-100%.[12] The blood sample required for this test is acquired via fingerstick, which can easily be performed in the community pharmacy setting. Rapid HIV Ag/Ab tests with comparable sensitivity and specificity that come to market in the future may also be used.

e. California, Oregon, and New York have each developed legislation which allows pharmacists to initiate PEP, recognizing the need for rapid access to treatment, particularly in rural areas where resources are not as readily available.[12-15] In New Mexico in 2018, it was estimated that over 30% of the state's population lives in rural areas where access to healthcare is variable and access to HIV care is even more limited.[17] At this time, there are six public health offices and clinics in the state that provide PEP services, and three are located outside the Albuquerque Metropolitan area.[17] This is not enough to provide for the 686,089 people living in rural New Mexico.[16] In contrast, there are over 80 pharmacies in rural areas with pharmacists capable of meeting this need in their communities.[17-19]

IV. **GUIDELINES**: All pharmacists participating in prescriptive authority for HIV PEP therapy 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 HIV PEP therapy 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 HIV PEP therapy 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.
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. Complete 2 hours of ACPE accredited continuing education credits in HIV PEP therapy, every 2 years, to maintain active certification.
j. 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. 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 HIV PEP therapy 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 HIV PEP therapy 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 HIV POST-EXPOSURE PROPHYLAXIS (PEP) THERAPY 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.

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.

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
ii. oPEP: Tenofovir disoproxil fumarate 300mg once daily + Emtricitabine 200mg once daily + Raltegravir 400mg twice daily
iii. Any preferred FDA-approved, CDC-recommended PEP regimens
iv. Any NMDOH recommended PEP regimen

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

XVII. RECORDS:

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

XVIII. REFERENCES:

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