New Mexico Register / Volume XXXI, Issue 21 / November 10, 2020

AMENDED NOTICE OF PUBLIC HEARING

The New Mexico Department of Health will hold a public hearing on the proposed Wholesale Prescription Drug Importation Program developed pursuant to the Wholesale Prescription Drug Importation Act 26-4-1 to 26-4-10 NMSA 1978. The public hearing will be held on December 2, 2020 at 9:30 a.m. via Cisco WebEx online and telephone conference, and written comments will be received until December 1, 2020 at 5pm. Verbal comments will be accepted and recorded during the hearing.

The hearing is being held via Cisco WebEx online and by telephone conference due to the concerns surrounding coronavirus and in accordance with Governor Michelle Lujan Grisham's Executive Order 2020-004, Declaration of a Public Health Emergency, and any subsequent executive orders and various Public Health Emergency Orders limiting mass gatherings due to COVID-19.

Pursuant to the Wholesale Prescription Drug Importation Act, 26-4-1 to 26-4-10 NMSA 1978, the hearing will be conducted to receive public comments regarding the proposed Wholesale Prescription Drug Importation Program prior to submission of the program for federal approval. A Prescription Drug Importation Advisory Committee was created consisting of the Secretary of Health, the Executive Director of the Board of Pharmacy, the Secretaries of Human Services and General Services and the Superintendent of Insurance, to advise the Department of Health on developing and implementing a program for the importation of eligible prescription drugs from Canada. Through the advisory committee, the department developed a drug importation program that complies with the requirements of 21 U.S.C Section 384 that will be formally submitted to the Secretary of the United States Department of Health and Human Services for certification of the proposed program. The proposal will include the following:

• How the program will comply with the requirements of 21 U.S.C. Section 384.

• Description of the cost savings of these prescription to New Mexico consumers.

• How the program will ensure that selected eligible imported prescription drugs meet standards for safety and effectiveness set forth by the US Food and Drug Administration.

• How the program will ensure compliance with the tracking and tracing verification and identification requirements of 21 U.S.C. Sections 360eee and 360eee-1.

• Prohibition of the distribution, dispensing, or sale of the imported prescription drugs outside of NM.

- Recommendation of an administrative charge to ensure funding of the program that does not impact consumer savings.
- Identification of an audit function.

Any interested member of the public may attend the hearing and offer public comments on the proposed rule during the hearing. To access the hearing by telephone: please call 1-408-418-9388. Your telephone comments will be recorded. To access the hearing via internet: please go to Webex.com; click the "Join" button; click the "Join a meeting" button; enter the following meeting number and password where indicated on screen-Meeting number (access code): 146 053 2913 #, Meeting password: QcZMPFPs225; click the "OK" button. You may also provide comment via Chat during the live streaming.

The foregoing are summaries of the proposed program. The proposed program includes various additional substantive revisions not identified here. Free copies of the full text of the proposed rule may be obtained online from the Department's website at https://www.nmhealth.org/about/phd/.

Written public comments may also be submitted to the mailing address shown below. Please submit any written comments regarding the proposed rule to the attention of:

Aryan Showers Director, Office of Policy and Accountability Runnels Building 1190 South S. Francis Drive Santa Fe, NM 87505 <u>Aryan.showers@state.nm.us</u> 505-470-4141

All written comments will be published on the agency's website at https://www.nmhealth.org/about/phd/ within 3 days of receipt and will be available at the New Mexico Department of Health Office of General Counsel for public inspection.

If you are an individual with a disability who is in need of special assistance or accommodations to attend or participate in the hearing, please contact Sheila Apodaca by telephone at (505) 827-2997. The Department requests at least ten (10) days advance notice to provide requested special accommodations.