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# New Mexico Register

The official publication for all official notices of rulemaking and filing of proposed, adopted and emergency rules.

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## **New Mexico Register**

Volume XXVIII, Issue 22 November 28, 2017

### **Table of Contents**

### **Notices of Rulemaking and Proposed Rules**

Energy, Minerals and N Mining Commission		_		
Notice of Public Meet	ting And He	earing	1078	
General Services Department Notice of Proposed Rulemaking.				
Human Services Depart Income Support Division Notice of Public Hear			1079	
Public Education Department Notice of Proposed Rulemaking  Public Regulation Commission Notice of Termination Of Rulemaking - CASE NO. 16-00003-UT				
Workforce Solutions, Do Notice of Rulemaking		nt of	1080	
	ŕ	Adopted Rules mergency, N = New, R = Repealed, Rn = Renumbered		
• •	•	Air Quality Control Board		
20.11.41 NMAC	A	Construction Permits	1082	
Commission of Public R				
1.13.12 NMAC	R	Designation Of Records Management Personnel		
1.13.30 NMAC	R	Disposition Of Public Records And Non-Records		
1.24.20 NMAC	R	Emergency Rules.		
1.13.12 NMAC	N	Designation Of Records Management Personnel		
1.13.30 NMAC 1.13.5 NMAC	N	Disposition Of Public Records And Non-Records		
1.13.5 NMAC 1.13.10 NMAC	A	New Mexico Historical Records Grant Program Guidelines		
1.13.10 NMAC 1.21.2 NMAC	A A	Records Storage And AccessRetention And Disposition Of Public Records		
1.21.2 INMAC	Α	Recention And Disposition Of I dolle Records	109/	

Regulation and Licensin	ıg Depar	tment	
Pharmacy, Board of			
16.19.8 NMAC	R	Wholesale Prescription Drug Distribution	109′
16.19.8 NMAC	N	Wholesale Distributors; Third-Party Logistics Providers;	
		Repackagers; Drug Supply Chain Security	109′
16.19.6 NMAC	A	Pharmacies	
16.19.12 NMAC	A	Fees	1122
16.19.17 NMAC	A	Dangerous Drugs And Dangerous Drug Research	
Speech-Language Patho	logy, Au	diology and Hearing Aid Dispensing Practices Board	
16.26.4 NMAC	A	Renewal of Licenses	1123
16.26.5 NMAC	A	Continuing Education	1124
16.26.6 NMAC	A	Fees	1126
16.26.7 NMAC	A	Grounds for Disciplinary Action	
16.26.8 NMAC	A	Procedures for Disciplinary Action	1128
16.26.10 NMAC	A	Emergency Licensure	1130
16.26.11 NMAC	A	Licensure for Military Service Members, Spouses and Veterans	1131
<b>Workers' Compensation</b>	n Admini	istration	
11.4.4 NMAC	R	Claims Resolution	113
11.4.4 NMAC	N	Claims Resolution.	1131
Other Material Rela	tod To	Administrativa Law	
Other Whaterian Keia	teu 10 A	Administrative Law	
Attorney General, Offic			
Notice of Proposed F	orm		1144

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### **Notices of Rulemaking and Proposed Rules**

#### ENERGY, MINERALS AND NATURAL RESOURCES DEPARTMENT MINING COMMISSION

#### NOTICE OF PUBLIC MEETING AND HEARING

The New Mexico Mining Commission will hold a regular meeting and a public hearing at 9:00 AM, Friday, February 23, 2018, in the Tony Anaya Building, 2550 Cerrillos Road, Rio Grande Conference Room, 2<sup>nd</sup> Floor, Santa Fe, New Mexico.

As prescribed by Section 69-36-8, NMSA, Regulations; adoption process, during the meeting, the Mining Commission will conduct a public hearing on a petition for rulemaking submitted by the Mining and Minerals Division (Petition 17-01) to consider adopting proposed rule 19.10.15 NMAC pursuant to the New Mexico Mining Act, Subsection V of Section 69-36-7. and Section 69-36-8 NMSA 1978. Proposed rule 19.10.15 NMAC will incorporate the requirements of the New Mexico Mining Act, Section 69-36-8 NMSA 1978, and changes to the State Rules Act in Laws of 2017, Chapter 137. Proposed rule 19.10.15 NMAC will also incorporate portions of the Commission's Guidelines for Rulemaking and replace those Guidelines. 19.10.15 NMAC is proposed to achieve four objectives: 1) to establish procedures used in rulemaking proceedings before the Commission that comply with Sections 14-4-1 through 14-4-11, NMSA (as amended 2017); 2) to encourage the participation in the hearings the Commission conducts for the promulgation of rules; 3) to make possible the effective presentation of the evidence and points of view of parties and members of the public; and 4) to assure that rulemaking hearings are conducted in a fair and equitable manner. In addition, the Commission may consider other matters that come before it.

The Commission's Guidelines for Rulemaking can be found at: http://www.emnrd.state.nm.us/ MMD/NMMC/documents/ guidelinesforrulemaking.pdf. Any person intending to present technical testimony at the public hearing must submit a notice of intent that identifies the party and the name of the technical witness, summarizes the testimony, includes any recommended modifications to the regulatory proposal, and lists and describes all anticipated exhibits. Notices of Intent to Present Technical Testimony must be received by Jane Tabor, Clerk of the Mining Commission, Mining and Minerals Division, 1220 South St. Francis Drive, Santa Fe, New Mexico 87505 not later than 5:00 PM, February 13, 2018, and should reference the petition number and the date of the hearing. Any member of the public may testify at the hearing. No prior notification to the Clerk is required to present non-technical testimony at the hearing. Any person may submit a written statement at the hearing, or may file the written statement prior to the hearing to the address listed in this notice.

A copy of the petition with the proposed regulatory change can be obtained on the MMD website at: <a href="http://www.emnrd">http://www.emnrd</a>. state.nm.us/MMD/NMMC/ MineCommProposedRuleChanges. <u>html</u> or by contacting Jane Tabor at (505) 476-3400. A copy of the agenda for the meeting/hearing will be available on the website 72 hours before the meeting or may be obtained by contacting Jane Tabor at (505) 476-3400. If you need a reader, amplifier, qualified sign language interpreter or any other form of auxiliary aid or service to attend or participate in the hearing, please contact Jane Tabor at (505) 476-3400 at least 48 hours prior to the hearing.

## GENERAL SERVICES DEPARTMENT

## NOTICE OF PROPOSED RULEMAKING

The New Mexico General Services Department (GSD), State Purchasing Division, ("Department") hereby gives notice that the Department will conduct a public hearing as indicated to obtain input on the proposed new administrative rule **ELECTRONIC SIGNATURES**.

SUMMARY AND PURPOSE OF PROPOSED RULE: This new rule provides detail to address the use of electronic signatures as it pertains to contracts:

- . Defining terms;
- 2. Clarifies the scope and procedures;
- 3. Provides the workflow process for each levels of signature authority for contracts awarded and contract amendments; and
- Addresses the delegation of approval authority.

Empirical examples identified over the last several years necessitate the need for a rule on electronic signatures to streamline the procurement process. No specific technical information serves as a basis for this proposed rule.

PUBLICATION: The proposed rules and hearing agenda have been published and are also posted for public view on the State Purchasing Division website: <a href="http://www.generalservices.state.nm.us/statepurchasing/">http://www.generalservices.state.nm.us/statepurchasing/</a>. A public hearing regarding the rules will be held on January 10, 2018 at 2:00 P.M. in the State Purchasing Bid Room on first floor of the Montoya Building, 1100 S. St. Francis Drive, Santa Fe, New Mexico 87505.

**HOW TO COMMENT ON THE PROPOSED RULE:** Interested individuals may testify regarding the proposed rulemaking relating to 1.4.9 NMAC ELECTRONIC

SIGNATURES at the public hearing scheduled on January 10, 2018 at 2:00 P.M. in the State Purchasing Bid Room on the first floor of the Montoya Building, 1100 S. St. Francis Drive, Santa Fe, New Mexico 87505. Written comments may also be submitted no later than January 10, 2018, the date of the public hearing, to: Mark Hayden, Bureau Chief, State Purchasing Division, New Mexico General Services Department, Room 2016, 1100 St. Francis Drive, Santa Fe, New Mexico 87505 or Mark. Hayden@state.nm.us.

PROPOSED RULE COPIES: The public hearing agenda and the full text of the proposed rule may be accessed on the State Purchasing Division website: <a href="http://www.generalservices.state.nm.us/statepurchasing/">http://www.generalservices.state.nm.us/statepurchasing/</a> or obtained from Mark Hayden by request to: Mark Hayden, Bureau Chief, State Purchasing Division, New Mexico General Services Department, Room 2016, 1100 St. Francis Drive, Santa Fe, New Mexico 87505 or <a href="mark-hayden@state.nm.us">Mark.Hayden@state.nm.us</a>, or Phone 505-827-2331, or Fax 505-827-2484.

SPECIAL NEEDS: Individuals with disabilities who require this information in an alternative format or need any form of auxiliary aid to attend or participate in this hearing are asked to contact State Purchasing Bureau Chief, Mark Hayden, (contact information provided above). The Department requests at least seven days advanced notice (by close of business 5:00 PM on December 27, 2017) for all requests regarding special accommodations.

#### STATUTORY AUTHORITY:

New Mexico Procurement Code, Sections 13-1-28 through 13-1-199 NMSA 1978; Uniform Electronic Transactions Act, Section 14-16-1 et seq. NMSA 1978.

## HUMAN SERVICES DEPARTMENT INCOME SUPPORT DIVISION

#### NOTICE OF PUBLIC HEARING

The New Mexico Human Services Department (HSD) adopted emergency rules for the Federal Poverty Level (FPL), effective October 1, 2017. The Department is holding a public hearing to adopt the rules to make them permanent pursuant to Section 14-4-5.6 NMSA 1978. The rules were implemented to comply with the Federal mandate; failure to implement the emergency rules would have placed the Department in violation of Federal law.

HSD will hold a public hearing to allow public comment on the amendment of the rules for the FPL regulations that were published September 26, 2017. The hearing will be held on Friday, December 29, 2017, from 9:30 a.m. to 10:30 a.m., at the HSD Income Support Division (ISD) conference room, 2009 S. Pacheco Street, Santa Fe, NM. The conference room is located in Room 120 on the lower level of Pollon Plaza.

The Human Services Register Vol. 40 No. 18 outlining the regulations is available on the HSD's website at: <a href="http://www.hsd.state.nm.us/">http://www.hsd.state.nm.us/</a>
<a href="LookingForInformation/income-support-division-registers.aspx">http://www.hsd.state.nm.us/</a>
<a href="LookingForInformation/income-support-division-registers.aspx">LookingForInformation/income-support-division-registers.aspx</a>
<a href="LookingForInformation-registers.aspx">http://www.hsd.state.nm.us/</a>
<a hre

If you are a person with a disability and you require this information in an alternative format, or you require a special accommodation to participate in any HSD public hearing, program, or service, please contact the Assistant General Counsel/American Disabilities Act Coordinator, at 505-827-6201 or through the New Mexico Relay system, at 711 or toll free at

1-800-659-1779. The Department requests at least a 10-day advance notice to provide requested alternative formats and special accommodations.

Individuals who do not wish to attend the hearing may submit written comments which must be received by 5:00 p.m. on the date of the hearing, Friday, December 29, 2017. Please send comments to:

Human Services Department P.O. Box 2348, Pollon Plaza Santa Fe, New Mexico 87504-2348

You may also send comments electronically to: <u>HSD-isdrules@</u> state.nm.us

#### PUBLIC EDUCATION DEPARTMENT

## NOTICE OF PROPOSED RULEMAKING

Public Hearing. The New Mexico Public Education Department (PED) gives notice that it will conduct a public hearing in Mabry Hall located at the Jerry Apodaca Education Building, 300 Don Gaspar Avenue, Santa Fe, New Mexico 87501, on Friday, January 5, 2018, from 9:00 a.m. to 12:00 p.m. (MDT). The purpose of the public hearing is to receive public input on the proposed repeal of 6.29.2 NMAC, Arts Education, to be replaced by 6.29.2 NMAC, New Mexico Core Arts Standards. At the hearing, the PED will provide a verbal summary statement on record. Attendees who wish to speak will be given three (3) minutes to make a statement concerning the rule changes on record. Written comment will also be accepted at the hearing.

**Rule Change Information.** The purpose of this proposed rule change is to adopt the New Mexico Core Arts Standards.

The statutory authorizations include the following:

Section 22-2-2 NMSA 1978 grants

the authority and responsibility for the assessment and evaluation of public schools, state-supported educational institutions and educational programs conducted in state institutions other than New Mexico military institute. Section 22-2-2 NMSA 1978 directs the department to set graduation expectations.

Section 22-2C-3 NMSA 1978 requires the department to adopt academic content and performance standards and to measure the performance of public schools in New Mexico.

No technical information served as a basis for this proposed rule change.

Public Comment. Interested parties may provide comment on the proposed repeal and replacement of this state rule at the public hearing or may submit written comments, or both, to Jamie Gonzales, Policy Division, New Mexico Public Education Department, Room 101, 300 Don Gaspar Avenue, Santa Fe, New Mexico 87501, or by electronic mail at rule.feedback@state.nm.us, or fax to (505) 827-6681. All written comments must be received no later than 5:00 p.m. (MDT) on the date of the public hearing. The PED encourages the early submission of written comments. The public comment period is from November 28, 2017 to January 5, 2018 at 5:00 p.m. (MDT).

Copies of the proposed rules may be accessed through the New Mexico Public Education Department's website under the "Public Notices" link at <a href="http://ped.state.nm.us/ped/PublicNotices.html">http://ped.state.nm.us/ped/PublicNotices.html</a>, or may be obtained from Jamie Gonzales by contacting her at (505) 827-7889 during regular business hours.

Individuals with disabilities who require the above information in an alternative format, or who need any form of auxiliary aid to attend or participate in the public hearing are asked to contact Jamie Gonzales at (505) 827-7889 as soon as possible before the date set for the public

hearing. The PED requires at least ten (10) calendar days advance notice to provide any special accommodations requested.

## PUBLIC REGULATION COMMISSION

NOTICE OF TERMINATION OF RULEMAKING - CASE NO. 16-00003-UT

The Public Regulation Commission (the "Commission") hereby gives notice of its termination of a proposed rulemaking promulgating revisions to Rule 17.11.23 NMAC concerning Retail Service Pricing Standards for Mid-Size Carriers.

The rulemaking was initiated by issuance of the Commission's Order Initiating Proposed Rulemaking on July 13, 2016, and the publication of a Notice of Proposed Rulemaking in the New Mexico Register on July 29, 2016. On November 1, 2017, the Commission issued its Final Order Adopting Certification of Stipulation and Closing Docket, terminating this rulemaking.

The terminated proposed rules may be accessed at the Commission's website (www.nmprc.state.nm.us) or by contacting Kathleen Segura at Kathleen.Segura1@state.nm.us, Post Office Box 1269, Santa Fe, New Mexico 87504 or 505-827-4501.

#### PUBLIC SAFETY, DEPARTMENT OF LAW ENFORCEMENT ACADEMY

## NOTICE OF CANCELLATION OF PUBLIC HEARING

The public hearing to allow public comment on the proposed amendment of Title 10 Public Safety and Law Enforcement, Chapter 29 Law Enforcement Academy of the New Mexico Administrative Code of the New Mexico Law Enforcement

Academy (NMLEA) Board has been CANCELLED.

The hearing was to be held on Friday, November 17, 2017, from 9:00 a.m. to 12:00 p.m., at the New Mexico Law Enforcement Academy (NMLEA) Main Building, Classroom TBD, 4491 Cerrillos Road, Santa Fe, NM.

This hearing will be postponed until a later date.

#### WORKFORCE SOLUTIONS, DEPARTMENT OF

#### NOTICE OF RULEMAKING

The New Mexico Department of Workforce Solutions ("Department") hereby gives notice that the Department will conduct a public hearing in the auditorium of the State Personnel Office located at 2600 Cerrillos Road, Santa Fe, New Mexico on January 4, 2018 from 10:00 A.M. to 12:00 P.M. The purpose of the public hearing will be to obtain input and public comment on the proposed amendments to 11.2.3 - Labor and Workers Compensation - Job Training - State Apprenticeship Policy Manual.

Under Section 50-7-1 to 50-7-4.1 and 50-7-7 NMSA 1978, the Department is the agency responsible for the State Apprenticeship Program and gives the Department legal authority for rule making.

The proposed changes alter the language in the rule from "State Apprenticeship Agency" to "State Apprenticeship Office" to reflect the appropriate entity and better define roles and responsibilities. The proposed changes to the rule update program responsibilities and expectations and amend the rule to align with current operating procedures.

Interested individuals may testify at the public hearing or submit written comments to State of New Mexico Department of Workforce Solutions, 401 Broadway NE, P.O. Box 1928, Albuquerque, N.M., 87103, attention Robert Dale Morrison. Written comments must be received no later than 5 p.m. on January 3, 2018. However, the submission of written comments as soon as possible is encouraged.

Copies of the amended rules may be accessed at http://www.dws.state.nm.us/ or obtained from Robert Dale Morrison at (505) 841-8672 or at RobertD.Morrison@state.nm.us. The proposed rules will be made available at least thirty days prior to the hearings.

Individuals with disabilities who require this information in an alternative format or need any form of auxiliary aid to attend or participate in this meeting are asked to contact Mr. Morrison as soon as possible. The Department requests at least ten (10) days advance notice to provide requested special accommodations.

End of Notices of Rulemaking and Proposed Rules

### **Adopted Rules**

#### Effective Date and Validity of Rule Filings

Rules published in this issue of the New Mexico Register are effective on the publication date of this issue unless otherwise specified. No rule shall be valid or enforceable until it is filed with the records center and published in the New Mexico Register as provided in the State Rules Act. Unless a later date is otherwise provided by law, the effective date of the rule shall be the date of publication in the New Mexico Register. Section 14-4-5 NMSA 1978.

#### ALBUQUERQUE/ BERNALILLO COUNTY AIR QUALITY CONTROL BOARD

This is an amendment to 20.11.41 NMAC, Sections 13, 14, 15, 28 and 32, effective 12/13/2017.

## **20.11.41.13** APPLICATION FOR PERMIT:

**Pre-application** requirements: A person who is seeking a permit pursuant to 20.11.41 NMAC shall contact the department in writing and request a pre-application meeting for information regarding the contents of the application and the application process. The meeting shall include discussion of approved emission factors and control efficiencies, air dispersion modeling guidelines, department policies, air quality permit fees, public notice requirements and regulatory timelines. The department may waive the pre-application meeting requirement.

В. Applicant's public notice requirements: [H the applicant is applying for a technical permit revision, then before the applicant submits the application required by Subsection Bof 20.11.41.28 NMAC, the applicant shall comply with the public notice requirements of Paragraph (1) of Subsection B of 20.11.41.13 NMAC. If the applicant is applying for a permit or permit modification, then before the applicant submits the application required by Subsection E of 20.11.41.13 NMAC, the applicant shall comply with the public notice requirements of Paragraphs (1) and (2) of Subsection B of 20.11.41.13 NMAC. If the applicant is applying for a portable stationary source relocation, then the department may require that the applicant comply with these same notice requirements. The applicant shall:

provide **(1)** public notice by certified mail or electronic mail to the designated representative(s) of the recognized neighborhood associations and recognized coalitions that are within one-half mile of the exterior boundaries of the property on which the source is or is proposed to be located; contact information shall be obtained from the most current records of the city of Albuquerque office of neighborhood coordination and the county of Bernalillo zoning, building and planning department; the public notice shall include all information required by Subsection C of 20.11.41.13 NMAC; the applicant may submit a written request to the department proposing an alternative approach to providing public notice if the proposed source or modification is located at a site with large property boundaries or campus-like facilities; the applicant shall obtain prior written approval from the department before using an alternative approach to providing public notice;

prior to submitting the application, post and maintain a weather-proof sign provided by the department, posted at the more visible of either the proposed or existing facility entrance or, if approved in advance and in writing by the department, at another location on the property that is accessible to the public; the applicant shall list all information required by Subsection C of 20.11.41.13 NMAC, on the sign; the applicant shall keep the sign posted until the department takes final action on the permit application; if an applicant can establish to the department's satisfaction that the applicat is prohibited by law from posting, at either location required by Paragraph (2) of Subsection B of

20.11.41.13 NMAC, the department may waive the posting requirement and may impose different notification requirements.

**C.** Additional public notice requirements: The public notice specified in Paragraphs (1) and (2) of Subsection B of 20.11.41.13 NMAC shall include the following:

applicant's name and address, and the names and addresses of the owner or operator of the source or proposed source:

(2) the actual or estimated date the application will be submitted to the department;

(3) the exact location of the source or proposed source;

**(4)** 

a description of the source and related facility, if any; the nature of the business; the process or the change for which the permit is being requested, including a preliminary estimate of the maximum quantities of each regulated air contaminant the source will emit if the permit is issued and the proposed construction or modification is completed; and, if the source is being modified, the net change in emissions;

(5) the maximum and normal operating schedules proposed for the source or facility; and

(6) the current address of the applicant to which comments and inquiries may be directed.

**D.** A person who is seeking a construction permit pursuant to 20.11.41 NMAC shall complete a permit application and file one complete original and one duplicate copy with the department. A person who is seeking a general construction permit shall complete the applicable general construction

form pursuant to Subsection C of 20.11.41.31 NMAC and file one complete original form and a duplicate copy with the department. All applications shall be submitted with the fee required by 20.11.2 NMAC.

contents: The following are the minimum elements that shall be included in the permit application before the department can determine whether the application is administratively complete and ready for technical review. It is not necessary to include an element if the department has issued a written waiver regarding the element and the waiver accompanies the application. However, the department shall not waive any federal requirements. The permit application shall include:

(1) a completed permit application form provided by the department;

(2) the name, street address and post office address, if any, of the applicant and the names, street addresses and post office addresses, if any, of the owner and all operators of the source if different than the applicant;

(3) the date the application was submitted to the department;

sufficient **(4)** attachments, including calculations, computations, EPA-approved air dispersion model as required, or models executed under a protocol as required that has been approved in advance and in writing by the department, and all other analyses used by the applicant to provide information to describe the potential emission rate and nature of all regulated air contaminants that the source may emit, and the actual emissions that the source will emit under routine operations after construction, modification, relocation or technical revision, and estimates of potential emissions during malfunction, startup and shutdown;

(5) an operational and maintenance strategy detailing:

(a)

the steps the applicant will take if a malfunction occurs that may cause emission of a regulated air contaminant to exceed a limit that is included in the permit;

(b

the nature of emissions during routine startup or shutdown of the source and the source's air pollution control equipment; and

(c)

the steps the applicant will take to minimize emissions during routine startup or shutdown;

(6) a map, such as a 7.5 minute topographic quadrangle map published by the United States geological survey or a map of equivalent or greater scale, detail and precision, including a city of Albuquerque or county of Bernalillo zone atlas map that shows the proposed location of each process equipment unit involved in the proposed construction, modification, relocation or technical revision of the source:

an aerial photograph showing the proposed location of each process equipment unit involved in the proposed construction, modification, relocation or technical revision of the source except for federal agencies or departments involved in national defense or national security as confirmed and agreed to by the department in writing;

(8) a complete description of all sources of regulated air contaminants and a process flow diagram depicting the process equipment unit or units at the facility, both existing and proposed, that are proposed to be involved in routine operations and from which regulated air contaminant emissions are expected to be emitted;

(9) a full description of air pollution control equipment, including all calculations and the basis for all control efficiencies presented, manufacturer's specifications sheets, and site layout and assembly drawings; UTM (universal transverse mercator) coordinates shall be used to identify the location of each emission unit;

(10) a description of the equipment or methods proposed by the applicant to

(11) the maximum and normal operating time schedules of the source after completion of construction, modification, relocation or technical

be used for emission measurement;

(12) any other relevant information as the department may reasonably require;

revision;

signature of the applicant, operator, owner or an authorized representative, certifying to the accuracy of all information as represented in the application and attachments, if any;

or money order for the appropriate application fee or fees required by 20.11.2 NMAC, Fees; the fees are established to offset some or all of the reasonable costs of the department reviewing and acting upon an application for a permit and implementing and enforcing the terms and conditions of the permit, excluding costs associated with an enforcement action; and

(15)

documentary proof that the applicant has complied with all public notice requirements, as required by Subsections B and C of 20.11.41.13 NMAC; documentary proof shall include proof of delivery of certified mail or e-mail of the public notice required by Paragraph (1) of Subsection B of 20.11.41.13 NMAC and a photograph of each notice posted as required by Paragraph (2) of Subsection B of 20.11.41.13 NMAC.

## F. Changing, supplementing or correcting applications:

the department makes a final decision regarding the application, the applicant shall have a duty to promptly supplement and correct information the applicant has submitted in the application to the department. Applicant's duty to supplement and correct the application includes relevant information acquired after the

applicant has submitted the application and additional information the applicant otherwise determines is relevant to the application and the department's review and decision.

While the department is processing an application, regardless of whether the department has determined the application is administratively complete, if the department determines additional information is necessary to evaluate or make a final decision regarding the application, the department may request, and the applicant shall provide the requested additional information. The request shall be in writing, identify the additional information requested, the reason the additional information is needed, and set a reasonable deadline for a response. The applicant shall submit the requested information in writing to the department on or before the response deadline.

## G. Protection of confidential information:

) All

records, reports or information relating to permit applications obtained by the department or the board from any person shall be available to the public for inspection and copying, unless a person has made a satisfactory showing to the department or the board, as confirmed and agreed to by the department in writing, that specific items or information or parts thereof, if made public, would divulge: confidential business records, methods or processes entitled to protection as trade secrets; information pertaining to national defense; or information pertaining to national security. If the items or information are specifically marked by the person as confidential at the time of submittal, the department and the board shall then protect the items and information listed in Subparagraphs (a) and (b) of Paragraph (1) of Subsection G of 20.11.41.13 NMAC as confidential and not to be made a part of any public record unless the person expressly agrees, in writing, to its inspection, copying, or publication:

(a)

records, reports or information relating to methods, processes or production techniques unique to the person, and

**(b)** 

data relating to the person's profits and costs or other confidential business information which have not previously been released to the public.

(2) Subsection G of 20.11.41.13 NMAC shall not be construed to prohibit the release of information concerning the nature and amount of emissions from any source.

department shall review all claims of confidentiality made by any person pursuant to 20.11.41 NMAC and shall notify the person of the department's determination by certified mail or electronic mail in a timely manner and shall include the reasons for the decision. The burden of proof for claims of confidentiality shall be upon the person submitting such claim.

(4) The department's determination regarding claims made pursuant to Subsection G of 20.11.41.13 NMAC shall be the final administrative determination.

department shall protect information claimed and subsequently found to be confidential in accordance with the provisions of 74-2-11 NMSA 1978 and 18 U.S.C. Section 1905, except that any such record, report or information may be disclosed:

(a)

to other officers, employees or authorized representatives of the department, the board and the EPA; or

any proceeding pursuant to the federal act or the state act, when relevant. [20.11.41.13 NMAC - Rp, 20.11.41.13 NMAC, 1/1/14; A, 12/13/17]

#### 20.11.41.14 PUBLIC NOTICE BY DEPARTMENT - PUBLIC PARTICIPATION:

A. The department shall maintain a list of all pending applications for permits available for public inspection.

**B.** If the department makes an affirmative administrative

completeness determination then:

(1) the department shall make the permit application and all supporting documentation available for public inspection at the department's air quality division office at One Civic Plaza NW, Albuquerque, NM 87102;

**(2)** 

the department shall publish the public notice [in the newspaper with the largest general circulation in Bernalillo county] on the website of the city of Albuquerque environmental health department; the notice shall state:

(a)

the applicant's name and address;

(b)

the proposed or existing location;

(c)

a brief description of the source and related facility, if any;

(d)

a brief preliminary summary of proposed emissions and the proposed net emissions increase if a permit modification is proposed;

(e)

the ambient air quality impact as determined by air dispersion modeling, if required by the department;

**(f)** 

the location where the permit application and the department's analysis if completed, are available for public review; the notice shall clearly state that any person who does not express such interest in writing prior to the end of the initial 30 day comment period will not receive notification of the availability of the analysis and so alert such a person of the need to express interest in writing if they desire to review and comment on the analysis;

**(g)** 

that the public has 30 days to submit written comments and evidence to the department regarding the proposed permit or to request a PIH regarding the application or both; the notice shall specify the date by which all comments and evidence or a request for a PIH shall be submitted;

(h)

that the department shall hold a PIH

pursuant to 20.11.41.15 NMAC if the director determines there is significant public interest and a significant air quality issue is involved; and

(i)

that any person who does not participate in the permitting action will not receive notification of the department's decision regarding the proposed permit, unless the person has delivered a written request for notice to the department;

- (3) the department shall provide the notice required by Paragraph (2) of Subsection B of 20.11.41.14 NMAC by regular mail or electronic mail to all individuals and organizations identified on a list maintained by the department of persons who have stated in writing a desire to receive notices of all applications filed pursuant to 20.11.41 NMAC;
- department shall allow all interested persons 30 days from the date the public notice is published to deliver to the department written comment and evidence regarding the application for a permit;
- the **(5)** department shall send notice of the department's action regarding the permit application and the reasons for the action to every person who participated in the permitting action; a request to inspect or copy shall not be considered participation for the purposes of Paragraph (5) of Subsection B of 20.11.41.14 NMAC; the applicant shall be notified by certified mail or electronic mail; all other interested persons who participated shall be notified by regular mail or electronic mail;
- department shall provide a copy of the public notice by certified mail or electronic mail to the designated representative(s) of the recognized neighborhood associations and recognized coalitions, that are within one-half mile of the exterior boundaries of the property on which the source is or is proposed to be located; contact information, if available, shall be obtained from the most current records of the city of

Albuquerque office of neighborhood coordination and the county of Bernalillo zoning, building and planning department;

- (7) the department shall mail a copy of the public notice by regular or electronic mail to every person who submits a written request for a copy to the department;
- department shall mail a copy of the public notice by regular or electronic mail to the state of New Mexico environment department within five days after the department deems the application complete; the department shall also mail a copy of the public notice by regular or electronic mail to EPA Region VI, if requested; and
- department shall mail a copy of the public notice by regular or electronic mail to all municipalities, Indian tribes and counties that are within one-half mile of the exterior boundaries of the property on which the source is or is proposed to be located.
- **C.** If a person expresses in writing an interest in the permit application, the department shall:
- (1) notify that person of the date that the department's analysis was or will be available for review and where the analysis may be obtained; and
- the permit until at least 30 days after the department's analysis is available for review. During the 30 day period, any person may submit written comments or request a PIH. [20.11.41.14 NMAC Rp, 20.11.41.14 NMAC, 1/1/14; A, 12/13/17]

## 20.11.41.15 PUBLIC INFORMATION HEARING (PIH):

A. Before the department makes a final decision regarding a permit application, the department shall hold a PIH if the director determines that there is significant public interest and a significant air quality issue is involved. A PIH is not an

- adjudicatory hearing on the merits. The PIH shall be held no fewer than 30 days before the deadline for the department to make a final decision regarding the permit application. The hearing officer shall determine whether to require attendees to be sworn before they can ask questions, provide comments or provide information. During the PIH, attendees can ask questions, provide comments and provide information regarding the requested air quality permitting action, but no final decision shall be made by the department at the close of the hearing.
- **B.** The department shall make all arrangements and pay all expenses of the hearing including:
- (1) arranging for a location for the PIH, which shall be held near the proposed source if reasonably feasible;
- (2) providing an English-Spanish and Spanish-English translator at the PIH if determined to be necessary by the department;
- a hearing officer; the hearing officer shall preside over the PIH; shall give all attendees present at the hearing a reasonable opportunity to ask questions, provide comments and provide information regarding the requested air quality permitting action and to examine attendees commenting at the hearing; but shall not make a recommendation or a final decision regarding the permit application;
- (4) requesting that the applicant present its proposal and to answer questions from attendees at the PIH;
- than [10] 30 days before the PIH, providing a copy of the public notice by certified mail or electronic mail to the applicant, the designated representative(s) of the recognized neighborhood associations and recognized neighborhood coalitions that are within one-half mile of the exterior boundaries of the property on which the source is or is proposed to be located; contact information, if available, shall be obtained from the most current records of the city of

Albuquerque office of neighborhood coordination and the county of Bernalillo zoning, building and planning department; the notice shall contain the information required by Paragraphs (1) and (3)-(5) of Subsection C of 20.11.41.13 NMAC, and the name of the contact person, the department and the address to which comments and inquiries may be directed; the notice of the PIH shall be in English and Spanish if the department determines notice in Spanish is necessary; if a PIH notice is returned to the department undelivered, the department shall promptly confirm the address through the appropriate local government entity, and, if an address is available, shall provide a second copy of applicant's PIH notice to the president or vice president of the neighborhood association or neighborhood coalition;

public notice of the PIH in the newspaper with the largest general circulation in Bernalillo county no fewer than [10] 30 days before the PIH; the notice shall include the date, time, and location of the PIH, the number of the proposed permit, and a statement that a final decision has not been made by the department regarding the proposed permit;

notice of the PIH to all interested persons who have submitted written comments or evidence to the department and to all interested persons who have delivered to the department a written request for notice regarding the application; a request to inspect or copy shall not be considered a written comment for the purposes of Paragraph (7) of Subsection B of 20.11.41.15 NMAC;

department staff to attend the PIH; be present during the applicant's requested presentation and the comments and questions by the attendees; and answer questions regarding the application and the permitting process; and

(9) recording the PIH and including the recording in the administrative record for the permit application; the department

shall provide a duplicate of the recording to any person who requests a copy; the person requesting shall reimburse the department for the cost of the copy before the department makes the copy; the person making the request for a copy may instead provide the department with recording media that meets the department specifications, and the department will not impose a charge for copying; if a person requests a transcript of the hearing (the requestor), the department shall obtain an estimate of the cost of the transcription and inform the requestor; the requestor shall pay the estimated cost before the department orders the transcription; if the actual cost of the transcription is more than the estimate, the requestor shall pay the additional amount before the department provides the transcription; if the actual cost of the transcription is less than the estimate, the department shall reimburse the difference. [20.11.41.15 NMAC - Rp,

20.11.41.15 NMAC, 1/1/14; A, 12/13/17]

## 20.11.41.28 ADMINISTRATIVE AND TECHNICAL PERMIT REVISIONS:

A. Administrative permit revision:

administrative permit revision may be used by the department or requested by a permittee to revise a permit that has been issued pursuant to 20.11.41 NMAC in order to:

(a)

correct a typographical error;

**(b)** 

identify a change in ownership, name, address or contact information of any person identified in the permit; or

incorporate a change in the permit if the change is limited to retiring an emission unit at the facility, which shall be effective when the department receives written notice that the emission unit has ceased operation; and

(d)

incorporate a change in the permit to include a source or activity at the facility if the facility or activity is exempted by Paragraph (3) of Subsection F of 20.11.41.2 NMAC.

(2) An

administrative permit revision shall:

(a)

not be subject to Subsection B of 20.11.41.13 NMAC, Applicant's Public Notice Requirements;

**(b)** 

not be subject to 20.11.41.14 NMAC, Public Notice by Department - Public Participation;

(c) be subject to 20.11.41.12 NMAC, Fees for Permit Application Review; and

submitted on forms provided by the department.

(3) When the department receives a revision form, the department shall review the form. If the department determines the revision qualifies as an administrative revision, the department shall file the revision with the permit. However, the procedure authorized by Subsection A of 20.11.41.28 NMAC may not be used to create federally enforceable conditions or emissions limitations to avoid any applicable requirement.

## B. Technical permit revision:

permit revision may be requested by a permittee provided that it does not require air dispersion modeling and meets one or more of the following criteria:

(a)

to incorporate a change in the permit if the change only involves a change in monitoring, record keeping or reporting requirements, if the department determines the change does not reduce the enforceability of the permit;

**b**) to

incorporate a change in the permit that only involves additional equipment with [a potential emission rate of nomore than one pound per hour for any pollutant for which a national or New Mexico ambient air quality standard has been set or one pound per hour for any VOC if the increase in potential emission rate does not result in an

exceedance of the applicable ambient standard;] no increase in potential emission rate;

(c)

to incorporate a change in the permit if the change only involves incorporating permit conditions, including emissions limitations, but only if the source existed on August 31, 1972, and the source has been in regular operation since that date;

(d)

if the permittee wishes to impose a voluntary reduction of an emission limitation that was included as a specific permit conditions pursuant to Subsection B of 20.11.41.19 NMAC, Permit Conditions:

(e)

to incorporate a change at a facility by replacing an emissions unit for which an allowable emissions limit has been established in the permit, but only if the replacement emissions unit as determined by the department:

(i`

is equivalent to the replaced emissions unit and serves the same function within the facility and process;

(ii)

has the same or lower capacity and potential emission rates;

(iii)

has the same or higher control efficiency and stack parameters that are at least as effective in dispersing air pollutants;

(iv)

would not result in an increase of the potential emission rate of any other equipment at the facility;

(v)

is subject to the same or lower allowable emissions limits as the current permit prior to making the replacement and to all other original permit conditions prior to making the technical permit revision request;

(vi)

will not cause or contribute to a violation of any NAAQS and NMAAQS when operated under applicable permit conditions;

(vii

will not require additional permit conditions to ensure the enforceability of the permit, such as additional record keeping or reporting in order to establish compliance; and

(viii)

does not emit a regulated air contaminant not previously emitted;

f)

reduce the potential emission rate of a unit or source, by incorporating terms and conditions in the permit, such as a cap on hours of operation, limitations on throughput of a specific product or products, or limitations on equipment capacity; or

**(g)** 

to incorporate a change in the permit that only involves the addition of air pollution control equipment or the substitution of a different type of air pollution control equipment to existing equipment if the requested addition or substitution shall not result in an increase in the potential emission rate [of more than one pound per hour for any pollutant for whicha national or New Mexico ambient air quality standard has been set, or one pound per hour for total VOCs if the increase in potential emission rate does not result in an exceedence of the applicable ambient standard].

) An

application for a technical revision to a permit shall:

(a)

<u>not</u> be subject to [Paragraph (1) of Subsection B of] 20.11.41.13 NMAC, Applicant's Public Notice Requirements;

**(b)** be

subject to 20.11.41.12 NMAC, Fees for Permit Application Review;

(c

not be subject to 20.11.41.14 NMAC, Public Notice by Department - Public Participation; and

(d)

be submitted on forms provided by the department, with all information submitted by the applicant certified as required by Paragraph (13) of Subsection E of 20.11.41.13 NMAC.

(**3**) Within 30

days of receipt of the application, the department shall approve or deny the application for the technical permit revision, or inform the applicant in writing that the request must be submitted as a permit modification.

[<del>(4)</del> If in

response to significant public interest the director decides to hold a PIH pursuant to 20.11.41.15 NMAC, the department shall inform the applicant and conduct the PIH within 90 days of receipt of the technical permit revision application.]

[<del>(5)</del>] <u>(4)</u> The

department may deny an application for a technical permit revision or require that the application be submitted as a permit modification if:

(a)

the <u>proposed</u> revision does not meet the criteria included in Subsection B of 20.11.41.28 NMAC;

(b)

in the judgment of the department, the revision would require a decision on a significant or complex issue, or involve a substantive change; or

(c)

in the judgment of the department, the permittee has submitted multiple or subsequent applications for technical permit revisions under 20.11.41.28 NMAC that segment a larger revision or modification that otherwise would not be eligible for a technical permit revision.

[<del>(6)</del>] <u>(5)</u> The

technical permit revision shall become effective when approved in writing by the department. The department shall file the technical permit revision with the permit. However, the procedure established in 20.11.41.28 NMAC may not be used to create federally enforceable conditions or emissions limitations to avoid an applicable requirement.

[20.11.41.28 NMAC - N, 1/1/14; A, 12/13/17]

## 20.11.41.32 ACCELERATED REVIEW OF APPLICATION:

## A. Request for accelerated review of application:

As provided by the state act at NMSA 1978 Section 74-2-7(B)(8) and (9), an applicant may request accelerated review if the applicant complies with the following requirements and all other requirements of 20.11.41.32 NMAC:

**(1)** 

20.11.41.12 NMAC, Fees for Permit Application Review;

**(2)** 

20.11.41.13 NMAC, Application for Permit;

(3)

20.11.41.15 NMAC, Public Information Hearing;

(4)

20.11.41.16 NMAC, Permit Decisions and Air Board Hearing on the Merits;

(5)

20.11.41.18 NMAC, Applicant's Additional Legal Responsibilities;

(6)

20.11.41.19 NMAC, Permit Conditions;

**(7**)

20.11.41.20 NMAC, Permit Cancellation, Suspension or Revocation;

(8)

20.11.41.21 NMAC, Permittee's Obligation to Inform the Department and Deliver an Annual Emissions Inventory;

(9)

20.11.41.22 NMAC, Performance Testing;

(10)

20.11.41.23 NMAC, Temporary Relocation of Portable Stationary Sources;

(11)

20.11.41.24 NMAC, Emergency Permits;

(12)

20.11.41.25 NMAC, Nonattainment Area Requirements;

(13)

20.11.41.26 NMAC, Compliance Certification;

(14)

20.11.41.27 NMAC, Enforcement;

(15)

20.11.41.28 NMAC, Administrative and Technical Permit Revisions;

**(16)** 

20.11.41.29 NMAC, Permit Modification;

(17)

20.11.41.30 NMAC, Permit Reopening, Revision and Reissuance;

(18)

20.11.41.31 NMAC, General Construction Permits; and

(19)

20.11.41.33 NMAC, Significant Ambient Concentrations - Nonattainment.

B. Public notice provided by the department: The department shall provide the public notice as required by Paragraphs [(2)] (1) through (9) of Subsection B of 20.11.41.14 NMAC.

## C. Qualified outside contractors:

(1) The department shall request proposals from persons interested in providing assistance as a qualified outside contractor in the accelerated review of permit applications pursuant to 20.11.41 NMAC.

(2) The department shall evaluate the proposals submitted by the interested persons. To be eligible to contract with the department as a qualified outside contractor, a person must be:

(a)

legally qualified to contract with the department; and

**(b)** 

qualified to assist the department in review of permit applications, as determined by the department.

(3) Persons who are selected as qualified outside contractors shall be under contract with the department to provide accelerated review of permit applications pursuant to 20.11.41.32 NMAC.

## D. Requests for accelerated review:

**(1)** An applicant for a permit pursuant to 20.11.41 NMAC may request accelerated permit review of the application by a qualified outside contractor. Applications for accelerated review shall be preceded by a pre-application meeting between the applicant and the department. Requests for accelerated review shall not be granted unless there is at least one qualified outside contractor under contract with the department as required by Paragraph (3) of Subsection C of 20.11.41.32 NMAC. If there are no persons under contract to provide accelerated review, the department shall review the application in accordance with 20.11.41.16 NMAC.

(2) A request

for accelerated permit review shall be submitted with the permit application and a certified check or money order in the amount of the accelerated review filing fee as required by 20.11.2 NMAC. The department shall notify the applicant of the names and addresses of the qualified outside contractors. The applicant shall deliver a copy of the application, by mail or hand delivery, to each qualified outside contractor identified by the department, unless the applicant is aware of a conflict of interest.

(3) Applicants who have chosen accelerated review pursuant to 20.11.41.32 NMAC shall pay the accelerated review fee required by 20.11.2 NMAC in addition to all other applicable fees imposed by 20.11.2 NMAC.

**(4)** 

Participation in the accelerated permit review process shall not relieve the applicant of any responsibilities imposed by a board regulation.

(5) Qualified outside contractors under contract that are interested in performing accelerated review of a specific application shall submit to the department:

**(a)** a

statement of interest;

**(b)** 

a statement of qualifications for the specific application;

(c) an

estimate of:

(i)

the cost for the review;

(ii)

the schedule for the review; and

(d)

a notarized affidavit attesting that no conflict of interest exists regarding the specific permit application.

(6) The

department shall review the submittals and determine which persons qualify to review a specific application.

(7) If no qualified outside person meets the requirements of Paragraph (5) of Subsection D of 20.11.41.32 NMAC, the department shall impose the accelerated review filing fee and the

permit application review fee required by 20.11.2 NMAC and review the application on an accelerated schedule without the assistance of a qualified outside contractor and as required by 20.11.41.16 NMAC.

the department determines whether an application for accelerated review is administratively complete, the department shall provide the applicant with a written bid summary of the qualified outside contractor submittals that shows the costs of the accelerated review and the anticipated schedule for reviewing the application, drafting the permit and issuing the permit. The department shall determine whether an application for accelerated review is administratively complete.

(9)

## Applicant's responsibilities for response to bid summary:

(a)

Within five working days after the applicant receives the department's bid summary, the applicant shall either:

(i) submit to the department a written recommendation asking the department to accept one of the accelerated review bids, or a prioritized list of more than one of the accelerated review bids, including a brief justification for the recommendation, with a certified check or money order payable to the department in the amount specified in the bid summary and a notarized affidavit attesting that no conflict of interest exists regarding the applicant's recommended selections; or

(ii)

submit to the department a written withdrawal of the request for accelerated review.

**(b)** 

The department shall deem the applicant's request for accelerated review withdrawn if the applicant fails to submit a written recommendation or written withdrawal within five working days after the applicant has received the department's bid summary unless the applicant has submitted a written request for an

extension and the department has granted an extension in writing.

(10)

## Department's selection of qualified outside contractor:

(a)

If the request for accelerated review is withdrawn, the department shall retain the accelerated review filing fee required by 20.11.2 NMAC and shall review the application without the assistance of a qualified outside contractor and pursuant to 20.11.41.16 NMAC.

**(b)** 

If the applicant recommends a qualified submittal, the department shall determine whether to accept the recommended submittal. If the department accepts the recommended submittal, the department shall instruct the qualified outside contractor to begin review of the application. If the department rejects the recommended submittal, the department shall inform the applicant and allow the applicant to recommend an alternate submittal pursuant to Paragraph (9) of Subsection D of 20.11.41.32 NMAC or, if there are no other qualified submittals, the department shall retain the accelerated review filing fee required by 20.11.2 NMAC and review the application without the assistance of a qualified outside contractor pursuant to 20.11.41.16 NMAC.

## E. Disclosure of conflict of interest during accelerated review:

applicant and the qualified outside contractor have a continuing obligation to investigate potential conflicts of interest and to immediately disclose any conflict of interest to the department in writing. If a conflict of interest is not disclosed as required by Subparagraph (d) of Paragraph (5) of Subsection D of 20.11.41.32 NMAC and is later disclosed or discovered, the department may:

(a)

deny the application pursuant to Subsection F of 20.11.41.17 NMAC;

(b)

terminate accelerated review and

review the application pursuant to 20.11.41.16 NMAC; or

(c)

allow accelerated review to continue after elimination of the conflict.

i) In

choosing among the options provided by Subparagraphs (a)-(c) of Paragraph (1) of Subsection E of 20.11.41.32 NMAC, the department shall consider whether the conflict of interest was disclosed or discovered, the timing of the disclosure or discovery, the applicant's diligence in investigating potential conflicts of interest, any indication of intentional or willful failure to disclose, the significance of the conflict of interest, and the applicant's ability to eliminate the conflict of interest in a timely manner.

## F. Issuance of a permit after accelerated review:

**(1)** Upon completion of the review, the qualified outside contractor shall provide the department with a draft permit and all documentation pertaining to the permit application, including all communications, notes and drafts. At any time during the review, the qualified outside contractor shall provide the department with all documentation pertaining to a specific application requested by the department in writing. The documentation shall be subject to the Inspection of Public Records Act, Chapter 14, Article 2 NMSA 1978, and the confidential information section of the state act at NMSA

department shall review the analysis prepared by the qualified outside contractor and shall issue the permit, issue the permit subject to conditions or deny the requested permit pursuant to 20.11.41.17 NMAC. The department retains final authority to accept or reject the qualified outside contractor's analysis regarding the permit application.

1978, Section 74-2-11.

(3) The department shall not issue the permit until the applicant has paid both the accelerated review processing fee and the permit review fee required by 20.11.2 NMAC.

[20.11.41.32 NMAC - N, 1/1/14; A, 12/13/17]

## COMMISSION OF PUBLIC RECORDS

The State Commission of Public Records, approved at its 11/14/2017 hearing, to repeal its rule 1.13.12 NMAC - Designation of Records Management Personnel (filed 11/17/2015) and replace it with 1.13.12 NMAC - Designation of Records Management Personnel, adopted on 11/14/2017 and effective 11/28/2017.

The State Commission of Public Records, approved at its 11/14/2017 hearing, to repeal its rule 1.13.30 NMAC - Disposition of Public Records and Non-Records (filed 11/17/2015) and replace it with 1.13.30 NMAC - Disposition of Public Records and Non-Records, adopted on 11/14/2017 and effective 11/28/2017.

The State Commission of Public Records, approved and adopted, at its 11/14/2017 hearing, to repeal its rule 1.24.20 NMAC - Emergency Rules (filed 2/15/2000), effective 11/28/2017.

## COMMISSION OF PUBLIC RECORDS

TITLE 1 GENERAL
GOVERNMENT
ADMINISTRATION
CHAPTER 13 PUBLIC
RECORDS
PART 12 DESIGNATION
OF RECORDS MANAGEMENT
PERSONNEL

**1.13.12.1 ISSUING AGENCY:** State Commission of Public Records. [1.13.12.1 NMAC - Rp, 1.13.12.1, 11/28/2017]

**1.13.12.2 SCOPE:** All agencies that utilize the records center services and state archives.

[1.13.12.2 NMAC - Rp, 1.13.12.2, 11/28/2017]

**1.13.12.3 STATUTORY AUTHORITY:** Public Records Act, Section 14-3-4 NMSA 1978. [1.13.12.3 NMAC - Rp, 1.13.12.3, 11/28/2017]

## 1.13.12.4 DURATION: Permanent.

[1.13.12.4 NMAC - Rp, 1.13.12.4, 11/28/2017]

## **1.13.12.5 EFFECTIVE DATE:** November 28, 2017, unless a later date is cited at the end of a

[1.13.12.5 NMAC - Rp, 1.13.12.5, 11/28/2017]

section

#### **1.13.12.6 OBJECTIVE:**

To establish requirements for the designation of personnel to interact with the commission of public records and the state records administrator for the access, storage and disposition of records stored at the state records center and archives.

[1 13 12 6 NMAC - Rp. 1 13 12 6

[1.13.12.6 NMAC - Rp, 1.13.12.6, 11/28/2017]

#### **1.13.12.7 DEFINITIONS:**

#### A. "Custodial

**agency"** means the agency responsible for the creation, maintenance, safekeeping and preservation of public records, regardless of physical location.

B. "Destruction" means the disposal of records of no further operational, legal, fiscal, or historical value by shredding, burial, pulping, electronic overwrite or some other process, resulting in the obliteration of information contained on the record.

# C. "Disposition" means final action that puts into effect the results of an appraisal decision for a series of records (i.e., transfer to archives or destruction).

# **D.** "Pending litigation" means threatened, pending or active proceedings in a court of law whose activity is in progress but not yet completed.

#### E. "Records

custodian" means the statutory head of the agency using or maintaining the records or the custodian's designee as defined in Section 14-3-2 NMSA, 1978.

# F. "State archives" means the principle location within the state records center and archives that maintains, preserves and makes available to the public the permanent and historical records of the state of New Mexico.

[1.13.12.7 NMAC - Rp, 1.13.12.7, 11/28/2017]

#### 1.13.12.8 RECORDS MANAGEMENT PROGRAM PERSONNEL HEIRARCHY:

A. The statutory records custodian for each agency may designate one individual to act as a designated records custodian on his or her behalf. The designee shall be appointed each fiscal year using a form approved by the administrator. For designated records custodian responsibilities please see 1.13.12.9 NMAC.

B. The records custodian for each agency may designate one chief records officer to oversee the agency's records management program. The chief records officer shall be appointed each fiscal year using a form approved by the administrator. For chief records officer responsibilities, refer to 1.13.12.10 NMAC.

C. The records custodian for each agency may designate one or more records liaison officer(s) responsible for authorizing the storage and destruction of agency records. The records liaison officer shall be appointed each fiscal year using a form approved by the administrator. For record liaison officer responsibilities, refer to 1.13.12.11 NMAC.

**D.** A records custodian, chief records officer or records liaison officer may designate personnel to pick-up agency records from the records center. Pick-up personnel shall be appointed each fiscal year using a form approved by the administrator. For pick-up personnel responsibilities, refer to 1.13.12.12

NMAC.

- E. If a records custodian does not designate a chief records officer or record liaison officer, the records custodian shall remain responsible for all of the duties of the personnel listed above.
- F. The records custodian shall notify the state commission of public records concerning any status changes regarding designated records management personnel.
  [1.13.12.8 NMAC Rp, 1.13.12.8, 11/28/2017]

## 1.13.12.9 DESIGNATED RECORDS CUSTODIAN: If a

statutory records custodian elects to designate an individual to serve on his or her behalf as a designated records custodian, the following requirements and responsibilities are assigned.

- A. The designated records custodian shall be the individual responsible for satisfying all statutory requirements of the records custodian as delineated in the Public Records Act (14-3-1 NMSA, 1978).
- **B.** All designated records custodians shall attend the required basic records management training offered by the state commission of public records before they can store, withdraw, access or request the disposition of records.
- C. Designated records custodians are required to attend the basic records management training once every three years.

  [1.13.12.9 NMAC N, 11/28/2017]

# **1.13.12.10 CHIEF RECORDS OFFICER:** If a chief records officer is designated by the records custodian, the following responsibilities are assigned.

- **A.** The chief records officer shall be the individual with the authority to oversee the agency's records management program.
- **B.** The chief records officer shall perform the following duties:
- (1) coordinate the response to the disposition authorization (destruction and transfer

to state archives):

(2) establish and maintain a centralized tracking system for the agency's storage containers (including the containers' indices, metadata and locators) and the disposition of records;

(3)

disseminate information on any pending litigation, a discovery order, subpoena, government investigation or audit;

- (4) ensure staff is adequately trained on proper records management practices; and
- policies and procedures pertaining to records management issues (i.e., handling confidential materials, new hire orientation, e-mail management, disposition of records when an employee leaves the agency, metadata development, etc.).
- C. The chief records officer shall have the same authorities and responsibilities as a record liaison officer. The chief records officer shall have the authority to submit records for direct transfer to archives.
- **D.** All chief records officers shall attend the required basic records management training offered by the state commission of public records before they can store, withdraw, access or request the disposition of records.
- E. Chief records officers are required to attend the basic records management training once every three years.
  [1.13.12.10 NMAC Rp, 1.13.12.9, 11/28/2017]

# **1.13.12.11 RECORDS LIAISON OFFICER:** If a record liaison officer is designated by the records custodian, the following responsibilities are assigned.

- A. Records liaison officers shall be authorized to interact with the state commission of public records and the state records administrator for the purposes of storage, withdrawal, access or disposition of records.
- **B.** All records liaison officers shall attend the required basic records management training

offered by the state commission of public records before they can store, withdraw, access or request the disposition of records.

C. Records liaison officers are required to attend the basic records management training once every three years.
[1.13.12.11 NMAC - Rp, 1.13.12.10, 11/28/2017]

# **1.13.12.12 PICK-UP ONLY PERSONNEL:** Pick-up personnel are authorized to pick-up agency records from the records center. [1.13.12.12 NMAC - Rp, 1.13.12.11, 11/28/2017]

## 1.13.12.13 DIGITAL SIGNATURE ISSUANCE AND USAGE:

- A. A records custodian, chief records officer or records liaison officer may request a digital signature. This signature may be used exclusively for the purpose of submitting approved designation and destruction forms to the state commission of public records.
- B. To request a digital signature, records management personnel shall submit a digital signature request each fiscal year using a form approved by the administrator. The original signed form must be:
- (1) submitted in person to the agency analysis bureau by the records custodian, chief records officer or records liaison officer and accompanied by a government issued form of photo identification; or
- (2) submitted to the agency analysis bureau by mail and include the notarized signature of the records custodian, chief records officer or records liaison officer.
- C. The records custodian shall notify the state commission of public records concerning any status changes regarding the authority to utilize a digital signature by designated records management personnel.
- **D.** The digital signature shall be the last function performed on an electronic form

before saving and submitting the form. Forms modified after a digital signature has been affixed will be rejected.

[1.13.12.13 NMAC - Rp, 1.13.12.12, 11/28/2017]

## HISTORY OF 1.13.12 NMAC: [RESERVED]

#### **History of Repealed Material:**

1.13.12. NMAC, Designation Of Records Management Personnel, filed 11/17/2015 - Repealed effective 11/28/2017.

#### **NMAC History:**

1.13.12. NMAC, Designation Of Records Management Personnel (filed 11/17/2015) was replaced by 1.13.12. NMAC, Designation Of Records Management Personnel, effective 11/28/2017.

## COMMISSION OF PUBLIC RECORDS

TITLE 1 GENERAL
GOVERNMENT
ADMINISTRATION
CHAPTER 13 PUBLIC
RECORDS
PART 30 DISPOSITION OF
PUBLIC RECORDS AND NONRECORDS

#### 1.13.30.1 ISSUING

**AGENCY:** State Commission of Public Records and the State Records Administrator.

[1.13.30.1 NMAC - Rp, 1.13.30.1 NMAC, 11/28/2017]

- **1.13.30.2 SCOPE:** All state agencies and any public entity that use the state records center services. [1.13.30.2 NMAC Rp, 1.13.30.2 NMAC, 11/28/2017]
- **1.13.30.3 STATUTORY AUTHORITY:** Public Records Act, Sections 14-3-4 and 14-3-6 NMSA 1978.

[1.13.30.3 NMAC - Rp, 1.13.30.3 NMAC, 11/28/2017]

#### 1.13.30.4 **DURATION**:

Permanent.

[1.13.30.4 NMAC - Rp, 1.13.30.4 NMAC, 11/28/2017]

#### 1.13.30.5 **EFFECTIVE**

**DATE:** November 28, 2017, unless a later date is cited at the end of a section.

[1.13.30.5 NMAC - Rp, 1.13.30.5 NMAC, 11/28/2017]

**1.13.30.6 OBJECTIVE:** To establish requirements for the proper and orderly destruction of public records.

[1.13.30.6 NMAC - Rp, 1.13.30.6 NMAC, 11/28/2017]

#### **1.13.30.7 DEFINITIONS:**

#### A. "Chief records

**officer"** means a person designated by an agency's records custodian to administrate the agency's records management program, refer to 1.13.12.9 NMAC.

B. "Confidential" means information provided to, created by or maintained by a government agency and that is exempt from release under state or federal laws

#### C. "Custodial

**agency"** means the agency responsible for the creation, maintenance, safekeeping and preservation of public records, regardless of physical location.

- D. "Degaussing" means the process of removing magnetism from magnetically recorded tape thereby rendering the information unreadable.
- E. "Destruction"
  means the disposal of records of no
  further operational, legal, fiscal or
  historical value by shredding, burial,
  pulping, electronic overwrite or
  some other process, resulting in the
  obliteration of information contained
  on the record
- F. "Disposition" means final action that puts into effect the results of an appraisal decision for a series of records (i.e., transfer to archives or destruction).
- G. "Functional records retention and disposition schedule" means a rule adopted by

the commission pursuant to Section 14-3-6 NMSA 1978 describing the function of records, establishing a timetable for their life cycle and providing authorization for their disposition.

- H. "Inactive record" means a record no longer needed to conduct current business but required to be maintained for operational, legal, fiscal or historical purposes until it meets its retention.
- T. "Non-record" means extra copies of documents kept solely for convenience of reference, stocks of publications, transitory records, records not usually included within the scope of the official records of an agency or government entity and library material intended only for reference or exhibition. The following specific types of materials are non-records: materials neither made nor received in pursuance of statutory requirements nor in connection with the functional responsibility of the officer or agency, extra copies of correspondence, preliminary drafts, blank forms, transmittal letters or forms that do not add information, sample letters and informational files.
- J. "On-site destruction" means destruction of records approved by the state records administrator to be destroyed at a location other than the records center.
- K. "Permanent records" means records considered unique or so valuable in documenting the history or business of an organization that they are preserved in an archives.
- L. "Records" means information preserved by any technique in any medium now known or later developed, that can be recognized by ordinary human sensory capabilities either directly or with the aid of technology (1.13.70 NMAC).
- M. "Records liaison officer" means a person designated by the records custodian to interact with the state commission of public records, refer to 1.13.12.10 NMAC.
- N. "Records management" means the systematic

control of all records from creation or receipt through processing, distribution, maintenance and retrieval, to their ultimate disposition.

- O. "Recycling" means the process that recovers the raw materials of a medium allowing for the reuse of various media. Overwriting on magnetic media is a means of recycling.
- P. "Retention" means the period of time during which records shall be maintained by an organization because they are needed for operational, legal, fiscal, historical or other purposes.
- Q. "State archives" means the principle location within the state records center and archives that maintains, preserves and makes available to the public the permanent and historical records of the state of New Mexico.
- R. "Transitory"
  means messages which serve to
  convey information of temporary
  importance in lieu of oral
  communication. Transitory messages
  are only required for a limited
  time to ensure the completion of
  a routine action or the preparation
  of a subsequent record. Transitory
  messages are not required to control,
  support or to document the operations
  of government.
- S. "Trigger event" means the closing event of a record which begins the retention period. [1.13.30.7 NMAC Rp, 1.13.30.7 NMAC, 11/28/2017]

## 1.13.30.8 ASSIGNMENT OF RESPONSIBILITIES: Section

14-3-4 NMSA 1978 authorizes the commission of public records to appoint a state records administrator to carry out the purposes of the Public Records Act. The state records administrator is responsible for establishing records management programs within state government for the purpose of ensuring the efficient and economical management of public records throughout their lifecycle from their creation, utilization, maintenance, retention, preservation and final disposition.

**A.** The commission

- of public records hereby delegates the authority to order the routine destruction of public records, in accordance with adopted records retention and disposition schedules, to the state records administrator.
- **B.** The state records administrator shall prescribe the appropriate method of destruction of public records.
- C. The state records center and archives, in accordance with the rules established by the state records administrator and the commission of public records, is the authorized facility for the receipt, storage or disposition of all inactive and infrequently used records of present or former state agencies.

  [1.13.30.8 NMAC Rp, 1.13.30.8 NMAC, 11/28/2017]

## 1.13.30.9 DISPOSITION OF RECORDS:

- **A.** Agencies shall ensure the proper authorized disposition of their records regardless of format or medium.
- **B.** Records may be destroyed with the written approval of the state records administrator and the written consent of the records custodian, designated chief records officer or records liaison officer of the custodial agency.
- C. Records may be transferred to the state archives with the written approval of the state records administrator and the written consent of the records custodian or designated chief records officer of the custodial agency; once the transfer is authorized and the records are in the physical custody of the state archives, the legal custody of the records is vested in the state records administrator.
- **D.** Agencies shall follow rules issued by the state records administrator governing the methods of destruction.

  [1.13.30.9 NMAC Rp, 1.13.30.9 NMAC, 11/28/2017]

#### 1.13.30.10 DIRECT TRANSFER OF RECORDS TO THE STATE ARCHIVES:

**A.** An agency may

- transfer records with a retention of permanent directly to the state archives. Records eligible for direct transfer to archives shall be submitted on a form approved by the state records administrator. No direct transfer of records shall occur without the review and approval of the state records administrator.
- В. Records transferred directly to state archives shall be accompanied by an itemized records index on a form approved by the state records administrator. A copy of the index for each box shall be placed in the corresponding box. The complete index shall be attached to the request and an electronic copy shall be submitted to the state archives on a format approved by the state records administrator. The shipment box number (i.e., 1 of 10, 2 of 20, etc.) shall be affixed to the boxes prior to delivery to the state archives. All folders in the box shall be clearly labeled and identify the contents of the folder.
- **C.** Records involved in litigation, an audit or investigation are not eligible for transfer to the state archives.
- **D.** Only closed records shall be accepted for transfer to the state archives.

  [1.13.30.10 NMAC Rp, 1.13.30.10 NMAC, 11/28/2017]

## 1.13.30.11 ON-SITE DESTRUCTION OF RECORDS:

On-site destruction of records may occur at the custodial agency's location. For approval of on-site destruction, the records custodian, chief records officer or records liaison officer shall submit a request on a form approved by the state records administrator.

- **A.** The form may be submitted electronically with a valid digital signature issued by the state records administrator.
- **B.** The state records administrator or designee may inspect records prior to approval of on-site destruction.
- C. The state records administrator may order the transfer of records to the state archives for

review and appraisal.

D. For legal and audit purposes, the agency shall retain a certificate of destruction as proof of the records destroyed. The certificate of destruction shall include but not limited to the following information:

> place and **(1)**

date of pick up;

**(2)** printed name and signature of employee(s) performing service;

printed name and signature of witnesses;

**(4)** number of pounds destroyed/shredded (vendor) or number of boxes (agency certified);

> date of **(5)**

destruction/shredding;

identification of company's authorizing agent by name and position;

**(7)** printed name and signature of official certifying the destruction (vendor or records liaison officer): and

**(8)** statement that shredded records cannot be read. interpreted, or reconstructed.

E. Approved methods for on-site destruction of records are as follows:

**(1)** Records that contain confidential or sensitive information shall be destroyed through a bonded, insured, and national association for information destruction (NAID) AAA document recycling vendor by shredding in such a manner that the information cannot be read, interpreted or reconstructed.

Records that do not contain confidential or sensitive information shall be destroyed by:

recycling by a bonded document recycling vendor;

**(b)** 

shredding; or

(c)

dumpsite burial.

**(3)** Records which have been contaminated may be destroyed by:

(a)

any of the approved methods

described above: or

**(b)** 

incineration.

**(4)** Agencies shall select from the following methods of destruction for electronic records:

(a)

erasure from electronic media and all back up media;

**(b)** 

overwriting of reusable magnetic media multiple times as recommended by the United States (U.S.) department of defense;

(c)

degaussing of the magnetic media; or (d)

physical destruction of the media as recommended by the U.S. department of defense.

[1.13.30.11 NMAC - Rp, 1.13.30.11 NMAC, 11/28/2017]

#### 1.13.30.12 RECORDS DELIVERED TO THE RECORDS CENTER FOR DESTRUCTION:

Agencies storing records at their location may deliver records that have met their retentions to the records center for destruction. For approval to deliver records to the records center for destruction, the records custodian. chief records officer or records liaison officer shall submit a request on a form approved by the state records administrator.

The form may be A. submitted electronically with a valid digital signature issued by the state records administrator.

The state records administrator or designee may inspect records prior to the acceptance of the shipment for destruction.

C. The state records administrator may order the transfer of records to the state archives for review and appraisal.

D. The approved request for destruction shall match items delivered to the records center for destruction. When a discrepancy is found between what is listed on the approved request and what is delivered to the records center, the shipment shall be rejected and the agency shall remove the shipment

from the records center.

- Agencies utilizing E the records centers for destruction services shall use boxes equivalent to 15" x 10" x 12" in size.
- F. Records destroyed through the records center shall be assessed a fee per box. Agencies shall have a purchase order in place prior to delivery of the shipment to the records center. For information on the fee schedule, refer to 1.13.2 NMAC. [1.13.30.12 NMAC - Rp, 1.13.30.12 NMAC, 11/28/2017]

#### DISPOSITION 1.13.30.13 OF RECORDS STORED IN THE RECORDS CENTER:

- A. Upon receiving a disposition authorization notice for records stored in the records center, only the custodial agency's records custodian or chief records officer shall review the report of records to be destroyed or transferred to archives and respond by the established deadline. Records liaison officers do not have authority to sign the disposition authorization notice for records stored at the records center.
- B. Failure to return a completed disposition authorization notice by the established deadline shall result in a storage fee for records that are eligible for destruction. In addition, the return of withdrawn boxes, storage and disposition services will be suspended. For information on the fee schedule, refer to 1.13.2 NMAC.
- C. Records destroyed through the annual destruction process shall be assessed a fee per box. For information on the fee schedule, refer to 1.13.2 NMAC.

[1.13.30.13 NMAC - Rp, 1.13.30.13 NMAC, 11/28/2017]

#### 1.13.30.14 DESTRUCTION **OF NON-RECORDS:** Destruction

of non-records is the sole responsibility of the custodial agency and does not require the prior approval of the state records administrator. That responsibility includes identifying whether the information is a non-record or a public record. All state agencies and any public entity that use the state records center services shall submit a request on a form approved by the state records administrator. For the proper destruction of records with or without confidential or sensitive information, refer to 1.13.30.11 NMAC.

[1.13.30.14 NMAC - Rp, 1.13.30.14 NMAC, 11/28/2017]

## 1.13.30.15 DESTRUCTION OF RECORDS HELD BY

CONTRACTORS: All records or data created or managed by a contractor or non-government entity for a governmental agency shall be disposed of in accordance with the procedures established in 1.13.30 NMAC.

[1.13.30.15 NMAC - Rp, 1.13.30.15 NMAC, 11/28/2017]

## 1.13.30.16 MANAGEMENT RESPONSIBILITIES: The

development and implementation of a records management program is the responsibility of each agency records custodian, as defined by the Public Records Act. It is also management's responsibility to provide guidance to employees on the proper legal disposition of public records and non-records. Agency records management programs must clearly define the roles and responsibilities of users disposing public records and non-records.

[1.13.30.16 NMAC - Rp, 1.13.30.16 NMAC, 11/28/2017]

#### **HISTORY OF 1.13.30 NMAC:**

**Pre-NMAC History:** The material in this part was derived from that previously filed with the State Records Center:

SRC Rule No. 70-3, Records Management Division, Regulations Regarding Destruction of Records and Appointment of Liaison Officers, filed 9/9/1970.

SRC Rule No. 89-05, Regulations Regarding the Public Records Act, filed 5/22/1989.

#### **History of Repealed Material:**

1.13.30 NMAC, Destruction of Public Records, filed 6/16/2004 - Repealed effective 6/01/2006.

1.13.30 NMAC, Destruction of Public Records and Non-Records, filed 5/10/2006 - Repealed effective 11/30/2015.

1.13.30 NMAC, Destruction of Public Records and Non-Records, filed 11/17/2015 - Repealed effective 11/28/2017.

#### **NMAC History:**

1 NMAC 3.55, Destruction of Public Records, filed 12/1/1994.
1 NMAC 3.2.50.1, Destruction of Public Records, filed 4/18/1997.
1.13.30 NMAC, Destruction of Public Records, filed 6/16/2004.
1.13.30 NMAC, Destruction of Public Records and Non-Records, filed

5/10/2006. 1.13.30 NMAC, Destruction of Public Records and Non-Records, filed (11/17/2015) was replaced by 1.13.30 NMAC, Destruction of Public

1.13.30 NMAC, Destruction of Publi Records and Non-Records effective 11/28/2017.

## COMMISSION OF PUBLIC RECORDS

This is an amendment to 1.13.5 NMAC, Sections 8, 9, and 10, effective 11/28/2017.

#### **1.13.5.8 ELIGIBILITY:**

A. To be **eligible** for an historical records grant, the applicant shall be one of the entities listed below.

(1) A governmental organization including:
(a)

state agencies as prescribed in the Public Records Act; except the commission;

**(b)** 

county offices;

(c)

municipal offices;

(d)

political subdivisions; or

(e)

tribal government offices.

(2) A non-

profit and tax-exempt organization [registered with the New Mexico-secretary of state, ] verified as such by:

(a)

a copy of its <u>IRS issued letter</u> establishing tax-exempt [or 501(e)(3), or equivalent,] status; and

**(b)** 

a copy of certification of its good standing status with the New Mexico secretary of state[and].

[<del>(c)</del>

evidence that it has made provisions for the transfer of its holdings to a like organization or an appropriate repository for public access upon dissolution.

- **B.** Previous grant recipients shall be in compliance with the stipulations of all previous awards in order to be eligible.
- C. To be eligible for an historical records grant, applicants shall not be disbarred, suspended or otherwise excluded from or ineligible for participation in federal assistance programs.
- <u>D.</u> Board member organizations or their employers are not eligible to apply for NMHRAB funding.
- E. Funding shall not be used to process any collection held by the commission of public records.

  [1.13.5.8 NMAC Rp, 1.13.5.8 NMAC, 8/1/2015; A, 11/28/2017]

#### 1.13.5.9 CONDITIONS FOR RECEIVING A HISTORICAL RECORDS GRANT:

A. The applicant shall:

demonstrate legal custody of [or written permission from the organization that has legal custody of] historically significant original records at the time of the grant application deadline;

(2) provide a copy of its collection policy or a statement from its governing body indicating its commitment to sound practices concerning the historical material included in the project;

(3)

demonstrate the ability to carry out the objective of the proposal within the grant period;

(4) describe the records, their importance in

documenting New Mexico's history and the proposed project that affects the records:

- (5) include a mechanism for evaluating the impact of the project on its historical records' environment; and
- (6) provide a letter from its governing body indicating support of the project and continuation of the project's purposes beyond the grant period.
- **B.** Upon approval, the applicant shall become a vendor pursuant to state law.
- Records treated in the proposed project shall be made available in New Mexico for public research to all qualified users on equal terms unless specific exemption is granted by the commission. Specific records in proposals submitted by tribal governments, for example, may be excluded from this criterion.
- **D.** The applicant shall not charge fees for public access to the materials in its holdings. However, reasonable fees may be charged for copying material or providing special services or facilities not provided to all researchers.
- **E.** A person qualified by credentials or training shall carry out the objectives of the proposed project.
- F. Proposals for digitization projects shall be acceptable only if they take into consideration the issue of migration to newer technologies. Digitization projects shall follow scanning guidelines specified by the commission for creating master and access copies.

[1.13.5.9 NMAC - Rp, 1.13.5.9 NMAC, 8/1/2015; A, 11/28/2017]

**1.13.5.10 TYPES OF PROJECTS FUNDED:** Following are examples of projects that could be funded.

A. Preservation
projects that mitigate unstable
or deteriorating conditions of
historical records through the
identification, organization and
description, conservation treatment
or reformatting of the records to

another medium. National historical publications and records commission funding shall not be used for the following activities:

undertake an archival project centered on the papers of an appointed or elected public official who remains in major office, or is politically active, or the majority of whose papers have not yet been accessioned in a repository; and

undertake arrangement, description or preservation projects involving federal government records that are in the custody of the national archives and records administration, in the custody of some other federal agency or that have been deposited in a non-federal institution without an agreement authorized by the national archives and records administration.

- B. Access projects that promote the availability of historical records by developing finding aids, indexing significant collections, creating electronic catalog records, distributing collection guides, providing online access to finding aids, digitizing historical records and placing copies in other repositories that have agreed to accept them.
- C. Regional or statewide training programs that focus on developing best practices that can be used to train staff in more than one repository or in a repository experiencing high turnover.
- D. [Research projects that provide original scholarly exposition or interpretation of documentary evidence of New-Mexico history based on original records or oral history and documentary edition projects that publish original records for general usage. National historical publications and records commission funding shall not be used for the following activities:

(1) to undertake oral history projects unrelated to Native Americans; and (2) to undertake a documentary editing

project to publish the papers of

someone who has been deceased for

fewer than 10 years.

E.] Program development projects that establish or elevate standards of archival or records management practice in the applicant's repository.

programs such as exhibits, conferences, papers and documentaries that promote New Mexico history through the use of historical records.]
[1.13.5.10 NMAC - Rp, 1.13.5.11 NMAC, 8/1/2015; A, 11/28/2017]

## COMMISSION OF PUBLIC RECORDS

This is an amendment to 1.13.10 NMAC, Sections 9, and 14, effective 11/28/2017.

## 1.13.10.9 BOX REQUIREMENTS:

- A. Agencies utilizing the records center shall use storage boxes 15" x 12" x 10" in size.

  Records with a retention of permanent must be submitted in acid-free boxes.

  Agencies submitting boxes for storage containing paper records shall:
- (1) place only one type of record classification with disposition dates within a three year range in each box;
- (2) place the records in the box vertically, in the same order in which the records were maintained and shall coincide with the records index;
- (3) place letter-sized folders across the 12-inch side, facing the front of the box;
- legal-sized folders across the 15-inch side, starting from left to right;
- (5) leave at least one-inch of space for ease of access;
  - (6) place the

lid on the box;

(7) place all documents (with the exception of oversize materials) in accurately labeled standard file folders; and

(8) do not place hanging file folders in the

boxes.

- **B.** The records management division has the final authority with regard to the rejection of any box shipment or portion thereof. Reasons for rejection include, but are not limited to, the following:
- shipment that does not agree with its corresponding storage or disposition forms shall be rejected upon delivery. The custodial agency shall be required to remove the boxes from the records center immediately.
- shipment submitted for storage that is damaged or overfilled shall be rejected upon delivery. The custodial agency shall be required to remove the shipment from the records center immediately.
- shipment submitted for storage or disposition that is deemed hazardous by the administrator shall be rejected upon delivery. The custodial agency shall be required to remove the shipment from the records center immediately. For any box rejected for contamination, the custodial agency will be required to request permission from the administrator for onsite destruction.
- submitted for storage that is less than three quarters full (12 inches) shall be returned to the agency, including any boxes withdrawn for viewing.
- shipment containing glossy exterior boxes.
- C. Blueprints and maps submitted for storage shall be placed in boxes designed for that purpose. [1.13.10.9 NMAC Rp, 1.13.10.10 NMAC, 11/30/2015; A, 11/28/2017]

## 1.13.10.14 STORAGE OF MICROFILM:

- A. For storage requirements, refer to 1.13.10.11 and 1.13.10.12 NMAC.
- **B.** All state agencies and any public entity shall have an approved microphotography plan on file with the records management division before master microfilm

can be stored. For microfilm plan requirements, refer to 1.14.2 NMAC. For information on the fee schedule, refer to 1.13.2 NMAC.

**C.** Microfilm shall pass inspection before it is approved for storage.

[1.13.10.14 NMAC - Rp, .1.13.10.16 NMAC, 11/30/2015; A, 6/28/2017; A, 11/28/2017]

## COMMISSION OF PUBLIC RECORDS

This is an amendment to 1.21.2 NMAC, Sections 336 and 337 effective 11/28/2017.

## 1.21.2.336 CASE FILES - LOANS:

#### A. Category:

Financial and accounting - [grant,] financial aid and loan management.

#### B. Description:

Records related to loan programs including, but not limited to, loan documents and tracking.

**C. Retention:** destroy three years from close of fiscal year in which file closed.

[1.21.2.336 NMAC - N, 10/01/2015; A, 11/28/2017]

## 1.21.2.337 EDUCATIONAL FINANCIAL AID:

#### A. Category:

Financial and accounting - [grant,] financial aid and loan management.

#### B. Description:

Records related to scholarships, loans, grants and other aid.

**C. Retention:** destroy three years from the date file closed. [1.21.2.337 NMAC - N, 10/01/2015; A, 11/28/2017]

#### REGULATION AND LICENSING DEPARTMENT PHARMACY, BOARD OF

On 11/13/2017, the Pharmacy Board repealed its rule 16.19.8 NMAC, Wholesale Prescription Drug Distribution, filed 11-03-2009, and replaced it with 16.19.8 NMAC,

Wholesale Distributors; Third-Party Logistics Providers; Repackagers; Drug Supply Chain Security, effective 11-28-2017.

#### REGULATION AND LICENSING DEPARTMENT PHARMACY, BOARD OF

TITLE 16 OCCUPATIONAL
AND PROFESSIONAL
LICENSING
CHAPTER 19 PHARMACISTS
PART 8 WHOLESALE
DISTRIBUTORS; THIRD-PARTY
LOGISTICS PROVIDERS;
REPACKAGERS; DRUG SUPPLY
CHAIN SECURITY

## **16.19.8.1 ISSUING AGENCY:** Regulation and Licensing Department - Board of Pharmacy.

[16.19.8.1 NMAC - Rp, 16.19.8.1 NMAC, 11-28-2017]

#### **16.19.8.2 SCOPE:** All

individuals and entities engaged in the wholesale distribution of prescription drugs, including, own-label distributors, private-label distributors, jobbers, brokers, manufacturer's warehouses, distributor's warehouses, chain drug warehouses, wholesale drug warehouses, independent wholesale drug traders and retail pharmacies that conduct wholesale distribution; third-party logistics providers; manufacturers and repackagers.

[16.19.8.2 NMAC - Rp, 16.19.8.2 NMAC, 11-28-2017]

#### 16.19.8.3 STATUTORY

AUTHORITY: Paragraph (6) of Subsection A of Section 61-11-6 NMSA 1978 directs the board of pharmacy to provide for the licensing of drug manufacturers, repackagers and wholesale drug distributors and for the inspection of their facilities and activities. Paragraph (7) of Subsection A of Section 61-11-6 NMSA 1978 authorizes the board to enforce the provisions of all state laws pertaining to the practice of pharmacy and the manufacture, production, sale or distribution of drugs, cosmetics or

poisons, including the New Mexico Drug, Device and Cosmetic Act, Chapter 26, Article I NMSA 1978. Pursuant to Section 26-1-18 of the Drug, Device and Cosmetic Act, the board is authorized to promulgate regulations for the efficient enforcement of the act. [16.19.8.3 NMAC - Rp, 16.19.8.3 NMAC, 11-28-2017]

#### **16.19.8.4 DURATION:**

Permanent.

[16.19.8.4 NMAC - Rp, 16.19.8.4 NMAC, 11-28-2017]

#### **16.19.8.5 EFFECTIVE**

**DATE:** November 28, 2017, unless a different date is cited at the end of a section.

[16.19.8.5 NMAC - Rp, 16.19.8.5 NMAC, 11-28-2017]

#### **16.19.8.6 OBJECTIVE:**

The objective of Part 8 of Chapter 19 is to implement the Federal Food, Drug and Cosmetic Act, 21 United States Code (U.S.C.) 351 et seq., as amended by the Drug Supply Chain Security Act of 2013 (Pub. L. 113-54), by providing minimum standards, terms and conditions for the licensing by the board of wholesale distributors, third-party logistics providers and repackagers; and by replicating the federal requirements relating to product tracing, identification and verification.

[16.19.8.6 NMAC - Rp, 16.19.8.6 NMAC, 11-28-2017]

#### **16.19.8.7 DEFINITIONS:**

**A.** "Adulterated" a drug or device shall be deemed to be adulterated if it:

- (1) consists in whole or part of any filthy, putrid, or decomposed substance;
- produced, prepared, packed or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;
- (3) is a drug and the methods used in or the facilities of controls used for its manufacture, processing, packing

or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of the New Mexico Drug, Device and Cosmetic Act (this article) as to safety and has the identity and strength and meets the quality and purity characteristics which purports or is represented to possess;

- (4) is a drug and its container is composed in whole or part of any poisonous or deleterious substance which may render the contents injurious to health;
- and it bears or contains for purposes of coloring only a color additive which is unsafe within the meaning of the Federal Act or it is a color additive the intended use of which in drugs is for the purpose of coloring only and is unsafe within the meaning of the Federal Act:
- purports **(6)** to be or is represented as a drug the name of which is recognized in an official compendium and its strength differs from or its quality or purity falls below the standard set forth in such compendium; such determination as to strength, quality and purity shall be made in accordance with the tests or methods of assay set forth in such compendium or in the absence of or inadequacy of such rests or methods of assay, those prescribed under the authority of the Federal Act; no drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality or purity therefore set forth if such standard is plainly stated on its label; whenever a drug is recognized both in the United States pharmacopoeia and the homeopathic pharmacopoeia of the United States it shall be subject to the requirements of the United States pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the homeopathic pharmacopoeia of the United States and not those of the United States pharmacopoeia;
  - (7) is not

subject to the provisions of Paragraph (6) of this subsection and its strength differs from or its purity or quality falls below that which it purports or is represented to possess;

- (8) is a drug and any substance has been mixed or packed therewith so as to reduce its quality or strength or substituted wholly or in part therefore.
- **B.** "Affiliate" means a business entity that has a relationship with a second business entity if, directly or indirectly:
- business entity controls, or has the power to control, the other business entity; or
- party controls, or has the power to control, both of the business entities.

C. "Authorized" means:

- (1) in the case of a manufacturer or repackager, having a valid registration as a drug establishment with the FDA under Section 510 of the Federal Act:
- (2) a licensed wholesale distributor, who is compliant with the licensure reporting requirements under section 503(e) of the Federal Act;
- (3) a licensed third-party logistics provider, who is compliant with the licensure reporting requirements under section 584(b) of the Federal Act;
- (4) in the case of a dispenser, having a valid license under New Mexico state law.
- **D.** "Blood" means the whole blood collected from a single donor and processed either for transfusion or further manufacturing.
- E. "Blood component" means that part of blood separated by physical or mechanical means.
- F. "Co-licensed partner or product" means an instance where two or more parties have the right to engage in the manufacturing or marketing of a prescription drug, consistent with FDA's implementation of the Drug Supply Chain Security Act (DSCSA).
  - G. "Common carrier"

means any person or entity who undertakes, whether directly or by any other arrangement, to transport property including prescription drugs for compensation.

- **H.** "Counterfeiting" means engaging in activities that create a counterfeit drug.
- I. "Counterfeit drug" means a drug that is deliberately and fraudulently mislabeled with respect to its identity, ingredients or sources. Types of such pharmaceutical counterfeits may include:
- (1) identical copies: which are counterfeits made with the same ingredients, formulas and packaging as the originals but not made by the original manufacturer;

(2)

look-alikes: which feature highquality packaging and convincing appearances but contain little or no active ingredients and may contain harmful substances:

- (3) rejects: which are drugs that have been rejected by the manufacturer for not meeting quality standards;
- (4) re-labels: which have passed their expiration dates or have been distributed by unauthorized foreign sources and may include placebos created for latephase clinical trials.
- J. "Counterfeit prescription drug" means a dangerous drug which, or the container or labeling of which, without authorization:
- the trademark, trade name, or other identifying mark, print, device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packaged, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by such other drug manufacturer, processor, packer, or distributor;
- (2) from the original manufacturer is an imitation of another dangerous drug or has been deliberately mislabeled (for example,

as to its strength or expiration date) but it shall not include a dangerous drug or placebo intended for use in a clinical trial that is intentionally labeled or marked to maintain proper blinding of the study.

- K. "Dangerous drug" also known as a "prescription drug" means a drug other than a controlled substance enumerated in Schedule I of the Controlled Substance Act. that because of potentiality for harmful effect or the method of its use or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such drug and hence for which adequate directions for use (directions under which the layman can use a drug or device safely and for the purposes for which intended) cannot be prepared. A drug shall be dispensed only upon the prescription of a practitioner licensed by law to administer or prescribe the drug if it:
- habit-forming drug and contains any quantity of a narcotic or hypnotic substance or a chemical derivative of such substance that has been found under the Federal Act and the board to be habit-forming;
- of its toxicity or other potential for harmful effect or the method of its use or the collateral measures necessary to its use is not safe for use except under the supervision of a practitioner licensed by law to administer or prescribe the drug;
- by an approved application by Section 505 of the Federal Act to the use under the professional supervision of a practitioner licensed by law to administer or prescribe the drug;
- (4) bears the legend "Caution: federal law prohibits dispensing without prescription";
- (5) bears the legend "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian";
- (6) bears the legend "RX only"; or
  - (7) has been

declared a dangerous drug by the board of pharmacy.

L. "Designated representative" means an individual designated by the wholesale distributor, third-party logistics provider, or repackager who will serve as the responsible individual of the wholesale distributor, third-party logistics provider, or repackager with the board who is actively involved in and aware of the actual daily operation of the wholesale distributor, third-party logistics provider, or repackager. The designated representative is responsible for all aspects of the facility operations.

M. "Dispenser" means:

pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and

(2) does not include a person who dispenses only products to be used in animals in accordance with Section 512(a)(5) of the Federal Act.

N. "Disposition" with respect to a product within the possession or control of an entity, means the removal of such product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other appropriate handling and other actions, such as retaining a sample of the product for further additional physical examination or laboratory analysis of the product by a manufacturer or regulatory or law enforcement agency.

or distribution" means the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a drug pursuant to a prescription.

P. "Drug" means articles:

(i)

- as drugs in any official compendium or supplement thereto, designated from time to time by the board for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals:
- (2) intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals;
- (3) other than food, intended to affect the structure or any function of the body of humans or other animals;
- (4) intended for use as a component of any articles specified in Paragraphs (1), (2), (3) or (4) of this subsection.
- Q. "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug as defined by the Prescription Drug Marketing Act of 1987.
- **R.** "DSCSA" means the Drug Supply Chain Security Act.
- S. "Emergency medical reasons" include, but are not limited to:
- or sales by a pharmacy to nearby emergency medical services, i.e. ambulance companies and firefighting organizations in the same state or same marketing or service area or nearby licensed practitioners of prescription drugs for use in the treatment of acutely ill or injured persons, consistent with the DSCSA and successor FDA regulations;
- provision of minimal emergency supplies of prescription drugs by a pharmacy to nearby nursing homes for use in emergencies or during hours of the day when necessary prescription drugs cannot be obtained;
- (3) the transfer or sale of naloxone by a dispenser for rescue use in accordance with Section 24-23-1 NMSA 1978 of the Public Health Act;
- (4) the transfer or sale of a drug pursuant to a specific patient need.
- T. "Exclusive distributor" means the wholesale

distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser.

- U. "Facility" means facility of a wholesale distributor, repackager, or third-party logistics provider where prescription drugs are stored, handled, repackaged or offered for sale.
- V. "FDA" means food and drug administration, a federal agency within the United States department of health and human services, established to set safety and quality standards for drugs, food, cosmetics and other consumer products.
- W. "Federal Act" means the Federal Food, Drug and Cosmetic Act.
- X. "Homogeneous case" means a sealed case containing only product that has a single NDC number belonging to a single lot.
- Y. "Illegitimate product" means a product for which credible evidence shows that the product:
- (1) is counterfeit, diverted, or stolen;
  - **(2)** is

intentionally adulterated such that the product would result in serious adverse health

consequences or death to humans;

(3) is the

subject of a fraudulent transaction; or (4) appears

otherwise unfit for distribution such that the product would be reasonably likely

to result in serious adverse health consequences or death to humans.

Z. "Immediate container" means a container and does not include package liners.

AA. "Licensed" means:
(1) in the case

of a wholesale distributor:

(a)

having valid licensure with the board; and

(b)

for facilities located outside of New Mexico:

having valid licensure by the state from which the drug is distributed; or

(ii)

if the state from which the drug is distributed has not established a licensure requirement, is licensed by the FDA (beginning at such time as federal regulations are promulgated to implement Section 583 of the Federal Act).

(2) in the case of a third-party logistics provider:

(a)

for facilities located outside of New Mexico:

(i)

having valid licensure by the state from which the drug is distributed when required by that state; and

(ii)

having a valid registration with the FDA (beginning at such time as federal regulations are promulgated to implement Section 584 of the Federal Act), unless the FDA has made a finding that the third-party logistics provider does not utilize good handling and distribution practices and publishes notice thereof; or

(iii)

having valid licensure with the board.

(b)

for facilities located in New Mexico: having valid licensure with the board.

BB. "Manufacturer" means:

- that holds an application approved under Section 505 of the Federal Act or a license issued under Section 351 of the Federal Public Health Service Act for such drug, or if such drug is not the subject of an approved application or license, the person who manufactured the drug;
- (2) a colicensed partner of the person described in Paragraph (1) that obtains the drug directly from a person described in Paragraph (1) or (3) of this subsection; or
- (3) an affiliate of a person described in Paragraph (1) or (2) of this subsection that receives the product directly from a person described in Paragraph (1) or (2) of

this subsection.

#### CC. "Manufacturing" means the production, preparation, propagation, conversion or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis; and includes packaging or repackaging, labeling or relabeling and the promotion and marketing of such drugs or devices; also included is the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, licensed practitioners or other persons.

- "Misbranded" DD. means a label to an article that is misleading. In determining whether the label is misleading there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device or any combination of the foregoing, but also the extent to which the label fails to reveal facts material in the light of such representations or material with respect to consequences that may result from the use of the article to which the label relates under the conditions of use prescribed in the label or under such conditions of use as are customary or usual.
- **EE.** "NDC" means national drug code.
- FF. "Official compendium" means the official USP-NF or the official homeopathic pharmacopoeia of the United States or any supplement to either of them.
- GG. "Package" means the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product. An individual saleable unit is the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser.
- HH. "Prescription drug" means any human drug required by federal or state law or

regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to Section 503(b) of the Federal Food, Drug and Cosmetic Act.

- II. "Product" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but does not include:
- (1) blood or blood components intended for transfusion;
- drugs or radioactive biological products (as defined in Section 600.3(ee) of title 21, Code of Federal Regulations) that are regulated by the Nuclear Regulatory Commission or by the state pursuant to an agreement with such commission under Section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021);
- (3) imaging drugs;
- (4) an intravenous product described in Paragraph (14), (15), or (16) of definition XX. ("transaction");
- (5) any medical gas as defined in Section 575 of the Federal Act;

(6)

homeopathic drugs marketed in accordance with applicable guidance under the federal act; or

(7) a drug compounded in compliance with Section 503A or 503B of the Federal Act.

#### JJ. "Product

identifier" means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product, meeting the requirements of the DSCSA.

KK. "Product tracing information" means, for each

transaction: the recorded transaction history, transaction information, and transaction statement meeting the requirements of the DSCSA.

LL. "Quarantine" means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use or through other procedures.

MM. "Repackage" means repackaging or otherwise changing the container, wrapper or labeling to further the distribution of a prescription drug excluding that completed by the pharmacists responsible for dispensing product to the patient.

NN. "Repackager" means a person who owns or operates a facility that repackages and re-labels a product or package for:

(1) further

sale; or

(2) distribution without a further transaction.

OO. "Return" means providing product to the authorized immediate trading partner from which such product was purchased or received, or to a returns processor or reverse logistics provider for handling of such product.

PP. "Returns
processor or reverse logistics
provider" means a person who owns
or

operates an establishment that dispositions or otherwise processes saleable or non-saleable product received from an authorized trading partner such that the product may be processed for credit to the purchaser, manufacturer, or seller or disposed of for no further distribution.

QQ. "Selling of drugs, devices or cosmetics" shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession and holding of any such article for sale and the sale and the supplying or applying of any such article in the conduct of a drug or cosmetic establishment.

**RR.** "Significant loss" means any loss of a prescription

means:

drug that exceeds a reasonable level established by like persons which requires that loss to be reported to the board or as required by the DEA or other state or federal agencies for prescription drugs and controlled substances.

- SS. "Specific patient need" means the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.
- TT. "Standardized numerical identifier" means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the NDC that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.
- **UU.** "Suspect product" means a product for which there is reason to believe:
- (1) is potentially counterfeit, diverted, or stolen;
- (2) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
- (3) is potentially the subject of a fraudulent transaction; or
- (4) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

VV. "Third-party logistics provider" means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

WW. "Trading partner"

manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or

(2) a thirdparty logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.

XX. "Transaction" means the transfer of product between persons in which a change of ownership occurs, but does not include:

(1) intracompany distribution of any product between members of an affiliate or within a manufacturer;

distribution of a product among hospitals or other health care entities that are under common control; for the purposes of this section "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;

the distribution of a product for emergency medical reasons including a federal or state declared public health emergency, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(4) the dispensing of a product pursuant to a prescription executed in accordance with Section 503(b)(1) of the Federal Act;

distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with Section 503(d) of the Federal Act;

**(6)** the

distribution of blood or blood components intended for transfusion;

(7) the distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;

- (8) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in Section 501(c)(3) of the Internal Revenue Code of 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
- distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;
- (10) the dispensing of an approved animal drug product approved under Section 512(c) of the Federal Act;
- (11) products transferred to or from any location that is licensed by the Nuclear Regulatory Commission or by the state pursuant to an agreement with such commission under Section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021);

combination product that is not subject to approval under Section 505 or licensure under Section 351 of the Public Health Service Act, and that is:

a product comprised of a device and one or more other regulated components (such as a device and a drug, biologic, or drug and biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

two or more separate products
packaged together in a single package
or as a unit and comprised of a drug
and device or device and biological
product; or

two or more finished medical devices

plus one or more drug or biological products that are packaged together in what is referred to as a "medical convenience kit" as described in Paragraph (13) below;

the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this paragraph as a "medical convenience kit") if:

the medical convenience kit is assembled in an establishment that is registered with the FDA as a device manufacturer in accordance with Section 510(b)(2) of the Federal Act;

the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

in the case of a medical convenience kit that includes a product, the person that manufacturers the kit:

purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

does not alter the primary container or label of the product as purchased

from the manufacturer or wholesale distributor; and

> (d) in

the case of a medical convenience kit that includes a product, the product is:

an intravenous solution intended for the replenishment of fluids and electrolytes;

(ii)

a product intended to maintain the equilibrium of water and minerals in the body;

a product intended for irrigation or reconstitution;

(iv)

an anesthetic;

(v)

an anticoagulant;

a vasopressor; or

(vii)

a sympathomimetic;

(14)the

distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(15)

distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

the

distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(17)distribution of a medical gas (as defined in Section 575 of the Federal Act); or

(18)the

distribution or sale of any licensed product under section 351 of the Public Health Service Act that meets the definition of a medical device under Section 201(h) of the Federal Act.

#### "Transaction YY.

**history**" means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

#### "Transaction ZZ. information" means:

the

proprietary or established name or names of the product;

the

strength and dosage form of the product;

> the NDC (3)

number of the product;

**(4)** the

container size;

**(5)** the number

of containers;

the lot **(6)** 

number of the product;

the date of

the transaction:

**(8)** the date of the shipment, if more than 24 hours

after the date of the transaction:

**(9)** the

business name and address of the person from whom ownership is being transferred: and

the

business name and address of the person to whom ownership is being transferred.

AAA. "Transaction

**statement**" means a statement, in paper or electronic form, that the entity transferring ownership in a transaction:

> **(1)** is

authorized as required under the DSCSA;

**(2)** received the product from a person that is

authorized as required under the DSCSA;

> (3) received

transaction information and a transaction statement from the prior owner of the product, as required under Section 582 of the Federal Act;

> **(4)** did

not knowingly ship a suspect or illegitimate product;

had

systems and processes in place to comply with verification requirements under Section 582 of the Federal Act;

did not

knowingly provide false transaction information; and

did not

knowingly alter the transaction history.

> BBB. "USP-NF

standards" means standards published in the current official United States Pharmacopeia-National Formulary.

> CCC. "Verification or

verify" means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager, as applicable in accordance with Section 582 of the Federal Act?

DDD. "Wholesale drug distribution" means the distribution

of a prescription drug to a person

other than a consumer or patient, or receipt of a prescription drug by a person other than the consumer or patient, but does not include:

(1)

intracompany distribution of any drug between members of an affiliate or within a manufacturer;

(2) the distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;

(3) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a federal or state declared public health emergency, except that, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(4) the dispensing of a drug pursuant to a prescription;

(5) the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;

(6) the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(7) the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

(8)

the distribution of a drug by the manufacturer of such drug;

(9) the receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;

(10) a common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

(11) the distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks

it in accordance with Section 582(e) of the Federal Act;

(12) saleable drug returns when conducted by a dispenser;

distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to as a "medical convenience kit") if:

(a)

the medical convenience kit is assembled in an establishment that is registered with the FDA as a device manufacturer in accordance with Section 501(b)(2) of the federal act;

**(b)** 

the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970 [21 U.S.C. 801 et seq.];

(c)

in the case of a medical convenience kit that includes a product, the person that manufacturers the kit:

purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and (ii)

does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

(**d**) in

(i)

the case of a medical convenience kit that includes a product, the product is

an intravenous solution intended for the replenishment of fluids and electrolytes;

a product intended to maintain the equilibrium of water and minerals in the body;

(iii) a product intended for irrigation or reconstitution;

an anesthetic;

(iv) (v) an anticoagulant;

(vi)

a vasopressor; or

(vii)

a sympathomimetic;

distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(15) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(16) the distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(17) the distribution of medical gas, as defined in Section 575 of the Federal Act;

(18) facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or

(19)the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in Section 581(16)(B) and registered under Section 510 of the Federal Act for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

**EEE.** "Wholesale distributor" means a person or entity (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale drug distribution.

[16.19.8.7 NMAC - Rp, 16.19.8.7 NMAC, 11-28-2017]

16.19.8.8 WHOLESALE DRUG DISTRIBUTOR LICENSING REQUIREMENTS:

- A. Every wholesale drug distributor, wherever located, who engages in wholesale distribution into, out of, or within this state must be licensed by the board in accordance with the laws and regulations of this state before engaging in wholesale distribution of prescription drugs.
- **B.** Wholesale distributors cannot operate from a place of residence.
- C. Where wholesale distribution operations are conducted at more than one location, each such location shall be licensed by the board of pharmacy.
- **D.** A wholesale distributor located in New Mexico shall be located apart and separate from any pharmacy.
- E. Common or contract carriers or warehousemen, or an employee thereof, whose involvement in the wholesale distribution of prescription drugs occurs in the usual course of his business or employment shall not be required to obtain a wholesale drug distributor license from the board. [16.19.8.8 NMAC Rp, 16.19.8.8 NMAC, 11-28-2017]

#### 16.19.8.9 MINIMUM REQUIRED INFORMATION FOR WHOLESALE DRUG DISTRIBUTION LICENSURE:

- A. Every wholesale distributor who engages in the wholesale distribution of drugs shall be licensed with the board by submitting an application and providing information required by the board on an application approved by the board, including but not limited to:
- (1) applicant's full name; all trade or business names used by the licensee (includes "is doing business as" and "formerly known as") which cannot be identical to the name used by another unrelated wholesale distributor, third-party logistics provider, or repackager licensed by the board; full business address and telephone number;
- (2) typ of ownership, e.g. individual,

partnership, limited liability company or

corporation;

(3) name(s) of the owner(s) of the applicant, including;

**a**)

if a person, the name, address, social security number or Federal Employer Identification Number (FEIN), and date of birth;

(b)

if other than a person, the name, address, social security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director and the federal employer identification number:

(c)

if a corporation, the state of incorporation; and

(d)

if a publicly traded corporation, the information in Subparagraph (b) of this paragraph is not required for corporate officers and corporate directors:

(e)

any other relevant information that the board requires;

(4) name(s), business address(es), telephone number(s) of a person(s) to serve as the designated representative(s) for each facility of the wholesale distributor that engages in the distribution of drugs:

of criminal background checks and fingerprinting of the applicant, if a person, and of the applicant's designated representative; the background check shall be sufficient to include all states residence since the person has been an adult;

(6) a list of all state and federal licenses, registrations or permits, including the license, registration or permit numbers issued to the wholesale drug distributor by any other state and federal authority that authorizes the wholesale distributor to purchase, possess and distribute drugs;

(7) a list of all disciplinary actions or any other sanction by state and federal agencies

against the wholesale distributor as well as any such actions against principals, owners, directors or officers;

(8) a full description of each facility and warehouse located in New Mexico, including all locations utilized for drug storage or distribution; the description must include the following:

(a)

square footage;

**(b)** 

security and alarm system descriptions;

(c)

terms of lease or ownership;

(d)

address and;

(e)

temperature and humidity controls;

(9)

a description of the wholesale distributor's drug import and export activities;

- (10) a copy of the wholesale distributor's written policies and procedures as required in Subsection I of 16.19.8.13 NMAC, (Written policies and procedures);
- (11) a facility located outside of New Mexico shall submit a copy of a current satisfactory inspection report issued by the FDA, or state licensing authority, or by a third-party inspection service approved by the FDA or the state authority licensing such wholesale distributor, or by the board;
- (12) the information collected pursuant to Paragraphs (5), (8) and (10) of this subsection shall be made available only to the board, and to state and federal law enforcement officials; the board shall make provisions for protecting the confidentiality of the information collected under this section.
- **B.** Every wholesale drug distributor who engages in wholesale distribution shall submit a reasonable fee to be determined by the board.
- C. Each facility located in New Mexico that engages in wholesale drug distribution must

undergo an inspection by the board for the purpose of inspecting the wholesale drug distribution facility and operations prior to initial licensure. Manufacturing facilities located outside of this state are exempt from inspection by the board if the manufacturing facilities are currently registered with the food and drug administration in accordance with Section 510 of the Federal Act.

- **D** All wholesale distributors must publicly display or have readily available all licenses and the most recent inspection report administered by the board.
- E. Changes in any information in this section shall be submitted to the board within 30 days of such change unless otherwise noted.
- submitted by the wholesale drug distributor to the board that is considered trade secret or proprietary information as defined under this states privacy and trade secret or proprietary statutes shall be maintained by the board as private or trade secret proprietary information and be exempt from public disclosure.
- **G.** The board shall have the authority to recognize a third-party to accredit and inspect wholesale distributors.
- **H.** The board may license by reciprocity, a wholesale distributor that is licensed under the laws of another state if:
- applicant submits documentation of a current satisfactory inspection conducted by the FDA, or state licensing authority, or by a third-party inspection service approved by the FDA or the state authority licensing such wholesale distributor, or the board; and
- (2) the requirements of that state are deemed by the board to be substantially equivalent.
- I. Every wholesale distributor must furnish a bond or other equivalent means of security, as follows:
- (1) for the issuance or renewal of a wholesale

distributor license, an applicant that is not a government owned and operated wholesale distributor shall submit a surety bond of \$100,000 or other equivalent means of security acceptable to the board;

purposes of Paragraph (1) above, the board may accept a surety bond in the amount of \$25,000 if the annual gross receipts of the previous tax year for the wholesaler is \$10,000,000 or less;

(3) if a wholesale distributor can provide evidence that it possesses the required bond in a state, the requirement for a bond in New Mexico shall be waived. [16.19.8.9 NMAC - Rp, 16.19.8.9 NMAC, 11-28-2017]

## 16.19.8.10 MINIMUM QUALIFICATIONS:

- **A.** The board shall prohibit a person from receiving or maintaining licensure for wholesale distribution if the person:
- convicted of any felony for conduct relating to wholesale distribution, any felony violation of Subsection (i) or (k) of Section 301, or any felony violation of Section 1365 of title 18, United States Code, relating to product tampering; or
- (2) has engaged in a pattern of violating the requirements of this section, or state requirements for licensure, that presents a threat of serious adverse health consequences or death to humans.
- **B.** The board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs within the state:
- (1) any conviction of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances:
- (2) any felony convictions of the applicant under federal, state or local law;
- (3) the applicant's past experience in

the manufacture or distribution of prescription drugs, including controlled substances;

(4) the furnishing by the applicant of false or fraudulent material in any application; (5)

suspension, revocation or any other sanction by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(6) compliance with regulatory and licensing requirements under previously granted licenses, if any;

(7)

compliance with requirements to maintain or make available to the board or to federal, state, or local law enforcement officials those records required under 16.19.8 NMAC; and

(8) any findings by the board that the applicant has violated or been disciplined, or the subject of administrative action or other sanction, by a regulatory or licensing agency in any state for violating and federal, state, or local laws relating to

(9) any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

drug or device wholesale distribution;

- The board shall C. consider the results of a criminal and financial background check and fingerprinting of the applicant, and designated representative to determine if an applicant or others associated with the ownership, management or operations of the wholesale distributor have committed criminal acts that would constitute grounds for denial of licensure. Manufacturers licensed by the FDA in accordance with Section 510 of the Federal Act shall be exempt from criminal and financial background checks.
- **D.** The applicant shall provide and attest to a statement providing a complete disclosure of any past criminal convictions and violations of the state and federal laws regarding drugs or devices or

an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts.

- E. The board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest. Public interest considerations shall be based upon factors and qualifications that are directly related to the protection of the public health and safety.
- F. Request for an alternative reduced wholesale license fee: The board shall collect the full license fee as set by the board unless the board determines that collection of the license fee would be inconsistent with the public interest. The applicant/petitioner shall provide the board with any information necessary to make that determination including:
- (1) business/ organization profit status under federal and state code;
- (2) impact on the health and safety of New Mexico citizens:
- (3) volume of distribution in New Mexico;
- (4) sole source of dangerous drugs; and
- (5) financial hardship for applicant/registrant. [16.19.8.10 NMAC Rp, 16.19.8.10 NMAC, 11-28-2017]

#### 16.19.8.11 **PERSONNEL:** As a condition of receiving and retaining a wholesale drug distributor license, the licensee shall require each person employed in any prescription drug wholesale distribution activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety and security will at all times be maintained by law. Each person that is issued an initial or renewal license as a wholesale distributor whether in state or out of state must designate in writing on a form required by the board a person for each facility to serve as the designated representatives of the

wholesale distributor.

- **A.** To be certified as a designated representative a person must:
- (1) submit an application on a form furnished by the board and provide information that includes but is not limited to;

(a)

evidence of criminal background check and fingerprinting, the background check shall be sufficient to include all states residence since the person has been an adult;

**(b)** 

date of birth and social security number;

(c)

occupations, positions of employment and offices held during the past seven years;

(d)

whether the person during the past seven years has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating and state or federal laws regulating the possession, control or wholesale distribution of prescription drugs or devices, together with details of such events;

(e)

whether the person has been during the past seven years, the subject of any proceeding for the revocation of any professional or business license or any criminal violation and if so, the nature of the proceeding and the disposition of the proceeding;

**(f)** 

description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund during the past seven years, which manufactured, administered, prescribed, wholesale distributed or stored prescription drugs and devices in which such businesses were names as a party in a lawsuit;

**(g)** 

description of any criminal offense (not including minor traffic violations) of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere; if the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the board a copy of the final written order of disposition; and

(h)

any other information the board deems relevant;

- as the designated representative for only one wholesale distributor at any one time, except where more than one licensed wholesale distributor is colocated in the same facility and such wholesale distributors are members of an affiliated group as defined in Section 1504 of the Internal Revenue Code;
- (3) be actively involved in and aware of the actual daily operations, purchasing and inventory control of the wholesale distributor;

(a)

employed full-time in a managerial position by the wholesale distributor;

(b)

physically present at the wholesale distributor during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation or other authorized absence;

(c)

aware of and knowledgeable about all policies and procedures pertaining to the operations of the wholesale distributor.

- B. The criminal and financial information collected pursuant to this section shall be made available only to the board, a third-party recognized by the board and to state and federal law enforcement officials. The board and a third-party recognized by the board shall make provisions for protecting the confidentiality of the information collected under this section.
- C. Each licensed wholesale distributor located outside of this state that wholesale distributes prescription drugs in this state shall designate a registered agent in this

state for service of process. Any licensed wholesale distributor that does not so designate a registered agent shall be deemed to have designated the secretary of state of this state to be its true and lawful attorney, upon who may be served all legal processes in any action or proceeding against such licensed wholesale distributor growing out of or arising from such wholesale distribution. A copy of any such service or process shall be mailed to such wholesale distributor by the board by certified mail, return receipt requested, postage prepaid, at the address such licensed wholesale distributor has designated on its application for licensure in this state. If any such wholesale distributor is not licensed in this state, service on the secretary of state only shall be sufficient service.

**D.** A designated representative must complete training programs that address applicable state and federal laws and are provided by qualified in-house specialists, outside counsel or counseling specialists with capabilities to help ensure compliance.

[16.19.8.11 NMAC - Rp, 16.19.8.11 NMAC, 11-28-2017]

**16.19.8.12 VIOLATIONS AND PENALTIES:** The board shall have the authority to suspend or revoke any licenses granted under this part on the grounds established by law or regulations; and may impose fines or civil penalties if allowed by law. [16.19.8.12 NMAC - Rp, 16.19.8.12 NMAC, 11-28-2017]

16.19.8.13 MINIMUM
REQUIREMENTS FOR THE
STORAGE AND HANDLING OF
PRESCRIPTION DRUGS AND
FOR THE ESTABLISHMENT
AND MAINTENANCE OF
PRESCRIPTION DRUG
DISTRIBUTION RECORDS
BY WHOLESALE DRUG
DISTRIBUTORS AND
THEIR OFFICERS, AGENTS,
REPRESENTATIVES, AND
EMPLOYEES:

A. Facilities. All

facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security;

a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, counterfeit or suspected of being counterfeit or adulterated, suspect or illegitimate, otherwise unfit for distribution or wholesale distribution or that are in immediate or sealed, secondary containers that have been opened;

(4) be maintained in a clean and orderly condition; and

(5) be free from infestation by insects, rodents, birds, or vermin of any kind; and

(6) be a commercial location and not a personal dwelling or residence; and

(7) provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information; and

(8) provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting or diversion of prescription drugs or devices; and

(9) controlled substances must be isolated from non-controlled substance drugs and stored in a secure area in accordance with DEA security requirements and standards.

B. Security and anticounterfeiting. All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(1) Access from outside the premises shall be kept to a minimum and be well-controlled.

(2) The outside perimeter of the premises shall be well-lighted.

(3) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(4) All facilities shall be equipped with an alarm system to detect entry after hours.

facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(6) All facilities shall be equipped with a security system that will provide suitable protection against, detect and document any instances of theft, diversion or counterfeiting.

c. Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or in compliance with standards in the current edition of an official compendium, such as the USP-NF.

storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality and purity are not adversely affected.

(2)

Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices or logs shall be utilized to document proper storage of prescription drugs.

## D. Examination of Materials.

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated

prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, adulteration, misbranding, counterfeiting, contraband, suspected of being counterfeit or contraband, or other damage to the contents.

(2)

Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

#### F. Theft or Loss:

A wholesale distributor shall have and follow diversion detection and prevention plan that includes prescription drugs. Wholesale distributors shall report any theft, suspected theft, diversion or other significant loss of any prescription drug or device to the board and where applicable, to the DEA.

G. Product tracing, product identifier, and verification: Wholesale distributors licensed by the board shall comply with the requirements for tracing products through the distribution system as defined in Sections 353 and 360eee, et seq., of the DSCSA, 21 U.S.C. 301, et seq., and successor FDA regulations, with respect to the role of such wholesale distributor including any requirements with respect to: transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system.

# **H.** Authorized trading partners: The trading partners of a wholesale distributor may be only authorized trading partners.

I. Written policies and procedures. Wholesale drug distributors shall establish, maintain, and adhere to written policies and

procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories; wholesale drug distributors shall include in their written policies and procedures the following:

**(1)** 

a procedure whereby the oldest approved stock of a prescription drug product is distributed first; the procedure may permit deviation from this requirement, if such deviation is temporary and appropriate;

**(2)** 

a procedure to be followed for handling recalls and withdrawals of prescription drugs; such procedure shall be adequate to deal with recalls and withdrawals due to:

(a)

any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state licensing agency;

**(b)** 

any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(c)

any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design;

procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that

affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

**(4)** a

procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed; this procedure shall provide for written documentation of the disposition of outdated prescription drugs; this documentation shall be maintained for three years after disposition of the outdated drugs;

**(5)** 

a procedure for the destruction of outdated prescription drugs in accordance with state and federal laws, including all necessary documentation, maintained for a minimum of three years, and the appropriate witnessing of the destruction of outdated prescription drugs in accordance with all applicable federal and state requirements;

procedure for the disposing and destruction of containers, labels and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, maintained for a minimum of three years, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers or containers in accordance with all applicable federal and state requirements;

(7)

a procedure for identifying, investigating and reporting significant prescription drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband or suspect of being contraband, in the inventory and reporting of such discrepancies within 10 business days to the board and appropriate federal or state agency upon discovery of such discrepancies;

procedure for reporting criminal or suspected criminal activities involving the inventory of prescription drug(s)

the inventory of prescription drug(s) to the board, FDA as required by the agency, and if applicable, DEA, within three business days;

**(9)** a

procedure that ensures all common carriers contracted with or utilized by the wholesale distributor conduct a criminal background check and drug screen of the employees whose responsibilities include the known handling of prescription drugs;

(10)

procedure for conducting periodic assessments of the security provisions of common carriers contracted with or utilized by the wholesale distributor that at a minimum must specify that vehicles must be secured by locks on all doors and windows when the driver is not present, there shall be no unapproved stops during the delivery route and that the vehicle must not be left running in the absence of the driver;

(11)

a procedure or set procedures designated to address high-risk deliveries that may require the common carriers contracted with or utilized by the wholesale distributor to make deliveries only to highly-visible, well-lit locations during certain prescribed time periods agreed upon with the customer and the use of varied routing.

J. Responsible persons. Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

# K. Compliance with federal, state, and local law: Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

**(1)** Wholesale drug distributors shall permit board authorized personnel and authorized federal, state and local law enforcement officials, to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law, and to confiscate prescription drugs and records to the extent authorized by law or rules. Such officials shall be required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.

(2) Wholesale drug distributors that deal in

controlled substances shall register with the board and with the DEA, and shall comply with all applicable state, local and DEA regulations.

wholesale distributor may distribute only to authorized trading partners. Product shall be delivered only to the licensed address of the authorized trading partner.

(4) Controlled substances may only be distributed or delivered to persons in this state who are registered by the board and the DEA to possess controlled substances.

L. Salvaging and reprocessing. Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing including Subsection I of 16.19.8.13 NMAC, (Written Policies and Procedures). [16.19.8.13 NMAC - Rp, 16.19.8.13 NMAC, 11-28-2017]

## 16.19.8.14 THIRD-PARTY LOGISTICS PROVIDER LICENSING REQUIREMENTS:

A. Every third-party logistics provider, wherever located, who engages in providing third-party logistics into, out of, or within this state must be licensed by the board in accordance with the laws and regulations of this state before engaging as a third-party logistics provider of prescription drugs.

- **B.** Third-party logistics providers cannot operate from a place of residence.
- C. Where third-party logistics operations are conducted at more than one location, each such location shall be licensed by the board.
- **D.** A third-party logistics provider located in New Mexico shall be located apart and separate from any pharmacy. [16.19.8.14 NMAC Rp, 16.19.8.14 NMAC, 11-28-2017]

## 16.19.8.15 MINIMUM REQUIRED INFORMATION FOR THIRD-PARTY LOGISTICS PROVIDER LICENSURE:

A. Every third-party logistics provider, located in New Mexico or located in another state and not licensed as a third-party logistics provider by the FDA, who engages in third-party logistics activities involving product shall be licensed with the board, by submitting an application and providing information required by the board on an application approved by the board, including but not limited to:

(1) applicant's full name; all trade or business names used by the licensee (includes "is doing business as" and "formerly known as"), which cannot be identical to the name used by another unrelated wholesale distributor, third-party logistics provider, or repackager licensed by the board; full business address and telephone number;

(2) type of ownership, e.g. individual, partnership, limited liability company or corporation;

(3) name(s) of the owner(s) of the applicant, including;

(a)

if a person, the name, address, social security number or FEIN, and date of birth;

(b)

if other than a person, the name, address, social security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director and the federal employer identification number;

(c)

if a corporation, the state of incorporation; and

(d)

if a publicly traded corporation, the information in Subparagraph (b) of this paragraph is not required for corporate officers and corporate directors.

(e)

any other relevant information that the board requires;

(4) name(s), business address(es), telephone number(s) of a person(s) to serve as the designated representative(s)

for each facility of the third-party logistics provider that engages in the distribution of drugs;

- of criminal background checks and fingerprinting of the applicant, if a person, and of the applicant's designated representative; the background check shall be sufficient to include all states residence since the person has been an adult;
- (6) a list of all state and federal licenses, registrations or permits, including the license, registration or permit numbers issued to the third-party logistics provider by any other state and federal authority that authorizes the third-party logistics provider to possess and distribute drugs;
- (7) a list of all disciplinary actions or any other sanction by state and federal agencies against the third-party logistics provider as well as any such actions against principals, owners, directors or officers:
- (8) a full description of each facility and warehouse located in New Mexico, including all locations utilized for drug storage or distribution; the description must include the following:

(a)

square footage;

(b)

security and alarm system descriptions;

(c)

terms of lease or ownership;

(d)

address and;

(e)

temperature and humidity controls.

(9)

a

description of the third-party logistics provider's drug import and export activities;

- (10) a copy of the third-party logistics provider's written policies and procedures as required in Subsection D of 16.19.8.18 NMAC;
- (11) a facility located outside of New Mexico shall submit a copy of a current satisfactory inspection report issued by the

FDA, or state licensing authority, or by a third-party inspection service approved by the FDA or the state authority licensing such third-party logistics provider, or by the board;

- (12) the information collected pursuant to Paragraphs (5), (8) and (10) of this subsection shall be made available only to the board, and to state and federal law enforcement officials; the board shall make provisions for protecting the confidentiality of the information collected under this section.
- **B.** Every third-party logistics provider who engages in third-party logistics activities involving prescription drugs and required to be licensed by the board shall submit a reasonable fee to be determined by the board.
- C. Each facility located in New Mexico that engages in third-party logistics must undergo an inspection by the board for the purpose of inspecting the third-party logistics facility and operations prior to initial licensure.
- **D.** All third-party logistics providers must publicly display or have readily available all licenses and the most recent inspection report administered by the board.
- E. Changes in any information in Subsection A of 16.19.13 NMAC shall be submitted to the board within 30 days of such change unless otherwise noted.
- submitted by the third-party logistics provider that is considered trade secret or proprietary information as defined under this states privacy and trade secret/proprietary statutes shall be maintained by the board as private or trade secret proprietary information and be exempt from public disclosure.
- **G.** The board shall have the authority to recognize a third-party to inspect third-party logistics providers.
- **H.** The board may license by reciprocity, a third-party logistics provider that is licensed under the laws of another state if:
  - (1) the

applicant submits documentation of a current satisfactory inspection conducted by the FDA, or state licensing authority or by a third-party inspection service approved by the FDA or the state authority licensing such third-party logistics provider, or by the board; and

(2) the requirements of that state are deemed by the board to be substantially equivalent.

[16.19.8.15 NMAC - Rp, 16.19.8.15 NMAC, 11-28-2017]

## 16.19.8.16 MINIMUM QUALIFICATIONS:

- A. The board will not license a third-party logistics provider when the FDA has made a finding that the third-party logistics provider does not utilize good handling and distribution practices and published notice thereof.
- **B.** The board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in providing third-party logistics of prescription drugs within the state:
- (1) any conviction of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
- (2) any felony convictions of the applicant under federal, state or local law;
- (3) the applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;
- (4) the furnishing by the applicant of false or fraudulent material in any application;
- suspension, revocation or any other sanction by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;
- (6) compliance with regulatory and licensing requirements under previously

granted licenses, if any;

**(7)** 

compliance with requirements to maintain or make available to the board or to federal, state, or local law enforcement officials those records required under this part; and

(8) any findings by the board that the applicant has violated or been disciplined, or the subject of administrative action, by a regulatory or licensing agency in any state for violating and federal, state, or local laws relating to drug or device distribution;

(9) any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

- C. The board shall consider the results of a criminal and financial background check and fingerprinting of the applicant and designated representative responsible for facility operations, to determine if an applicant or others associated with the ownership, management or operations of the third-party logistics provider have committed criminal acts that would constitute grounds for denial of licensure.
- provide and attest to a statement providing a complete disclosure of any past criminal convictions and violations of the state and federal laws regarding drugs or devices or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts.
- E. The board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest. Public interest considerations shall be based upon factors and qualifications that are directly related to the protection of the public health and safety.

  [16.19.8.16 NMAC Rp, 16.19.8.16 NMAC, 11-28-2017]

### 16.19.8.17 **PERSONNEL**:

As a condition of receiving and retaining a third-party logistics provider license, the licensee shall

require each person employed in any prescription drug third-party logistics activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety and security will at all times be maintained by law. Each person that is issued an initial or renewal license as a third-party-logistics provider whether in state or out of state must designate in writing on a form required by the board a person for each facility to serve as the designated representatives of the third-party logistics provider.

**A.** To be certified as a designated representative a person must:

(1) submit an application on a form furnished by the board and provide information that includes but is not limited to;

(a)

evidence of criminal background check and fingerprinting, the background check shall be sufficient to include all states residence since the person has been an adult;

**(b)** 

date of birth and social security number;

(c)

occupations, positions of employment and offices held during the past seven years;

(d)

whether the person during the past seven years has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating and state or federal laws regulating the possession, control or wholesale distribution of prescription drugs or devices, together with details of such events;

(e)

whether the person has been during the past seven years, the subject of any proceeding for the revocation of any professional or business license or any criminal violation and if so, the nature of the proceeding and the disposition of the proceeding;

**(f)** 

description of any involvement

by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund during the past seven years, which manufactured, administered, prescribed, distributed or stored prescription drugs and devices in which such businesses were names as a party in a lawsuit;

**(g)** 

description of any criminal offense (not including minor traffic violations) of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere; if the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the board a copy of the final written order of disposition;

(h)

any other information the board deems relevant;

as the designated representative for only one third-party logistics provider at any one time, except where more than one licensed third-party logistics provider is co-located in the same facility and such third-party logistics providers are members of an affiliated group as defined in Section 1504 of the Internal Revenue Code;

(3) be actively involved in and aware of the actual daily operations and inventory control of the third-party logistics provider;

(a)

employed full-time in a managerial position by the third-party logistics provider;

**(h)** 

physically present at the third-party logistics provider during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation or other authorized absence;

(c)

aware of and knowledgeable about all policies and procedures pertaining to the operations of the third-party logistics provider.

- B. The criminal and financial information collected pursuant to this section shall be made available only to the board, a third-party recognized by the board, and to state and federal law enforcement officials. The board and a third-party recognized by the board shall make provisions for protecting the confidentiality of the information collected under this section.
- C. No third-party logistics provider shall have as an owner or designated representative anyone convicted of any felony violation of Subsection (i) or (k) of Section 301 or any violation of Section 1365 of title 18, United States Code relating to product tampering;
- D. Each licensed third-party logistics provider located outside of this state that distributes prescription drugs into this state shall designate a registered agent in this state for service of process. Any licensed third-party logistics provider that does not so designate a registered agent shall be deemed to have designated the secretary of state of this state to be its true and lawful attorney, upon who may be served all legal processes in any action or proceeding against such licensed third-party logistics provider growing out of or arising from such drug distribution. A copy of any such service or process shall be mailed to such third-party logistics provider by the board by certified mail, return receipt requested, postage prepaid, at the address such licensed third-party logistics provider has designated on its application for licensure in this state. If any such third-party logistics provider is not licensed in this state, service on the secretary of state only shall be sufficient service.
- E. A designated representative must complete training programs that address applicable state and federal laws and are provided by qualified in-house specialists, outside counsel or counseling specialists with capabilities to help ensure compliance.

[16.19.8.17 NMAC - Rp, 16.19.8.17 NMAC, 11-28-2017]

# 16.19.8.18 MINIMUM STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS:

- **A. Reporting**: Each facility of a third-party logistics provider shall comply with the FDA annual reporting requirements.
- B. Storage practices, facilities: All third-party logistics provider facilities at which prescription drugs are stored, warehoused, handled, held, or displayed shall:
- (1) be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
- storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security;
- a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, counterfeit or suspected of being counterfeit or adulterated, suspect or illegitimate, otherwise unfit for distribution or that are in immediate or sealed, secondary containers that have been opened;
- (4) be maintained in a clean and orderly condition; and
- (5) be free from infestation by insects, rodents, birds, or vermin of any kind; and
- (6) be a commercial location and not a personal dwelling or residence; and
- (7) provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information; and
- (8) provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting or diversion of prescription drugs or devices; and
- (9) controlled substances must be isolated from non-controlled substance drugs and stored in a secure area in accordance

- with DEA security requirements and standards.
- C. Security and anticounterfeiting: All facilities used for third-party logistics drug storage or distribution shall be secure from unauthorized entry.
- (1) Access from outside the premises shall be kept to a minimum and be well-controlled.
- (2) The outside perimeter of the premises shall be well-lighted.
- (3) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
- (4) All facilities shall be equipped with an alarm system to detect entry after hours.
- facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
- (6) All facilities shall be equipped with a security system that will provide suitable protection against, detect and document any instances of theft, diversion or counterfeiting.
- D. Policies and procedures: Each third-party logistics provider must have written policies and procedures to:
- (1) address receipt, security, storage, inventory, shipment, and distribution of a product;
- (2) identify, record, and report confirmed significant losses, or thefts in the United States;
- (3) correct errors and inaccuracies in inventories;
- (4) provide support for manufacturer recalls:
- (5) prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the

facility, such as a strike, fire, or flood;

(6) ensure that any expired product is segregated from other products and returned to the manufacturer, repackager, or their agent, or destroyed;

(7) maintain the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory; and

(8)

quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency;

- E. Storage: All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or in compliance with standards in the current edition of an official compendium, such as the USP-NF.
- (1) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality and purity are not adversely affected.
- (2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices or logs shall be utilized to document proper storage of prescription drugs.
- F. Inspection: Each third-party logistics provider facility located in New Mexico shall be inspected as a condition of initial licensure and periodically inspected to ensure compliance with board regulations.
- G. Trading partner list: A third-party logistics provider must provide the board, upon a request by the board, a list of all product manufacturers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services at such facility.
- H. Compliance with federal, state, and local law: Third-party logistics providers shall operate

in compliance with applicable federal, state, and local laws and regulations.

- Third-(1) party logistics providers shall permit board authorized personnel and authorized federal, state and local law enforcement officials, to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law, and to confiscate prescription drugs and records to the extent authorized by law or rules. Such officials shall be required to show appropriate identification prior to being permitted access to third-party logistics providers' premises and delivery vehicles.
- party logistics providers that deal in controlled substances shall register with the board as required, and with the DEA, and shall comply with all applicable state, local and DEA regulations.
- (3) A thirdparty logistics provider may distribute only to authorized trading partners. Product shall be shipped only to the address listed on the licensee's license.
- substances may only be distributed or delivered to persons in this state who are registered by the board and the DEA to possess controlled substances. [16.19.8.18 NMAC Rp, 16.19.8.18 NMAC, 11-28-2017]

## 16.19.8.19 REPACKAGER LICENSING REQUIREMENTS:

- A. Every repackager, wherever located, who engages in distribution into, out of, or within this state must be licensed by the board in accordance with the laws and regulations of this state before engaging in repackaging or distribution of prescription drugs.
- **B.** A repackager shall have valid registration with the FDA as a drug establishment under section 510 of the Federal Act.
- **C.** Repackagers cannot operate from a place of residence.
  - **D.** Where repackaging

operations are conducted at more than one location, each such location shall be licensed by the board.

E. The repackaging facility shall be located apart and separate from any pharmacy licensed by the board.

[16.19.8.19 NMAC - Rp, 16.19.8.19 NMAC, 11-28-2017]

### 16.19.8.20 MINIMUM REQUIRED INFORMATION FOR REPACKAGER LICENSURE:

- A. Every repackager who engages in the distribution of product shall be licensed with the board by submitting an application and providing information required by the board on an application approved by the board, including but not limited to:
- (1) applicant's full name; all trade or business names used by the licensee (includes "is doing business as" and "formerly known as"), which cannot be identical to the name used by another unrelated wholesale distributor, third-party logistics provider, or repackager licensed by the board; full business address and telephone number;

(2) type of ownership, e.g. individual, partnership, limited liability company or corporation;

(3) name(s) of the owner(s) of the applicant, including;

(a)

if a person, the name, address, social security number or FEIN, and date of birth;

**(b)** 

if other than a person, the name, address, social security number and date of birth of each partner, limited liability company member, or corporate officer and corporate director and the federal employer identification number;

(c)

if a corporation, the state of incorporation; and

(d)

if a publicly traded corporation, the information in Subparagraph (b) of this paragraph is not required for corporate officers and corporate directors.

(e)

any other relevant information that the board requires;

(4) name(s), business address(es), telephone number(s) of a person(s) to serve as the designated representative(s) for each facility of the repackager that engages in the distribution of drugs;

of criminal background checks and fingerprinting of the applicant, if a person, and of the applicant's designated representative; the background check shall be sufficient to include all states residence since the person has been an adult;

(6) proof of valid registration as a drug establishment with the FDA;

state and federal licenses, registrations or permits, including the license, registration or permit numbers issued to the repackager by any other state and federal authority that authorizes the repackager to purchase, possess, repackage and distribute drugs;

(8) a list of all disciplinary actions or any other sanction by state and federal agencies against the repackager as well as any such actions against principals, owners, directors or officers;

(9) a full description of each facility and warehouse located in New Mexico, including all locations utilized for drug storage or distribution; the description must include the following:

(a)

square footage;

**(b)** 

security and alarm system descriptions;

(c)

terms of lease or ownership;

(d)

address and;

**(e)** 

temperature and humidity controls;

(10)

description of the repackager's drug import and export activities;

(11) a copy of

the repackager's written policies and procedures as required in Subsection D of 16.19.8.23 NMAC;

(12) a facility located outside of New Mexico shall submit a copy of a current satisfactory inspection report issued by the FDA, or State licensing authority, or by a third-party inspection service approved by the FDA or the state authority licensing such repackager, or by the board.

(13) the information collected pursuant to Paragraphs (5), (9) and (11) of this subsection shall be made available only to the board, and to state and federal law enforcement officials; the board shall make provisions for protecting the confidentiality of the information collected under this section.

**B.** Every repackager shall submit a reasonable fee to be determined by the board.

C. Each facility located in New Mexico that engages in repackaging must undergo an inspection by the board for the purpose of inspecting the repackaging facility and operations prior to initial licensure.

**D.** All repackagers must publicly display or have readily available all licenses and the most recent inspection report administered by the board.

E. Changes in any information in this section shall be submitted to the board within 30 days of such change unless otherwise noted.

F. Information submitted by the repackager to the board that is considered trade secret or proprietary information as defined under this states privacy and trade secret/proprietary statutes shall be maintained by the board as private or trade secret proprietary information and be exempt from public disclosure.

**G.** The board shall have the authority to recognize a third-party to inspect repackagers.

**H.** The board may license by reciprocity, a repackager that is licensed under the laws of another state if:

applicant submits documentation of a current satisfactory inspection conducted by the FDA, or state licensing authority, or by a third-party inspection service approved by the FDA or the state authority licensing such repackager, or by the board; and

(2) the requirements of that state are deemed by the board to be substantially equivalent.

[16.19.8.20 NMAC - Rp, 16.19.8.20 NMAC, 11-28-2017]

## 16.19.8.21 MINIMUM QUALIFICATIONS:

**A.** The board shall prohibit a person from receiving or maintaining repackager licensure if the person:

(1) has been convicted of any felony for conduct relating to manufacturing or distribution, any felony violation of Subsection (i) or (k) of section 301, or any felony violation of Section 1365 of title 18, United States Code, relating to product tampering; or

engaged in a pattern of violating the requirements of this section, or state requirements for licensure, that presents a threat of serious adverse health consequences or death to humans.

**B.** The board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage as a repackager within the state:

conviction of the applicant under any federal, state or local laws relating to drug manufacture, samples, wholesale or retail drug distribution, or distribution of controlled substances;

(2) any felony convictions of the applicant under federal, state or local law;

(3) the applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

furnishing by the applicant of false or fraudulent material in any application;

**(5)** 

suspension, revocation or any other sanction by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(6) compliance with regulatory and licensing requirements under previously granted licenses, if any;

(7)

compliance with requirements to maintain or make available to the board or to federal, state, or local law enforcement officials those records required under this part; and

(8)

any findings by the board that the applicant has violated or been disciplined or subject to administrative action by a regulatory or licensing agency in any state for violating and federal, state, or local laws relating to drug or device wholesale distribution;

- (9) any other factors or qualifications the board considers relevant to and consistent with the public health and safety.
- C. The board shall consider the results of a criminal and financial background check and fingerprinting of the applicant and designated representative, to determine if an applicant or others associated with the ownership, management or operations of the repackager have committed criminal acts that would constitute grounds for denial of licensure.
- provide and attest to a statement providing a complete disclosure of any past criminal convictions and violations of the state and federal laws regarding drugs or devices or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts.
- E. The board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest. Public interest considerations shall be based upon factors and qualifications that

are directly related to the protection of the public health and safety. [16.19.8.21 NMAC - Rp, 16.19.8.21 NMAC, 11-28-2017]

16.19.8.22 **PERSONNEL:** As a condition of receiving and retaining a repackager license, the licensee shall require each person employed in any repackaging or distribution activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety and security will at all times be maintained by law. Each person that is issued an initial or renewal license as a repackager whether in state or out of state must designate in writing on a form required by the board a person for each facility to serve as the designated representatives of the repackager.

**A.** To be certified as a designated representative a person must:

(1) submit an application on a form furnished by the board and provide information that includes but is not limited to;

(a)

evidence of criminal background check and fingerprinting, the background check shall be sufficient to include all states residence since the person has been an adult;

(b)

date of birth and social security number;

(c)

occupations, positions of employment and offices held during the past seven years;

(d)

whether the person during the past seven years has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating and state or federal laws regulating the manufacturing, possession, control or distribution of prescription drugs or devices, together with details of such events;

**(e)** 

whether the person has been during the past seven years, the subject of any proceeding for the revocation of any professional or business license or any criminal violation and if so, the nature of the proceeding and the disposition of the proceeding;

f)

description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund during the past seven years, which manufactured, administered, prescribed, distributed or stored prescription drugs and devices in which such businesses were names as a party in a lawsuit;

**(g)** 

description of any criminal offense (not including minor traffic violations) of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere; if the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of the criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the board a copy of the final written order of disposition;

(h)

any other information the board deems relevant;

- as the designated representative for only one repackager at any one time, except where more than one licensed repackager is co-located in the same facility and such repackagers are members of an affiliated group as defined in Section 1504 of the Internal Revenue Code;
- (3) be actively involved in and aware of the actual daily operations, purchasing and inventory control of the repackager;

(a)

employed full-time in a managerial position by the repackager;

**(h)** 

physically present at the repackager facility during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation or other authorized absence; (c)

aware of and knowledgeable about all policies and procedures pertaining to the operations of the repackager.

- B. The criminal and financial information collected pursuant to this section shall be made available only to the board, a third party recognized by the board, and to state and federal law enforcement officials. The board and a third party recognized by the board shall make provisions for protecting the confidentiality of the information collected under this section.
- Each licensed C. repackager located outside of this state that distributes prescription drugs in this state shall designate a registered agent in this state for service of process. Any licensed repackager that does not so designate a registered agent shall be deemed to have designated the secretary of state of this state to be its true and lawful attorney, upon who may be served all legal processes in any action or proceeding against such licensed repackager growing out of or arising from such manufacture or distribution. A copy of any such service or process shall be mailed to such repackager by the board by certified mail, return receipt requested, postage prepaid, at the address such licensed repackager has designated on its application for licensure in this state. If any such repackager is not licensed in this state, service on the secretary of state only shall be sufficient service.
- **D.** A designated representative must complete training programs that address applicable state and federal laws and are provided by qualified in-house specialists, outside counsel or counseling specialists with capabilities to help ensure compliance.

[16.19.8.22 NMAC - Rp, 16.19.8.22 NMAC, 11-28-2017]

## 16.19.8.23 REPACKAGER MINIMUM STANDARDS:

A. Compliance with federal, state, and local law. A repackager shall operate in compliance with applicable federal,

state, and local laws and regulations.

repackager shall comply with 16.19.9 NMAC, including operation in compliance with the Federal Food, Drug, and Cosmetic Act; Good Manufacturing Practices, 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264; and 21 C.F.R. Parts 210 and 211.

(2) A

repackager shall permit board authorized personnel and authorized federal, state and local law enforcement officials, to enter and inspect its premises and delivery vehicles, and to audit its records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law, and to confiscate prescription drugs and records to the extent authorized by law or rules. Such officials shall be required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.

(3)

Inventories, records and written operating procedures shall be made available for inspection and photocopying by authorized inspectors employed by the board for a period of three years following disposition of the drugs.

**(4)** 

Repackagers that deal in controlled substances shall register with the board and with the DEA, and shall comply with all applicable state, local and DEA regulations.

 $(5) \qquad A$ 

repackager may distribute only to authorized trading partners. Product shall be delivered only to the licensed address of the authorized trading partner.

- (6) Controlled substances may only be distributed or delivered to persons in this state who are registered by the board and the DEA to possess controlled substances.
- (7) Product tracing, product identifier, and verification: Repackagers licensed by the board shall comply with the requirements for tracing products

through the distribution system as defined in Sections 353 and 360eee, et seq., of the DSCSA, 21 U.S.C. 301, et seq., and successor FDA regulations, with respect to the role of such repackager including any requirements with respect to: transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system.

- (8) Authorized trading partners: The trading partners of a repackager may be only authorized trading partners.
- **B. Shipment.** A repackager shall ship product only to the address listed on the licensee's license.
- C. Theft or loss. A repackager shall have and follow diversion detection and prevention plan that includes all prescription drugs. A repackagers shall report any theft, suspected theft, diversion or other significant loss of any prescription drug or device to the board and where applicable, to the DEA.
- D. Written policies and procedures. Repackagers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories; repackagers shall include in their written policies and procedures the following:

(1)

a procedure whereby the oldest approved stock of a prescription drug product is distributed first; the procedure may permit deviation from this requirement, if such deviation is temporary and appropriate;

(2

a procedure to be followed for

handling recalls and withdrawals of prescription drugs; such procedure shall be adequate to deal with recalls and withdrawals due to:

(a)

any action initiated at the request of the FDA or other federal, state, or local law enforcement or other government agency, including the state licensing agency;

**(b)** 

any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(c)

any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design;

(3)

procedure to ensure that repackagers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

**(4)** a

procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed; this procedure shall provide for written documentation of the disposition of outdated prescription drugs; this documentation shall be maintained for three years after disposition of the outdated drugs;

(5)

a procedure for the destruction of outdated prescription drugs in accordance with state and federal laws, including all necessary documentation, maintained for a minimum of three years, and the appropriate witnessing of the destruction of outdated prescription drugs in accordance with all applicable federal and state requirements;

(6)

а

procedure for the disposing and destruction of containers, labels and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, maintained for a minimum of three years, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers or containers in accordance with all applicable federal and state requirements;

**(7)** 

a procedure for identifying, investigating and reporting significant prescription drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband or suspect of being contraband, in the inventory and reporting of such discrepancies within 10 business days to the board and appropriate federal or state agency upon discovery of such discrepancies;

) a

procedure for reporting criminal or suspected criminal activities involving the inventory of prescription drug(s) to the board, FDA as required by the agency, and if applicable, DEA, within three business days;

**9**) a

procedure that ensures all common carriers contracted with or utilized by the repackager conduct a criminal background check and drug screen of the employees whose responsibilities include the known handling of prescription drugs;

(10) a

procedure for conducting periodic assessments of the security provisions of common carriers contracted with or utilized by the repackager that at a minimum must specify that vehicles must be secured by locks on all doors and windows when the driver is not present, there shall be no unapproved stops during the delivery route and that the vehicle must not be left running in the absence of the driver;

E. Responsible persons. Repackagers shall establish and maintain lists of officers, directors, managers, and other persons in charge of operations, storage, and handling, including a description of their duties and a summary of their qualifications.

F. Salvaging and reprocessing. Repackagers shall be subject to the provisions of any

applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing including Subsection D of 16.19.8.23 NMAC. [16.19.8.23 NMAC - Rp, 16.19.8.23 NMAC, 11-28-2017]

## 16.19.8.24 MANUFACTURER REQUIREMENTS:

A. Product tracing, product identifier, and verification: Manufacturers shall comply with the requirements for tracing products through the distribution system as defined in Sections 353 and 360eee, et seg., of the DSCSA, 21 U.S.C. 301, et seq., and successor FDA regulations, with respect to the role of such manufacturer including any requirements with respect to: transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system.

**B.** Authorized trading partners: The trading partners of a manufacturer may be only authorized trading partners.

C. Compliance with federal, state, and local law: Manufacturers shall operate in compliance with applicable federal, state, and local laws and regulations. Manufacturers that deal in controlled substances shall register with the board and with the DEA, and shall comply with all applicable state, local and DEA regulations.

[16.19.8.24 NMAC - Rp, 16.19.8.24 NMAC, 11-28-2017]

### **HISTORY OF 16.19.8 NMAC:**

**Pre NMAC History:** The material in this part was derived from that previously filed with the state records center and archives:

BOP 69-2, Rules and Regulations of the State Board of Pharmacy, filed 6/13/1969.

BOP 69-3, New Mexico Laws and Regulations, Pharmacy Act, Drug

and Cosmetic Act, Narcotic Drug Act, Poisons Act, Board of Pharmacy Rules and Regulations, filed 8/15/1969.

BOP 72-1, New Mexico Board of Pharmacy Rules and Regulations Promulgated Pursuant to New Mexico Drug and Cosmetic Act, Pharmacy Act, Controlled Substances Act, filed 7/31/1972.

Regulation No. 8, Minimum Standards For Wholesalers, filed 2/07/1980.

Regulation No. 8, Minimum Standards For Wholesalers, filed 10/23/1985.

Regulation No. 8, Minimum Standards For Wholesalers, filed 2/02/1987.

Regulation No. 8, Minimum Standards For Wholesalers, filed 7/27/1990.

Regulation No. 8, Wholesale Prescription Drug Distribution, filed 5/14/1992.

### **History of Repealed Material:**

BOP 72-1, New Mexico Board of Pharmacy Rules and Regulations Promulgated Pursuant to New Mexico Drug and Cosmetic Act, Pharmacy Act, Controlled Substances Act (filed 7/31/1972) repealed 10/29/1985.
16.19.8 NMAC, Wholesale Prescription Drug Distribution (filed 2/02/1996 and 3/1/2002) repealed 12/02/2009.

16.19.8 NMAC, Wholesale Prescription Drug Distribution, filed 11/03/2009, repealed 11/28/2017.

### **Other History:**

Regulation No. 8, Wholesale Prescription Drug Distribution (filed 5/14/1992) was renumbered, reformatted, amended and replaced by 16 NMAC 19.8, Pharmacists - Wholesale Prescription Drug Distribution, effective 2/15/1996. 16 NMAC 19.8, Pharmacists -Wholesale Prescription Drug Distribution (filed 2/02/1996) was reformatted and renumbered to 16.19.8 NMAC, Wholesale Prescription Drug Distribution, effective 3/30/2002. 16.19.8 NMAC, Wholesale Prescription Drug Distribution (filed 2/02/1996 and 3/01/2002) replaced by 16.19.8 NMAC, Wholesale Prescription Drug Distribution, effective 12/02/2009.

### STATUTORY AUTHORITY:

Paragraph (6) of Subsection A of Section 61-11-6 NMSA 1978 directs the board of pharmacy to provide for the licensing of drug manufacturers, repackagers and wholesale drug distributors and for the inspection of their facilities and activities. Paragraph (7) of Subsection A of Section 61-11-6 NMSA 1978 authorizes the board to enforce the provisions of all state laws pertaining to the practice of pharmacy and the manufacture, production, sale or distribution of drugs, cosmetics or poisons, including the New Mexico Drug, Device and Cosmetic Act, Chapter 26, Article I NMSA 1978. Pursuant to Section 26-1-18 of the Drug, Device and Cosmetic Act, the board is authorized to promulgate regulations for the efficient enforcement of the act.

## REGULATION AND LICENSING DEPARTMENT PHARMACY, BOARD OF

This is an amendment to 16.19.6 NMAC, Section 24 with a new Section 30 added, effective 11-28-2017.

## 16.19.6.24 NONRESIDENT PHARMACIES:

A. Definitions. (1) "Board"

means the New Mexico board of pharmacy.

**(2)** 

"Nonresident pharmacy" means any pharmacy located outside New Mexico that ships, mails or delivers in any manner prescription drugs to New Mexico patients or consumers. For purposes of this definition only, "delivers" includes the provision of dispensing process pharmacy services such as prescription entry, prospective drug review, or prescription verification.

(3)

"Prescription drugs" means any drug required by federal or New Mexico law or regulation to be dispensed only by a prescription and includes "dangerous drugs" and "controlled substances" as defined by federal and New Mexico law.

(4) "Resident state" means the state in which the nonresident pharmacy is a resident.

## B. Licensure requirement.

nonresident pharmacy shall ship, mail or deliver prescription drugs to a patient in this state unless licensed by the board. In addition, no nonresident pharmacy shall ship, mail or deliver controlled substances to a patient in this state unless registered by the drug enforcement administration and the board for controlled substances.

(2) Separate Licensure. Any person that ships, mails or delivers prescription drug to New Mexico patients from more than one nonresident pharmacy shall obtain a separate New Mexico nonresident pharmacy license for each pharmacy.

## C. Requirements for obtaining licensure.

**(1)** 

Application. Each nonresident pharmacy applying for licensure or renewal of licensure shall submit an application to the board which includes the following minimum information:

(a

The address of the principle office of the nonresident pharmacy and the name and titles of all principal corporate officers and all pharmacists who are dispensing prescription drugs to persons in New Mexico. A report containing this information shall be made on an annual basis and within 10 days after any change of office location, corporate officer or pharmacist in charge;

(b)

(c)

Proof that the nonresident pharmacy maintains a valid license, permit or registration to operate the pharmacy in compliance with the laws of the resident state;

A copy of the most recent inspection report resulting from an inspection of the nonresident pharmacy conducted by the regulatory or licensing agency of the resident state;

 $(\mathbf{d})$ 

If compounded sterile preparations (CSP) are to be shipped into New Mexico, a copy of the most recent CSP operations inspection report conducted by the regulatory or licensing agency of the resident state (or party recognized by that agency to perform such inspection, or party recognized by the board) which demonstrates the pharmacy operates in conformance with the requirements of applicable USP/NF General Chapters numbered below 1000. The inspection must have occurred within the 12 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in the inspection report have been corrected. For entities also acting as outsourcing facilities, the required standard of operation shall be <u>current</u> good manufacturing practices cGMP.

(e)

The policy and procedure manual required by Paragraph (2) of Subsection D of 16.19.6.24 NMAC;

**(f)** 

Proof that the nonresident pharmacy has a toll-free telephone service available to New Mexico patients;

g)

The name and address of a resident in New Mexico for service of process;

h)

If the nonresident pharmacy wants to ship, mail or deliver controlled substances to New Mexico patients, then the pharmacy must submit an application for controlled substances under 16.19.20 NMAC; and

(i)

All fees required by 16.19.12 NMAC.

(2) Agent

of record. Each nonresident pharmacy that ships, mails or delivers prescription drugs to a patient in New Mexico shall designate a resident agent in New Mexico for service of process. If a nonresident pharmacy does not designate a registered agent, the shipping, mailing, or delivering of prescription drugs in the state of New Mexico shall be deemed an appointment by such nonresident pharmacy of the secretary of state to be its true and lawful attorney upon whom may be served all legal process in any action or proceeding against such pharmacy growing out of or arising from such delivery.

## D. Conditions of licensure.

**(1)** 

Compliance. Each nonresident pharmacy licensed by the board must comply with the following:

(a) all

statutory and regulatory requirements of the state of New Mexico regarding controlled substances, drug product selection, and the labeling, advertising, and dispensing of prescription drugs including all requirements that differ from federal law or regulations, unless compliance would violate the laws and regulations of the resident state;

**(b)** 

maintain, at all times, a valid license, permit, or registration to operate the pharmacy in compliance with the laws of the resident state:

(c)

maintain, if applicable, a federal registration for controlled substances;

(d)

supply, upon request from the board or the regulatory or licensing authority of the resident state, all information needed to carry out the board's responsibilities under state and federal law;

(e)

provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the nonresident pharmacy who has access to the patient's records. A nonresident pharmacy shall provide the toll-free telephone service during its regular hours of operation, but not less than six days a week and for a minimum of 40 hours a week. The toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

procedure manual. Each nonresident pharmacy shall develop and provide the board with a policy and procedure manual that sets forth:

(a)

normal delivery protocols and times;

(b)

the procedure to be followed if the patient's medication is not available at the nonresident pharmacy, or if delivery will be delayed beyond the normal delivery time;

(c)

the procedure to be followed upon receipt of a prescription for an acute illness, which policy shall include a procedure for delivery of the medication to the patient from the nonresident pharmacy at the earliest possible time (i.e., courier delivery), or an alternative that assures the patient the opportunity to obtain the medication at the earliest possible time;

(d)

the procedure to be followed when the nonresident pharmacy is advised that the patient's medication has not been received within the normal delivery time and that the patient is out of medication and requires interim dosage until mailed prescription drugs become available.

## E. Disciplinary proceedings.

(1) The

board may withhold, suspend, or revoke any nonresident pharmacy license held or applied for upon the grounds established by law or regulations, including, without limitation, the failure to comply with the conditions specified in Subsection C of 16.19.6.24 NMAC. The board shall suspend or revoke a nonresident pharmacy license when the license, permit, or registration to operate the pharmacy in the resident state has been suspended or revoked. A certified copy of the record of suspension or revocation by the resident state is conclusive evidence.

(2) Upon receipt of information indicating that the nonresident pharmacy may have violated the laws or regulations of the resident state, the board may file

a complaint against the nonresident pharmacy with the regulatory or licensing authority of the resident state.

### F. Limitations.

(1) Nothing in this regulation shall be construed to authorize the dispensing of contact lenses by nonresident pharmacies.

(2) Nothing in this regulation is intended to replace or modify any requirements that a nonresident business may be subject to under any other law or regulation. [16.19.6.24 NMAC - Rp, 16 NMAC 19.6.24, 03-30-02; A, 06-09-17; A, 11-28-17]

# 16.19.6.30 REPACKAGING AND DISTRIBUTION BY A PHARMACY:

A. Scope: This section applies only to repackaging by a pharmacy licensed by the board, under the conditions specified in this section.

# B. Definitions as used in this section: (1)

"administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion or any other means as a result of an order of a licensed practitioner;

means the New Mexico board of pharmacy;

"distribute" means the delivery of a drug or device other than by administering or dispensing;

drug product" of a prescription drug is defined as that form of the drug which is, or is intended, to be dispensed or administered to the patient and requires no further manufacturing or processing other than packaging and labeling;

Act" means the federal Food Drug and Cosmetic Act;

"repackaging" means the act of taking a finished drug product from the container in which it was distributed by the original

manufacturer and placing it into a different container without further manipulation of the drug, excluding:

(a)

placing medication in a different container to dispense directly to the patient pursuant to a patient-specific prescription;

removing a drug product from the original container at the point of care for immediate administration to a single patient after receipt of a valid patient-specific prescription or order for that patient.

(7) "USP"
means United States Pharmacopoeia;
(8) "USP
standards" means standards
published in the current official
United States pharmacopoeia-national
formulary.

# C. A pharmacy licensed by the board may repackage under the following conditions:

**(1)** The pharmacy must qualify for an exemption from registration and listing requirements under Section 510 of the FD&C Act. Specifically, under Section 510(g) (1), the registration and listing requirements of Section 510 do not apply to: pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail.

product is not sold or transferred by an entity other than the entity that repackaged such drug product. For purposes of this condition, a sale or transfer does not include

administration of a repackaged drug product in a health care setting.

(3) The drug repackaged is a finished drug product of a prescription drug that is:

(a) a non-sterile solid or liquid oral dosage form;

(b) approved under Section 505 of the

FD&C Act;

(c)
repackaged by or under the direct

supervision of a pharmacist, and undergoes a final check by a pharmacist;

(d)

handled and repackaged in accordance with all applicable USP chapters numbered less than <1000>;

assigned a beyond use date in accordance with USP standards;

repackaged, stored, and shipped in a way that does not conflict with approved drug product labeling;

not adulterated by preparing, packing, or holding the drug product under insanitary conditions; and

repackaged into a sealed unit-dose container.

<u>repackaged drug product is distributed</u> <u>under the following conditions:</u>

by a managing pharmacy for use in an automated drug distribution system to supply medications for patients of a health care facility licensed under 16.19.11 NMAC, or inpatient hospice facility licensed under 16.19.10.12 NMAC, in accordance with 16.19.6.27 NMAC, or emergency kit;

(b) to

a correctional facility, licensed by the board under 16.19.10.11 NMAC, for administration to an inmate pursuant to a patient-specific prescription or order;

to a clinic licensed by the board under
16.19.10.11 NMAC, and under the
same ownership as the repackaging
pharmacy, for administration to a
patient of the clinic pursuant to a

patient-specific prescription	on or order.
(5)	All
units of repackaged medic	cation
must be labeled with the f	
	onowing
information:	
	<u>(a)</u>
name, address, and teleph	one number
of repackaging pharmacy,	unless
the repackaged drug is us	
automated drug distribution	
accordance with 16.19.6.2	27 NMAC;
	<u>(b)</u>
name, strength, and quant	ity of the
drug;	
<u> </u>	(c)
1 , 1 , 1	
lot number or control nun	
	<u>(d)</u>
name of manufacturer;	
-	(e)
havand usa data:	(6)
beyond use date;	(0)
	<u>(f)</u>
date drug was repackaged	·
	(g)
name or initials of repack	ager: and
name of mittais of repack	
0.1 1 1.1 1.0	<u>(h)</u>
federal caution label, if ap	-
(6)	A record of
drugs repackaged must be	maintained,
and include the following	
and merade the rone wing	<u>·</u> (a)
data of rangalizacina:	(a)
date of repackaging;	(L.)
	<u>(b)</u>
1	
name and strength of drug	
name and strength of drug	
	(c)
manufacturer assigned dru	(c) ug lot
	(c) ug lot nte;
manufacturer assigned drumber, and expiration da	(c) ug lot ate; (d)
manufacturer assigned dru	(c) ug lot ate; (d) er;
manufacturer assigned drumber, and expiration da	(c) ug lot ate; (d)
manufacturer assigned drunumber, and expiration daname of drug manufacture	(c) ug lot nte; (d) er; (e)
manufacturer assigned dra number, and expiration da name of drug manufacture assigned beyond-use date	(c) ug lot ate; (d) er; (e) and lot
manufacturer assigned drunumber, and expiration daname of drug manufacture	(c) ug lot nte; (d) er; (e) and lot
manufacturer assigned dra number, and expiration da name of drug manufacture assigned beyond-use date number or control numbe	(c) ug lot ate; (d) er; (e) and lot r; (f)
manufacturer assigned dri number, and expiration da name of drug manufacture assigned beyond-use date number or control numbe total number of dosage ur	(c) ug lot ate; (d) er; (e) and lot r; (f)
manufacturer assigned dra number, and expiration da name of drug manufacture assigned beyond-use date number or control numbe	(c) ug lot ate; (d) er; (e) and lot r; (f)
manufacturer assigned drunumber, and expiration daname of drug manufactures assigned beyond-use date number or control number total number of dosage ur	(c) ug lot ate; (d) er; (e) and lot r; (f)
manufacturer assigned drunumber, and expiration daname of drug manufacture assigned beyond-use date number or control numbe total number of dosage ur caps) repackaged;	(c) ug lot ate; (d) er; (e) and lot r; (f) nits (tabs,
manufacturer assigned dri number, and expiration da name of drug manufacture assigned beyond-use date number or control numbe total number of dosage ur caps) repackaged;	(c) ug lot ate; (d) er; (e) and lot r; (f) nits (tabs,
manufacturer assigned dri number, and expiration da name of drug manufacture assigned beyond-use date number or control numbe total number of dosage ur caps) repackaged;	(c) ug lot nte; (d) er; (e) and lot r; (f) nits (tabs,
manufacturer assigned dri number, and expiration da name of drug manufacture assigned beyond-use date number or control numbe total number of dosage ur caps) repackaged; quantity per each repacka container;	(c) ug lot nte; (d) er; (e) and lot r; (f) nits (tabs,  (g) ged unit (h)
manufacturer assigned dri number, and expiration da name of drug manufacture assigned beyond-use date number or control numbe total number of dosage ur caps) repackaged;	(c) ug lot nte; (d) er; (e) and lot r; (f) nits (tabs,  (g) ged unit (h)
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manufacturer assigned dri number, and expiration da name of drug manufacture assigned beyond-use date number or control numbe total number of dosage ur caps) repackaged; quantity per each repacka container;	(c) ug lot ate; (d) er; (e) and lot r; (f) nits (tabs,  (g) ged unit (h) rasted; and (i)
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manufacturer assigned dri number, and expiration da name of drug manufacture assigned beyond-use date number or control numbe total number of dosage ur caps) repackaged; quantity per each repacka container; number of dosage units w initials of repackager, and pharmacist performing fir	(c) ug lot ate; (d) er; (e) and lot r; (f) hits (tabs,  (g) ged unit  (h) easted; and (i) lof hal check.
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manufacturer assigned dri number, and expiration da name of drug manufacture assigned beyond-use date number or control numbe total number of dosage ur caps) repackaged; quantity per each repacka container; number of dosage units w initials of repackager, and pharmacist performing fir (7) as required by the Pharma including the Drug, Device	(c) ug lot ate; (d) er; (e) and lot r; (f) hits (tabs,  (g) ged unit  (h) easted; and (i) lof hal check. Records acy Act be, and
manufacturer assigned dri number, and expiration da name of drug manufacture assigned beyond-use date number or control numbe total number of dosage ur caps) repackaged; quantity per each repacka container; number of dosage units w initials of repackager, and pharmacist performing fir (7) as required by the Pharma	(c) ug lot ate; (d) er; (e) and lot r; (f) hits (tabs,  (g) ged unit  (h) easted; and (i) ed f hal check. Records hey Act he, and lled

shall be maintained.

[16.19.6.30 NMAC - N, 11-28-17]

## REGULATION AND LICENSING DEPARTMENT PHARMACY, BOARD OF

This is an amendment to Section 13 of 16.19 12 NMAC effective 11-28-2017.

### 16.19.12.13 LICENSE FEES: A. Drug manufacturer \$700.00 bi-ennially B. Wholesale drug distributor \$700.00 bi-ennially Drug manufacturer/ C. re-packager \$700.00 bi-ennially D. Re-packager \$700.00 bi-ennially Retail pharmacy Ε. \$300.00 bi-ennially Hospital pharmacy F. \$300.00 bi-ennially G. Nonresident \$400.00 bi-ennially pharmacy Seller or dispenser of contact lenses \$400.00 bi-ennially Dangerous drug I. research \$200.00 bi-ennially Drug warehouse J. \$200.00 bi-ennially Duplicate license or K. permit(for all types) \$10.00 per each request L. Letter of good standing, verification, and certification \$10.00 per each request M. Roster of New Mexico board of pharmacy license \$30.00 per license database

N. Outsourcing facility \$2000.00 bi-

ennially

category

O. Third party logistics provider \$700.00 bi-ennially [03-07-80...05-01-93; 16.19.12.13]

NMAC - Rn, 16 NMAC 19.12.13, 03-30-02; A, 09-30-03; A, 07-15-04; A, 01-15-2005; A, 12-15-05; A, 01-31-07; A, 11-15-10; A, 12-13-15; A, 03-23-16; A, 11-28-2017]

## **REGULATION AND**

## LICENSING DEPARTMENT PHARMACY, BOARD OF

This is an amendment to 16.19.17 NMAC, Sections 7 and 8, effective 11-28-2017.

### **16.19.17.7 DEFINITIONS:**

**A.** "Board" means the New Mexico board of pharmacy.

**B.** "Dangerous Drug" as defined in the New Mexico Drug, Device and Cosmetic Act, Subsection F of Section 26-1-2 NMSA 1978.

(1)

The

following substance(s) has(have) been declared by the N.M. board of pharmacy as "Dangerous Drugs" in accordance with Section 26-1-18 NMSA 1978 of the Drug. Device and Cosmetic Act, Section 26-1-18 NMSA 1978 and the Uniform Licensing Act (Sections 61-1-1 to 61-1-31 NMSA 1978). The board of pharmacy shall by regulation declare a substance a "dangerous drug" when necessary and notification shall be sent to all registered pharmacies in the state within 60 days of the adoption of the regulation. Ephedrine, USP, as ephedrine hydrochloride or ephedrine sulfate or as any other salt form. Any compound, mixture, or preparation containing one-half percent or less of ephedrine or of any salt form of ephedrine is exempt from the above. [The followingdrug products containing ephedrine, USP, as ephedrine hydrochloride or ephedrine sulfate are exempted from this schedule: Bronkaid® Caplets and Primatene® Tablets. These products are exempt because they are approved for sale over the counter (OTC) without a prescription under federal law, are labeled and marketed in a manner consistent with the pertinent OTC tentative final or final monograph, are manufactured and distributed for legitimate medical use in a manner that reduces or eliminates the likelihood for abuse, and are not marketed, advertised or labeled for an indication of stimulation, mental alertness, energy, weight loss, appetite control, or muscle enhancement. These approved OTC products shall be reported as required

of a pseudoephedrine containing product as defined in Subsection B of 16.19.20.53 NMAC.

(2)

dangerous drug shall be dispensed only upon the prescription of a practitioner licensed by law to administer or prescribe such drug.

C. "Drug storage area" means the area restricted to the storage, dispensing and distribution of dangerous drugs.

**D.** "Research protocol" is the written documentation stating the objective, method, means of measurement, and utilization procedure of the dangerous drug.

[04-19-92; 16.19.17.7 NMAC - Rn, 16 NMAC 19.17.7, 03-30-02; A, 07-15-2004; A, 09-15-06; A, 11-28-17]

## 16.19.17.8 RESEARCH LICENSING REQUIREMENTS:

A. Authorized persons to be licensed: public agencies, institutions of higher education and private organizations, or individuals for the purpose of conducting research, demonstration or special projects with the use of a dangerous drug.

B. The person applying for licensure must fill out a license for dangerous drug research application prior to purchasing any dangerous drug. The applicant must provide information pertinent to the research including:

(1) [personswho will be involved in handling of dangerous drug:

<del>(a)</del>

name, address, date of birth, and if they have been convicted of a felony;] name, address, and date of birth of persons who will be involved in handling of dangerous drugs, and if they have been convicted of a felony:

**(2)** drug

protocol:

(a)

formulary of dangerous drugs for research;

**(b)** 

(c)

how will the dangerous drug be utilized;

be used for each administered dose or experiment; (d)

how much of the dangerous drug will

how much drug will be purchased annually.

(3) policy and procedure manual including:

(a)

drug security: storage area, list of individuals with access to dangerous drugs;

(b)

drug procurement: invoices, receipts, and drug sources;

(c)

drug usage: records or logs for accountability;

(d)

drug waste/destruction: memorandum report describing accountability;

(e)

drug storage area;

**(f)** 

research protocol: proprietary or trade secrets are confidential and not subject to public disclosure;

(4)

qualifications of the applicant to conduct such research with dangerous drugs which may include:

(a)

degrees;

(b)

higher education;

(c)

specialized training.

C. The board will review all applicants for licensure for consistency with the public's best interest.

[16.19.17.8 NMAC - N, 09-15-06; A, 11-28-17]

# SPEECH-LANGUAGE PATHOLOGY, AUDIOLOGY AND HEARING AID DISPENSING PRACTICES BOARD

This is an amendment to 16.26.4 NMAC, Section 8 through 10, effective 11/28/2017

16.26.4.8 RENEWAL OF

### LICENSES:

A. All licensees except clinical fellows and apprentices shall apply for license renewal biennially on or before January 30 of the renewal year, on the renewal forms supplied by the board office. The renewal requirements for clinical fellows and apprentices are set forth in Sections 9 and 10 of Part 4.

**B.** Licensees shall assume the total responsibility for:

(1) filing a current mailing address <u>and electronic</u> <u>mail (email)</u> with the board office;

(2) completing the renewal form and ensuring its delivery to the board office on or before January 30 of the renewal year;

(3) enclosing

the appropriate fee; and

(4) enclosing documentation of meeting continuing education requirements.

C. To assist in the renewal process, the board office will:

renewal notices and the appropriate forms to the licensee's email address of record on or before December 15 prior to the expiration of the current license; and

(2) mail renewed and reinstated licenses no later than 30 days from day of receipt of application, fees and appropriate documentation.

speech-language pathology, audiology and hearing aid dispensing licenses expire on January 30 of [each] the renewal year and renewal forms must be complete and postmarked, if submitted by mail, no later than the expiration date or a late fee will be assessed without exception.

E. Grace period: There is a grace period permitting renewal of expired licenses which ends March 31 of the intended licensure year. However the license shall be considered expired during the grace period and the licensee must refrain from practicing.

F. Renewal of license during the grace period ending March 31 of the intended license year will require payment of a late

fee.[Individuals renewing during the grace period may not practice with the expired license.]

- G. If a licensee fails to renew within the grace period, the licensee must reapply as a new applicant, meet all applicable requirements, meet CEU requirements and pay the application fee, renewal fee and late penalty fee.
- **H.** Licensees shall be notified by the board office of all license expirations 10 days after the close of the grace period.
- Timely renewal of license(s) is the full and complete responsibility of the licensee, [pursuant] Pursuant to Subsection C of 16.26.4.8 NMAC of these regulations. [renewal forms are mailed to the licensee at address on record no later than December 15 If the renewal form is not receivedby the licensee within a reasonable time after December 15, it is the responsibility of the licensee to contact the board office.] Non-receipt of the renewal [form] notification by the licensee will not exempt licensure expiration or late penalty fees. [12/21/1971; 2/5/80; 4/5/1983; 11/9/1996; 11/7/1998; 11/27/1999; 16.26.4.8 NMAC - Rn & A, 16 NMAC 26.4.8, 2/3/2006; A, 11/29/2008; A, 6/7/2010; A, 1/29/2015; A, 11/28/2017]

## 16.26.4.9 RENEWAL OF CLINICAL FELLOW LICENSE:

The CFY must be completed within a maximum period of 36 consecutive months. Prior to or during the first 12 months of clinical fellow licensure, the clinical fellow must take and pass a nationally recognized examination in [their] the clinical fellow's field. Proof of passing this exam is required for renewing the CFY license. [Clinical fellowship licenses expire twelve (12) months after initial licensure.]

A. The clinical fellowship license shall be renewed annually on a form supplied by the board office and must be shall expire annually one year after the date of initial licensure. The renewal must be postmarked no later than the

expiration date.

- **B.** A late penalty fee will be assessed if the license is not renewed by the expiration date.
- renew within 60 days of expiration of the license, the licensee must reapply, meet all applicable requirements, meet CEU requirements and pay the application fee, renewal fee and late penalty fee.

[11/7/1998; 16.26.4.9 NMAC - Rn & A, 16 NMAC 26.4.9, 2/3/2006; A, 1/29/2015; A, 11/28/2017]

# 16.26.4.10 RENEWAL OF TEMPORARY PARAPROFESSIONAL LICENSE (APPRENTICE IN SPEECHLANGUAGE PATHOLOGY):

A. All temporary paraprofessional licensees shall apply for license renewal <u>annually</u> on or before August 30th and are required to provide the following documentation to the board each year:

(1) a

completed renewal form;

**(2)** the

required license renewal fee; and

(3)

a completed board approved verification of employment form verifying:

(a)

licensee's employment;

**(b)** 

performance responsibilities of the apprentice in speech-language;

(c)

limitations on employment practices of the apprentice in speech-language license holder (apprentice in speech-language):

(d)

provision for supervision by an SLP licensed according to this act;

**(4)** 

a completed board\_approved verification of education form verifying:

(a)

course work completed in communication disorders or other courses as outlined in the degree plan with a minimum GPA of 3.0;

**(b)** 

current degree plan once the licensee

is admitted to a master's degree program; and

(c)

copy of transcripts from college or university.

- **B.** Expiration: All temporary paraprofessional licenses expire on August 30th of each year and renewal of licenses must be postmarked no later than the expiration date of the license or a late fee will be assessed without exception.
- c. A temporary paraprofessional license may not be renewed if the licensee has not been accepted into a master's degree program within two years of initial licensure.
- **D.** If a licensee fails to renew within 60 days of expiration of the license, the licensee must reapply, meet all applicable requirements, meet CEU requirements and pay the application fee, renewal fee and late penalty fee.
- paraprofessional license as an apprentice in speech-language is a terminal license and as such may be renewed no more than [five] four times total.

  [11/7/1998; 11/27/1999; 16.26.4.10 NMAC Rn & A, 16 NMAC

NMAC - Rn & A, 16 NMAC 26.4.10, 2/3/2006; A, 11/29/2008; A, 11/28/2017]

# SPEECH-LANGUAGE PATHOLOGY, AUDIOLOGY AND HEARING AID DISPENSING PRACTICES BOARD

This is an amendment to 16.26.5 NMAC, Section 9 and 10, effective 11/28/2017.

# 16.26.5.9 CONTINUING EDUCATION REQUIREMENTS OF LICENSEES:

A. The board [will-require] requires 20 hours of continuing education every two years. These may be distributed over the two year period, or they may

all be obtained in one year. These continuing education hours must be in the field of [his or her] licensure, or in a related field if justified to the board office. The board office will consult with the board [and/or withthe New Mexico speech-language and hearing association (or similar statewide professional association) to resolve questions as to appropriate continuing education hours. Renewal of a license shall be contingent upon the fulfillment of the continuing education standards and the supplying of evidence thereof by the licensee. The board shall be the final authority on acceptance of any educational activity submitted by a licensee to meet the continuing education requirement.

- **B.** The number of continuing education hours required for renewal of a license may be prorated by the board office.
- (1) A [newly] licensed individual [or a person whoreinstates his or her license and] whose next renewal date occurs less than 12 months after the license is issued will be required to earn continuing education hours equivalent to one hour per month each month the license is issued or reinstated to the last day of the renewal month up to a maximum of 10 clock hours.
- (2) Any approved continuing education hours accrued prior to receiving a license during the year the license is issued can be applied toward the continuing education requirements.
- as both a speech-language pathologist and an audiologist or hearing aid dispenser must [fulfil] fulfill the requirements of 20 clock hours of continuing education every two years in [the] each field in which [they are] the licensee is licensed. [actively practicing.]

[2/5/1980; 8/4/1981; 11/9/1996; 16.26.5.9 NMAC - Rn & A, 16 NMAC 26.5.9, 2/3/2006; A, 11/29/2008; A, 11/28/2017]

16.26.5.10 CRITERIA

## APPLYING TO OFFER CONTINUING EDUCATION OPPORTUNITY:

- A. The board or board office will approve professional education activities sponsored or approved by a national or state professional association of speechlanguage pathologists, audiologists and hearing aid dispensers.
- **B.** All other proposed educational programs or seminars must be submitted to the board office prior <u>to</u> approval.
- c. Requests must be submitted in writing with appropriate fees to the board office at least 60 days prior to the program. The board office shall give written notice of the approval or disapproval of the educational program or seminar within 30 days of receiving the application.
- **D.** The individual/ organization requesting approval of an educational seminar or course must provide the board office with the following material:
- (1) name of the seminar or course;
  - (2) sponsor;
  - (3) objective

of the seminar or course;

- (4) format and subjects of seminar or course;
- (5) number of clock hours of study or continuing education units;
- (6) method of verification of attendance or completion of self study program; and
- (7) name and qualifications of faculty or institution material.

[4/5/1983; 11/919/96; 16.26.5.10 NMAC - Rn & A, 16 NMAC 26.5.10, 2/3/2006; A, 11/28/2017]

## Continued on the following page

**SPEECH-LANGUAGE** 

## PATHOLOGY, AUDIOLOGY AND HEARING AID DISPENSING PRACTICES BOARD

This is an amendment to 16.26.6 NMAC, Section 8, effective 11/28/2017.

**16.26.6.8 FEES:** All fees are payable to the board and are non-refundable. Fees are as follows:

	Initial fee	Renewal fee
Hearing aid dispenser trainee temporary permits g aid practical and written exam]	\$[ <del>300.00</del> ] <u>175.00</u>	
Temporary paraprofessional license (apprentice)	\$50.00	\$50.00
Clinical fellow license	\$50.00	\$50.00
Speech-language pathologist and audiologist license	\$100.00	\$170.00
Hearing aid dispensers	\$175.00	\$360.00
Hearing aid practical[, and written exams-] exam	\$200.00	
Endorsement to dispense hearing aids	\$100.00	\$190.00
Processing continuing education offerings per offering	\$50.00	
Bilingual-Multicultural Endorsement	\$50.00	[\$50.00]
Late renewal fee	\$75.00	
All application packet fees	\$10.00	
Dual licensure (SLP/audiology)	\$200.00	\$150.00
Verification of licensure	\$15.00	
Paper list	\$125.00	
Mailing labels	\$150.00	
Electronic list	\$175.00	
Duplicate license	\$10.00	
Insufficient funds	\$25.00	
	Temporary paraprofessional license (apprentice) Clinical fellow license Speech-language pathologist and audiologist license Hearing aid dispensers Hearing aid practical[, and written exams-] exam Endorsement to dispense hearing aids Processing continuing education offerings per offering Bilingual-Multicultural Endorsement Late renewal fee All application packet fees Dual licensure (SLP/audiology) Verification of licensure Paper list Mailing labels Electronic list Duplicate license	Hearing aid dispenser trainee temporary permits gaid practical and written exam]  Temporary paraprofessional license (apprentice) \$50.00  Clinical fellow license \$50.00  Speech-language pathologist and audiologist license \$100.00  Hearing aid dispensers \$175.00  Hearing aid practical[, and written exams   exam \$200.00  Endorsement to dispense hearing aids \$100.00  Processing continuing education offerings per offering \$50.00  Bilingual-Multicultural Endorsement \$50.00  Late renewal fee \$75.00  All application packet fees \$10.00  Dual licensure (SLP/audiology) \$200.00  Verification of licensure \$15.00  Paper list \$125.00  Mailing labels \$150.00  Electronic list \$175.00  Duplicate license \$10.00

[10/25/1991; 11/09/1996; 11/7/1998; 11/27/1999; 16.26.6.8 NMAC - Rn & A, 16 NMAC 26.6.8, 2/3/2006; A, 6/7/2010; A, 1/29/2015; A, 11/28/2017]

## SPEECH-LANGUAGE PATHOLOGY, AUDIOLOGY AND HEARING AID DISPENSING PRACTICES BOARD

This is an amendment to 16.26.7 NMAC, Section 8, effective 11/28/2017.

- 16.26.7.8 DISCIPLINARY GROUNDS: [In accordance with the provisions of the Uniform Licensing Act, the board may take disciplinary action if the board determines that the applicant or licensee has violated the Speech-Language Pathology, Audiology and Hearing Aid Dispensing Practices Act or the boards regulations. The following shall subject the applicant or licensee to disciplinary action by the board.

  A: Engaging in unprofessional conduct: Unprofessional conduct includes, but is not limited to, the following:
- (1) violations of the principles of ethics or the ethical proscriptions as set forth in board regulations concerning its Code of Ethics (16.26.9 NMAC):
- regulations concerning its Code of Ethics (16.26.9 NMAC);

  (2) committing a misdemeanor substantially related to the practice of speech language pathology, audiology or hearing aid dispensing or a misdemeanor involving moral turpitude; a certified copy of the record of
- conviction shall be conclusive evidence of conviction;

  (3) for an audiologist or dispensing otorhinolaryngologist to accept a case referred from a hearing aid dispenser and not return the case to the referring professional unless the person seeking the hearing aid refuses to return to the referring professional or if the professional determines, using his best professional judgement, the return of the case would not be in the person's best medical or audiological interest.
  - **B:** Engaging in acts that constitute incompetence: Incompetence includes, but is not limited to, the

following:	duties authorized in Subsection D of	(3)
(1) failure	16.26.2.18 NMAC of the boards rules.	committing any of these crimes, for
to possess the knowledge, apply the	E. Failing to deliver	which a certified copy of the record
skill or provide the care required	to any person supplied with a hearing	of conviction shall be conclusive
by generally accepted standards of	aid a receipt which contains the	evidence of conviction;
the professions of speech-language	following information:	(a) a
pathology, audiology or hearing aid	(1) licensee's	felony;
dispensing; or	license number and signature;	(b) a
(2) violation	(2) the	misdemeanor substantially related
of the principles of ethics II or the	sponsor's/supervisor's signature	to the practice of speech language
ethical proscriptions thereunder as set	approving of the fitting if the seller is	pathology, audiology or hearing
forth in board regulations relating to	a clinical fellow, graduate student or	aid dispensing or a misdemeanor
professional competence (Subsections	trainee;	involving moral turpitude; and
D and E of 16.26.9.8 NMAC);	(3) address	(c)
(3) a finding	of the licensee's regular place of	violating the Controlled Substances
of incompetence may be based upon a	business;	Act (Sections 30-31-1 to 30-31-41
single act or omission of competence	(4) make and	NMSA 1978).
or upon a course of conduct or series	model of the hearing aid;	(4) attempting
of acts or omissions which extend	(5) full	to practice with a license, certificate
over a period of time and which,	financial terms of the sale;	or registration to practice speech-
taken as a whole, demonstrate	(6) statement	language pathology, audiology
incompetence.	as to whether the hearing aid is new,	or hearing aid dispensing under a
C. Violation of the	used or reconditioned;	revoked, suspended or denied license
Controlled Substances Act (Sections	<del>(7)</del> statement	from another jurisdiction, territory
30-31-1 to 30-31-41 NMSA 1978).	that the purchaser was advised that	or possession of the United States or
A certified copy of the record of	the licensee was not a licensed	another country for actions similar to
conviction shall be conclusive-	physician and that the examination	acts described within this section.
evidence of conviction.	and recommendation was made as	(5)
• Aiding or abetting	a hearing aid dispenser, audiologist,	for an audiologist or dispensing
the practice by a person not licensed	clinical fellow, trainee or graduate	otorhinolaryngologist, accepting a
by the board. Aiding or abetting the	student and not as a medical diagnosis	referral from a hearing aid dispenser
practice of speech language pathology	or prescription;	but failing to return the case to the
by a person not licensed by the board	(8) terms of	referring professional unless the
includes, but is not limited to, the	guarantee, if any.] In accordance	person seeking the hearing aid refuses
following.	with the provisions of the Uniform	to return to the referring professional
<del>(1)</del> A	Licensing Act, the board may take	or if the professional determines,
licensee shall not authorize or	disciplinary action if the board	using his best professional judgement
otherwise permit a speech language	determines that the applicant or	the return of the case would not
paraprofessional or assistant working	licensee has violated the Speech-	be in the person's best medical or
under his or her supervision to	Language Pathology, Audiology and	audiological interest.
diagnose, conduct diagnostic testing,	Hearing Aid Dispensing Practices Act	(6) fraud or
interpret diagnostic testing, develop a	or the board's rules. The following	deceit in procuring or attempting to
plan of care or deviate from a plan of	shall subject the applicant or licensee	procure a license;
care.	to disciplinary action by the board.	(7) selling or
(2) A licensee	A. Engaging	fitting the first hearing aid of a child
shall ensure that a speech language	in unprofessional conduct:	under 16 years of age who has not
paraprofessional or assistant working	Unprofessional conduct includes, but	been examined and cleared for the
under his or her supervision follows	is not limited to, the following:	hearing aid by an otolaryngologist
the plan of care.	(1) violations	or a dispensing audiologist who has
(3) A licensee	of the principles of ethics or the	earned certification by a national
shall not authorize or otherwise	ethical proscriptions as set forth in	professional association;
permit an apprentice in speech-	board regulations concerning its Code	(8) selling
language pathology working under	of Ethics (16.26.9 NMAC);	or fitting a hearing aid on a person
his or her supervision to conduct any of the duties set forth in Subsection	(2) violating	who has not been tested, except for replacement aids;
E of 16.26.2.18 NMAC of the	a provision of the Speech-Language Pathology, Audiology and Hearing	(9) using
boards rules and shall ensure that	Aid Dispensing Practices Act	untruthful or misleading advertising;
the apprentice only engages in those	including practicing without a license:	(10)

misrepresenting the license or applicant's status as being a medical doctor;

(11) becoming addicted to a habit-forming drug or other substance to such a degree as to render the license or applicant unfit to practice;

willfully **(12)** or negligently practicing beyond the scope of the Speech-Language Pathology, Audiology and Hearing Aid Dispensing Practices Act.

В. Engaging in acts that constitute incompetence: Incompetence includes, but is not limited to, the following:

(1) failure to possess the knowledge, apply the skill or provide the care required by generally accepted standards of the professions of speech-language pathology, audiology or hearing aid dispensing; or

**(2)** violation of the principles of ethics II or the ethical proscriptions thereunder as set forth in board regulations relating to professional competence (Subsections D and E of 16.26.9.8 NMAC);

C. A finding of incompetence may be based upon a single act or omission of competence or upon a course of conduct or series of acts or omissions which extend over a period of time and which, taken as a whole, demonstrate incompetence.

D. Aiding or abetting the practice by a person not licensed by the board. Aiding or abetting the practice of speech language pathology by a person not licensed by the board includes, but is not limited to, the following:

**(1)** Authorizing or otherwise permitting a speech language paraprofessional or assistant working under the licensee's supervision to diagnose, conduct diagnostic testing, interpret diagnostic testing, develop a plan of care or deviate from a plan of care.

**(2)** Failing to ensure that a speech language paraprofessional or assistant working under the licensee's supervision follows the plan of care; and

Authorizing or otherwise permitting an apprentice in speech-language pathology working under the licensee's supervision to conduct any of the duties set forth in Subsection E of 16.26.2.18 NMAC of the boards rules.

(3)

Failing to deliver to any person supplied with a hearing aid a receipt which contains the following information:

licensee's **(1)** license number and signature; **(2)** the sponsor's/supervisor's signature approving of the fitting if the seller is a clinical fellow, graduate student or

**(3)** address of the licensee's regular place of business;

**(4)** model of the hearing aid; **(5)** full

make and

financial terms of the sale;

trainee;

(6) statement as to whether the hearing aid is new, used or reconditioned;

**(7)** statement that the purchaser was advised that the licensee was not a licensed physician and that the examination and recommendation was made as a hearing aid dispenser, audiologist, clinical fellow, trainee or graduate student and not as a medical diagnosis or prescription;

**(8)** terms of guarantee, if any. [11/7/1998, 11/27/1999, 12/5/1999; 16.26.7.8 NMAC - Rn & A, 16 NMAC 26.7.8, 2/3/2006; A, 11/28/2017]

## SPEECH-LANGUAGE PATHOLOGY, **AUDIOLOGY AND** HEARING AID **DISPENSING PRACTICES BOARD**

This is an amendment to 16.26.8 NMAC, Section 7, 9, 10 and 12, effective 11/28/2017.

#### 16.26.8.7 **DEFINITIONS:**

A. "Complaint" means a complaint filed with the board against an applicant for licensure or against a licensee.

"Complainant" В. means the party who files a complaint against a licensee or an applicant for licensure.

C. "Respondent" means the applicant for licensure or the licensee who is the subject of the complaint filed with the board.

"Hearing" means the formal process whereby the respondent is afforded the opportunity to be heard by the board, or its designated hearing officer, before the board takes action which might result in the disciplinary action against the respondent's application for licensure or [his or her] license to practice speech-language pathology, audiology or hearing aid dispensing.

E. "Violation" means a violation of the Speech-Language Pathology, Audiology and Hearing Aid Dispensing Practices Act or the rules and regulations duly adopted by the board.

"Notice of contemplated action" or "NCA" means the administrative process provided for by the Uniform Licensing Act whereby the respondent is notified of the boards intent to take action based upon the alleged violations of practice and whereby the respondent is afforded the opportunity for a hearing before the board.

G. "License revocation" means to prohibit the conduct authorized by the license.

H. "License suspension" means to prohibit, for a stated period of time, the conduct authorized by the license.

"License restricted I. subject to conditions" means to allow the conduct authorized by the license for a stated period of time, subject to conditions that are reasonably related to the grounds for disciplinary action. [11/7/1998; 16.26.8.7 NMAC - Rn,

16 NMAC 26.8.7, 2/3/2006; A, 11/28/2017]

### 16.26.8.9

**INVESTIGATION:** Upon receipt of the complaint, the board will cause an investigation to be made into the subject complaint by the board's [standards of practice] disciplinary committee.

[11/7/1998; 16.26.8.9 NMAC - Rn, 16 NMAC 26.8.9, 2/3/2006; A, 11/28/2017]

## 16.26.8.10 [STANDARDS OF PRACTICE] DISCIPLINARY

**COMMITTEE:** The [standards of practice] disciplinary committee is formed for the purpose of investigating disciplinary matters referred to it by the board. The board chairperson shall appoint a member or members of the board to the [standards of practice] disciplinary committee.

- A. The [standards of practice] disciplinary committee shall review all documentation provided to it in reference to the subject complaint.
- **B.** The [standards of practice] disciplinary committee may provide the respondent with a copy of the complaint and allow a reasonable time for the respondent to respond to the allegations in the complaint.
- C. The foregoing notwithstanding, the [standards of practice] disciplinary committee will not be required to provide the respondent with notice of the complaint filing, or a copy of the complaint, or any related investigatory evidence prior to the notice of contemplated action, if the committee determines that disclosure may impair, impede, or compromise the efficacy or integrity of the investigation.
- **D.** The [standards of practice] disciplinary committee may employ an investigator or other persons determined to be necessary in order to assist in the processing and investigation of the complaint.
- E. Upon completion of its investigation, the [standards-of practice] disciplinary committee shall submit to the board its proposed recommendations concerning the proper disposition of the subject

complaint.

- F. Upon review the board shall vote upon the proposed recommendations and either uphold, reverse, or modify the [standards of practice] disciplinary committee recommendations.
- g. [standards of practice] Disciplinary committee members who participate in the preparation of recommendations to the remaining board members shall not participate further in any actions initiated by the board against the licensee or applicant who is the subject of the complaint.
- H. If the board determines that it lacks jurisdiction, or that there is insufficient evidence or cause to issue a notice of contemplated action, the board may vote to dismiss or close the complaint.
- I. If the board determines that there is sufficient evidence or cause to issue a notice of contemplated action, it may vote to refer the complaint to the attorney general's office for possible prosecution in accordance with the provisions contained in the Uniform Licensing Act.
- J. The board may take any other action with regard to the complaint which is within its authority and which is within the law, including referring the complaint to the attorney general and/or the district attorney for prosecution of persons alleged to be practicing without a valid license.

[11/7/1998; 16.26.8.10 NMAC - Rn, 16 NMAC 26.8.10, 2/3/2006; A, 1/29/2015; A, 11/28/2017]

### **16.26.8.12 DISCIPLINARY**

ACTION: In accordance with the Uniform Licensing Act, the board has authority to impose penalties in disciplinary matters and may deny, revoke, suspend or impose conditions on a license. The Uniform Licensing Act allows discipline in many forms including but not limited to fines, letters of reprimand, corrective action plans, suspension, and revocation of license.

**A.** Formal letter of reprimand: The board shall have

discretionary authority to issue formal letters of reprimand or warning instead of revocation or suspension. Issuance of formal letters of reprimand shall be subject to the provisions of the Uniform Licensing Act and shall be matters of public record.

- B. Notice of
  Contemplated Action: The board may
  issue a notice of contemplated action
  (NCA) when appropriate.
- [B] (C). Prehearing motions: The board may appoint a hearing officer to decide non-dispositive motions filed prior to a hearing. Until such time as the board appoints a hearing officer, the chair of the board shall serve as hearing officer.
- [€] (D). Settlement agreements: Following the issuance of a notice of contemplated action, the board may enter into a settlement agreement with the respondent as a means of resolving a complaint.
- [Đ] (E). Costs of disciplinary proceedings: Licensees or applicants shall bear all costs of disciplinary proceedings unless they are excused by the board from paying all or part of the fees, or if they prevail at the hearing and an action in Section 61-1-3 NMSA 1978 of the Uniform Licensing Act is not taken by the board.
- [£] (F). Uniform licensing provisions: In accordance with Subsection G of Section 61-1-7 NMSA 1978 of the Uniform Licensing Act, a licensee who directly or through an agent intimidates, threatens, injures or takes any adverse action against a person for providing information to the board shall be subject to disciplinary action.
- [F] (G). License returned to the board: Any license, renewal license or temporary permit issued by the board must be returned to the board subsequent to revocation or suspension. Unless otherwise ordered by the board, a licensee or permit holder whose license has been suspended or revoked must return [his/her] the license or permit to the board no later than 30 days from reciept of a final order of suspension or revocation.

[G] (H). Federal fraud and abuse data bank: As required by federal law, final adverse disciplinary actions taken by the board against applicants or licensees will be reported to the federal health care integrity and protection data bank (or its successor data bank), which was established by the enactment of the federal Health Insurance Portability and Accountability Act of 1996. [11/719/98; 16.26.8.12 NMAC - Rn, 16 NMAC 26.8.12, 2/3/2006; A, 1/29/2015; A, 11/28/2017]

# SPEECH-LANGUAGE PATHOLOGY, AUDIOLOGY AND HEARING AID DISPENSING PRACTICES BOARD

This is an amendment to 16.26.10 NMAC, Section 8, effective 11/28/2017.

## 16.26.10.8 PROVISIONS FOR EMERGENCY LICENSURE:

[Speech-language] A speech-language pathologist, audiologist [and] or hearing aid dispenser currently licensed and in good standing, or otherwise meeting the requirements for New Mexico licensure in a state in which a federal disaster has been declared, may be licensed in New Mexico during the four months following the declared disaster at no cost upon [satisfying the following requirements: receipt by the board of a completed application that has been signed and notarized and that is accompanied by proof of identity, that may include a copy of a driver's license, passport or other photo identification issued by a governmental entity accompanied by an affidavit that the applicant was personally or professionally affected by the disaster.

[(1) receipt by the board of a completed application that has been signed and notarized and that is accompanied by proof of identity, that may include a copy of a driver's license, passport or other photo identification issued by a governmental entity;

(2) refer to 16.26.3.9, 16.26.3.10 and 16.26.3.11 NMAC and Section 61-14B-12.1 NMSA 1978;

affidavit that the applicant was personally or professionally affected by the disaster; the board will verify the qualifications of the applicant.

**B.** The board may waive the following requirements for <u>emergency</u> licensure:

(1) application and initial license fee:

examination for hearing aid dispensers (the applicant will be required to take and pass the practical exam within six months from the date the emergency license is issued); and

jurisprudence exam (the applicant will be required to take and pass the jurisprudence exam within 60 days from the date the emergency license is issued).

C. The board may waive [the specific] required forms [required under 16.26.3.9, 16.26.3.10 and 16.26.3.11 NMAC and Section 61-14B-12.1 NMSA 1978,] if the applicant is unable to obtain documentation from the federal declared disaster [areas] area.

applicant for licensure as a speechlanguage pathologist may submit a sworn affidavit if [they are] the applicant is unable to produce the following documentation:

transcripts verifying a master's degree in speech-language pathology or communication disorders;

certificate of clinical competence issued by the American speech-language hearing association (ASHA).

An applicant for licensure as an audiologist may submit a sworn affidavit if [they are] the applicant is unable to produce [the following] documentation that the applicant:

(a)

holds a master's degree in audiology or communication disorders; or an equivalent degree in audiology or communication disorders; or an equivalent degree awarded prior to January 1, 2007; meets the academic requirements for certification of clinical competence from a nationally recognized speech language or hearing association in the area that the applicant is seeking licensure; or

(b)

holds a doctoral degree in audiology or equivalent degree regardless of degree name and meets academic requirements for certification by a nationally recognized hearing association; and

(c)

has completed the current academic, practicum and employment requirements of a nationally recognized speech-language or hearing association; and has passed a nationally recognized standard examination in audiology.

(3) [If an]

An applicant for an emergency hearing aid dispenser <u>license</u> or an endorsement to dispense may submit a sworn affidavit [if they are] that the <u>applicant is</u> unable to produce the following documentation:

(a)

proof the applicant has a high school education or equivalent;

**(b)** a

business location in New Mexico;

(c)

proof of passing the HIS, or the NBC-HIS hearing aid written examination or a nationally recognized hearing aid [dispensers] dispenser examination approved by the board or other exams approved by the board with an overall score of at least seventy percent;

(d)

proof of passing a practical examination with an overall score of at least seventy percent; if the applicant has not taken the practical exam, [he/she] the applicant must take it within six months from the date the emergency license is issued; failure to pass the required practical exam will result in termination of the emergency license.

D. Nothing in this

section shall constitute a waiver of the requirements for licensure contained in 16.26.3.9, 16.26.3.10 and 16.26.3.11 NMAC.]

[E] D. Licenses issued under 16.26.10 NMAC shall expire six months following the date of issue, unless the board or an agent of the board approves a renewal application. Application for renewal shall be made on or before the expiration date, following the date of issue to avoid late renewal fees. The board reserves the right to request additional documentation, including but not limited to, recommendation forms and work experience verification forms prior to approving license renewal.

SPEECH-LANGUAGE PATHOLOGY,

[16.26.10.8 NMAC - N/E, 11/9/2005;

A, 2/3/2006; A, 11/28/2017

## AUDIOLOGY AND HEARING AID DISPENSING PRACTICES BOARD

This is an amendment to 16.26.11 NMAC, section 8, effective 11/28/2017.

## 16.26.11.8 APPLICATION REQUIREMENTS:

- **A.** Applications for registration shall be completed on a form provided by the board.
- **B.** A completed application shall include:
- (1) The required fee as outlined in 16.26.6 NMAC;

**(2)** 

Satisfactory evidence that [the-applicant holds a license that is-current and in good standing, issued by another jurisdiction, including a branch of armed forces of the United States, that has met the minimal licensing requirements that are substantially equivalent to the licensing requirements for the occupational or professional license the applicant applies for pursuant to Chapter 61, Articles 14B NMSA

1978; and] the applicant for licensure for a military service member, spouse or veteran from another state holds a current license in good standing with no pending disciplinary action, provided the requirements for the current license held meet or exceed requirements for licensure for Speech Language Pathology, Audiology or Hearing Aid Dispensing in the State of New Mexico; and

(3) Proof of honorable discharge (DD214), military ID card, or other recognized proof of military spouse status. [16.26.11.8 NMAC - N, 1/29/2015; A, 11/28/2017]

# WORKERS' COMPENSATION ADMINISTRATION

After the public hearing on October 27, 2017, the director of the Workers' Compensation Administration, repealed the rule 11.4.4 NMAC titled Workers' Compensation - Claims Resolution, filed October 1, 2014 and replaced it with 11.4.4 NMAC, titled Workers' Compensation - Claims Resolution, adopted November 13, 2017 and effective January 1, 2018.

# WORKERS' COMPENSATION ADMINISTRATION

TITLE 11 LABOR AND WORKERS COMPENSATION CHAPTER 4 WORKERS' COMPENSATION PART 4 CLAIMS RESOLUTION

11.4.4.1 ISSUING AGENCY: Workers' Compensation Administration ("the WCA"). [11.4.4.1 NMAC - Rp, 11.4.4.1 NMAC, 1/1/18]

11.4.4.2 SCOPE: These rules apply to parties involved in claims arising under the Workers' Compensation Administration Act and Occupational Disease and

Disablement Law (collectively "the act").

[11.4.4.2 NMAC - Rp, 11.4.4.2 NMAC, 1/1/18]

## 11.4.4.3 STATUTORY AUTHORITY: Section 52-5-4

NMSA 1978 authorizes the director to adopt reasonable rules and regulations for effecting the purposes of the act. [11.4.4.3 NMAC - Rp, 11.4.4.3 NMAC, 1/1/18]

### **11.4.4.4 DURATION:**

Permanent.

[11.4.4.4 NMAC - Rp, 11.4.4.4 NMAC, 1/1/18]

### **11.4.4.5 EFFECTIVE**

**DATE:** January 1, 2018, unless a later date is cited at the end of a section. [11.4.4.5 NMAC - Rp, 11.4.4.5 NMAC, 1/1/18]

### **11.4.4.6 OBJECTIVE:**

The objective of 11.4.4 NMAC is to establish rules governing the resolution of claim disputes under the act, including but not limited to the process for filing and service of pleadings and the conduct of mediation conferences, discovery, and formal hearings.

[11.4.4.6 NMAC - Rp, 11.4.4.6 NMAC, 1/1/18]

## **11.4.4.7 DEFINITIONS:** See 11.4.1.7 NMAC.

A. "Initial pleading" means a workers' compensation complaint, application to workers' compensation judge, application to director, petition for lump sum payment, or notice of change of HCP that opens or reopens an action or case before the WCA.

**B.** "Insurer" means any workers' compensation insurance carrier, a self-insured association or group, an individual self-insured employer, or a third party claims administrator operating in the state of New Mexico.

C. "Party representative" means an individual or firm that enters an appearance before the WCA to represent or advocate on behalf of a named party. This may

include attorneys licensed to practice law in the state of New Mexico, as well as claims administration or adjusting personnel.

[11.4.4.7 NMAC - Rp, 11.4.4.7 NMAC, 1/1/18]

#### 11.4.4.8 **OMBUDSMAN RULES:**

An ombudsman shall provide information and facilitate communication regarding the act. An ombudsman is required to maintain a neutral position when providing information or facilitating communication. When responding to inquiries, an ombudsman shall:

(1) confer with workers, employers, insurers, HCPs or other interested persons;

provide information or facilitate communication, when requested, about:

(a)

individual rights and responsibilities established by the act;

medical proof required to establish or deny the right to workers' compensation;

(c)

HCP selection;

mediation conferences, related forms, and other administrative practices and procedures;

(e)

determination of disability:

(f)

the right to representation by a lawyer or the right to proceed as a pro se party; and

other disputes arising under the act, except where prohibited by Subsection B of 11.4.4.8 NMAC;

> (3) help

workers, employers, insurers, HCPs or other interested parties complete mediation and HCP selection forms for submission to the administration;

actively (4) inquire into matters presented by workers, employers, insurers, HCPs or other interested persons. An ombudsman shall contact the parties involved and attempt to resolve the

problem informally; and

(5) refer all inquiries concerning uninsured employers to the WCA employer compliance bureau.

B. An ombudsman shall not:

(1) practice law or give legal advice;

act as an advocate for any person;

(3) attend a mediation conference as a representative of a party;

(4) provide assistance to any party beyond mediation;

provide (5) assistance to a party represented by an attorney;

offer an opinion on whether to accept or reject a settlement offer or a recommended resolution; or

(7) be called as a witness in a mediation conference or adjudication proceeding before a WCA judge.

[11.4.4.8 NMAC - Rp, 11.4.4.8 NMAC, 1/1/18]

### FILING AND 11.4.4.9 **SERVICE:**

A. General provisions:

WCA (1)

employees shall be addressed in a courteous and respectful manner at all times.

(2) Unless otherwise stated or necessarily implied in these rules, the rules of civil procedure for the district courts of New Mexico shall apply to and govern all proceedings conducted pursuant to these rules.

Pleadings (3) filed with the WCA Clerk shall:

include a caption identifying the state of New Mexico workers' compensation administration as the legal forum, the name of each party, a descriptive title of the document, and the WCA case number if one has been assigned; and

contain the signature of the party in interest or party representative(s)

followed by the typewritten name(s).

(4) Duplicate or multiple copies of the same pleading shall not be filed. Duplicate copies will not be docketed and may be destroyed.

(5) Amended or subsequent pleadings shall be clearly identified (e.g., "second complaint").

(6) Pleadings shall not be submitted to the clerk by facsimile transmission.

Pleadings shall not be submitted with cover letters or correspondence.

Parties (8) shall use the mandatory forms available on the WCA website. Items on the mandatory forms may not be deleted, but additional information may be provided at the end of the text. Mandatory forms include:

workers' compensation complaint;

summons for workers' compensation complaint;

(c)

worker's authorization for use and disclosure of health records;

informal response to workers' compensation complaint;

notice of acceptance or rejection of recommended resolution;

(f)

application to workers' compensation judge;

(g)

summons for application to workers' compensation judge;

(h)

subpoena or subpoena duces tecum;

(i)

request for setting;

(i)

health care provider disagreement

(k)

petition for lump sum payment;

summons for petition for lump sum payment;

joint request for expedited hearing;

(n)

application to director; and

(o)

summons for application to director.

(9) Filing of

initial pleadings:

(a)

The workers' compensation complaint shall be filed with a summons and, if filed by a worker, with an executed authorization to release the worker's medical information

(b)

The application to judge, application to director, or petition for lump sum payment shall be filed with a request for setting. A summons shall also be filed if no service of process has previously occurred in the case.

(10) WCA

clerk's review of submitted pleadings:

a)

The clerk may reject pleadings that do not conform to these rules. Rejected pleadings will not be filed and will be destroyed.

(b)

The clerk shall promptly notify the filing party or party representative of a rejection and the reason(s) for the rejection.

(c)

The clerk's rejection of a pleading does not extend or stay the period in which a pleading is due or otherwise delay an applicable deadline.

(d)

Reasons for rejecting a pleading may include, but are not limited to:

(i)

the caption, WCA number, or party information is not correct;

(ii)

the pleading is unsigned;

(iii)

the document is incomplete or pages are missing;

(iv)

the document is of such poor quality making the content unreadable;

(v)

the pleading was not submitted on a mandatory form; and

(vi)

initial pleadings to open or reopen the case were not submitted.

**B.** Electronic Filing:

(1) Effective

January 1, 2018, unless exempted

herein, all pleadings filed with the WCA shall be filed, served, and received by electronic means through the My E-File portal on the WCA website.

(2) E-filing is not mandatory for pro se workers or for uninsured employers; however, pro se workers and uninsured employers are encouraged to register and use My E-File.

(3)

All insurers providing workers' compensation coverage in New Mexico shall register with the WCA with a single, general delivery, e-mail address for receipt of documents including initial pleadings. Insurers shall promptly update the WCA on any changes to the registered email address.

(4) All party representatives, including attorneys and adjusters, shall register with the WCA with a single, general delivery, e-mail address and thereby consent to receive documents from other party representatives and the WCA at that address. Party representatives shall promptly update the WCA on any changes to the registered email address.

parties shall be familiar and comply with the My E-File filing requirements set forth in the WCA's My E-File user guide available on the WCA website.

(6) The WCA shall not be responsible for inoperable email addresses, unread email, or undeliverable emails.

(7) Pleadings filed through My E-File shall contain the electronic signature of the party in interest or party representative denoted by either a graphic version of the signature or an "s/" followed by signatory's typewritten name.

(8) The date that a pleading is filed through My E-File is the filing date for the purpose of filing deadlines. For purposes of electronic transmission, a day begins at 12:01 a.m. and ends at midnight.

(9) Registered parties shall have access through My

E-File to case documents after the final date of disposition in accordance with WCA electronic storage capabilities. The clerk shall provide paper copies of pleadings to parties and party representatives upon receipt of a records request. The clerk shall charge a reasonable fee for each copy requested. If the requested copies are mailed, adequate postage for mailing must be paid to the clerk.

**C.** Service of process:

(1) Initial

pleadings;

(a)

The clerk shall serve initial pleadings on a responding party. Service shall be accomplished through the My E-File system for registered parties or by certified mail for pro se workers or uninsured employers who have not registered to use My E-file. When the clerk's attempt at service is unsuccessful, the clerk shall notify the filing party using the e-mail address or postal address provided at the time of filing. The filing party shall then be responsible for service on the responding party.

(b)

An employer's insurer is the employer's registered agent for service of process of an initial pleading. If an employer is uninsured, the initial pleading shall so state and the clerk shall then serve the uninsured employer and the uninsured employers' fund separately.

(2) All other

pleadings;

(a

All pleadings generated by the WCA, including but not limited to orders and notices, shall be served by the clerk through My E-File except that the clerk shall serve all unregistered pro se workers and uninsured employers by U.S. mail.

(b)

The clerk shall serve notice of all other filed pleadings on registered parties and the parties shall be responsible for logging into the My E-File system to access said pleadings.

(c)

Unregistered pro se workers and uninsured employers shall be

responsible for service on all parties of record. Service on unregistered pro se workers and unregistered uninsured employers shall be the responsibility of the filing party.

D. The clerk shall accept a notice of lien filed by the child support enforcement bureau of the New Mexico department of human services. The notice of lien shall state the worker's name and social security number, and the total dollar amount of the lien. The notice of lien shall include a copy of the district court order requiring the payment of child support by the worker.

[11.4.4.9 NMAC - N, 1/1/18]

#### 11.4.4.10 MEDIATION **RULES:**

Mediation of complaints:

cases.

The (1) director's designee, a mediator, shall evaluate all initial complaints in new

The mediator shall evaluate and mediate the merits of the complaint for jurisdiction, proper parties, compensability, the nature and extent of any benefits due the worker, and the strength or availability of any defenses. A mediator may also evaluate the compliance of the parties with the mediation rules.

В. Mandatory production:

(1) The purpose of mandatory production is to ensure that the parties and the mediator have access to all pertinent information regarding the issues disputed in the complaint.

No later (2) than five days before the mediation, the parties shall exchange any and all of the following within the parties' possession:

medical records, including unpaid bills;

(b)

payroll records;

(c)

witness statements; and

(d)

any other documents related to a claim or defense.

(3) The documents outlined above need not be produced if they are unrelated to a claim or defense, were previously produced, or if there is a good faith objection or privilege.

(4) Parties shall deliver mandatory production directly to the mediation bureau. Mandatory production delivered to the mediation bureau shall not be part of the case record, although parties may file a notice with the clerk indicating compliance with the rule. Mandatory production shall be destroyed by the WCA following issuance of the recommended resolution.

C. Mediation conferences:

> (1) Responses: (a)

Respondent shall file an informal response to the complaint not less than five days prior to the mediation conference.

The response shall include a statement of facts and affirmative defenses together with a short summary of reasons for denials of any benefits claimed.

(c)

Respondent may file an answer as set forth in this rule, in lieu of an informal response.

> (2) Bv

agreement, the parties may reschedule a mediation conference to occur within 75 days of filing the complaint.

Mediation (3) conferences shall be held at the WCA in Albuquerque unless otherwise requested by the parties and agreed to by the assigned mediator. Parties to the conference who live outside of the Albuquerque area may appear via video conference at one of the WCA's regional offices. Mediation conferences may also be conducted telephonically with prior approval from the mediator.

The mediator may recommend an amendment to the caption of the complaint to correct an improperly named party or to reflect the joining of appropriate parties who otherwise have notice or attended the mediation conference.

(5) **Purposes** of mediation conferences and duties of the mediator:

bring the parties together and attempt to settle disputed issues by discussing the facts and applicable law pertaining to the complaint and by suggesting compromises or settlements using mediation and other dispute resolution techniques;

(b)

to define, evaluate, and make recommendations on all issues remaining in dispute;

state an opinion of the strength of any argument or position, and the possible

results if the complaint is tried by a judge;

to issue a recommended resolution within 60 days of the filing of the complaint;

to

identify all potential parties;

to make a recommendation regarding attorney's fees; and

to refer any violation of these rules or the act for administrative investigation, if appropriate.

> (6) Conduct of

mediation conferences:

(a)

Mediation conferences shall be in the control of the mediator.

Each party shall come to the mediation conference prepared to discuss settlement of the case.

(c)

The mediator shall be addressed in a courteous and respectful manner by all parties.

(d)

Mediation conferences are informal meetings with no transcript of the proceedings. No motions practice shall be allowed. Conferences shall be conducted in a civil, orderly manner, with all presentation geared towards discussion and negotiation of disputed issues. Attorneys and other

representatives of the parties shall be attired in an appropriate manner, suitable to a court proceeding.

(e)

Employer and attorney, or a representative if no attorney has entered an appearance, and worker and attorney, if any, shall appear in person at the mediation conference. The mediator may enter recommendations against any party failing to attend the conference, without a reasonable excuse as determined by the mediator.

(f

Appearances by a legal assistant, paralegal, or other agent or employee of the attorney, in lieu of a personal appearance by an attorney, are prohibited. This rule does not prohibit the appearance of an employer through an adjuster or third-party administrator, nor does it prohibit a worker from attending a mediation conference with the assistance of an unpaid assistant. The attendance of any other person at the mediation conference is subject to the discretion of the mediator.

(g)

All issues may be considered at the discretion of the mediator when consistent with the goals of economy and fairness, and when an opportunity can be granted for additional response.

(h)

The parties are encouraged to prepare written narratives and summaries to assist the mediator

**D.** Recommended resolutions:

(1) The mediator shall issue the recommended resolution within 60 days of the filing of the complaint unless the parties have stipulated to a waiver of the 60-day requirement and the mediator approves. The mediator may allow additional time to supplement the file prior to issuance of the recommended resolution.

(2) The clerk shall serve a copy of the recommended resolution on parties.

(3) Service

on an unregistered party by certified

mail domestic return receipt with a signature and date of receipt shall create a presumption of receipt of the recommended resolution on the indicated date. Service through My E-File shall create a presumption of receipt upon transmission.

(4) An acceptance or rejection of the recommended resolution must be filed with the WCA clerk on or before the 30th day after transmission of the recommended resolution. A rejection shall contain a statement of the party's reasons for rejecting the recommended resolution.

(5) Effect of recommended resolution:

(a)

A rejection in whole or in part of a recommended resolution shall result in assignment to a judge for a determination of all issues in a formal hearing.

(b)

Once a party has filed an acceptance or a rejection of a recommended resolution, the party is bound to the acceptance or rejection, unless permitted to withdraw it by written order of the director. The party requesting leave to withdraw a previously filed acceptance or rejection shall submit a written application and proposed order to the director, reciting good cause, within 30 days following receipt by that party of the recommended resolution. The clerk may cancel any judge assignment when a rejection is withdrawn.

(c)

If a rejection appears to be untimely, the clerk shall notify the parties of the untimeliness. A party requesting that a rejection be considered timely shall submit a written application to the director within 60 days of receipt of the recommended resolution. The application shall state the grounds to support a finding of excusable neglect.

E. Penalties:

(1) Willful failure or refusal to participate in the mediation process shall not preclude the issuance of a recommended resolution, and may constitute bad

faith or unfair claims processing.

(2) The assigned mediator, or any party, may refer any such violation for administrative investigation by the enforcement bureau.

(3) Failure to comply with the mediation rules, including those requiring mandatory production of evidence prior to the mediation conference, or failure to cooperate with an inquiry of the enforcement bureau may subject a party to penalties.

F. Amendment of recommended resolution: The recommended resolution may be amended by a mediator or by the agreement of the parties within the time allowed for acceptance or rejection of a recommended resolution, which time shall not be expanded or modified in any way by the issuance of an amended recommended resolution.

G. A mediator's notes taken in conducting a mediation conference are not subject to discovery and shall not be admissible as evidence in any legal proceeding. [11.4.4.10 NMAC - Rp, 11.4.4.10 NMAC, 1/1/18]

## 11.4.4.11 DIRECTOR'S MATTERS:

**A.** The following matters shall be pleaded on the mandatory application to director form:

(1) judge

assignment disputes;

(2) request for relief from an untimely rejection of a recommended resolution;

(3) request to withdraw an acceptance of a recommended resolution;

(4)

appointment of a recipient of benefits for a minor child or an incompetent worker;

(5) approval of an out of state health care provider, if necessary;

(6) attorney withdrawal when no judge is assigned;

(7) objection

to case management or utilization review by the WCA; and

(8) any other matter within the director's jurisdiction.

**B.** A party responding to an application to the director may submit a written response.

C. Recipient of benefits for minors and incompetent workers:

(1) General

provisions.

(a)

"Recipient" means the individual or entity approved to receive benefit payments on behalf of a minor child or incompetent worker pursuant to Section 52-5-11 NMSA 1978.

(b)

The director may designate a judge to resolve applications brought pursuant to Section 52-5-11 NMSA 1978 when other matters are pending before the judge.

(2)

Designation of recipient.

(a)

An application to the director and request for setting shall be filed and accompanied by a summons if one has not previously been issued in the case.

(b)

The application shall have attached any applicable marriage certificate, birth certificates for all known minor children, or a record reflecting worker's incompetency.

(c)

The proposed recipient shall provide a copy of a driver's license or other state issued identification at the hearing.

(d)

When it is in the best interests of the minor child or incompetent worker, the director may designate a recipient who does not have care, custody, and control of a minor or incompetent worker.

(e)

When it is in the best interests of a minor child or incompetent worker, the director may designate a professional or corporate recipient for a minor or incompetent worker. The employer shall pay reasonable administrative fees requested by the alternative recipient and approved by the director.

(f)

As a condition of appointment, the recipient must agree to manage and protect benefit payments for the benefit of the minor child or incompetent worker.

(g)

A minor child who has reached the age of 16 may apply to the director to receive benefit payments directly.

(3)

Accounting of benefits.

(a)

The director may require an accounting of how benefits were used on behalf of a minor child or incompetent worker. Unless otherwise ordered by the director, accountings shall be submitted on the approved form and shall be submitted quarterly for the first year and annually thereafter.

(b)

The director may suspend benefit payments, in whole or in part, for failure to provide the ordered accounting of benefits or failure to comply with any other condition placed on the recipient.

[11.4.4.11 NMAC - Rp, 11.4.4.11

### 11.4.4.12 HCP RULES:

**A.** HCP general

provisions:

NMAC, 1/1/18]

(1) These rules apply to claims governed by the 1990 amendments to the act.

(2) The assigned judge shall decide HCP choice disputes. If no judge has been assigned, a judge shall be appointed by the clerk solely to resolve the HCP dispute.

judge appointed by the clerk is not assigned pursuant to Subsection C of Section 52-5-5 NMSA 1978 (Repl. Pamp. 1991). The peremptory right to disqualify a judge allowed by Subsection D of Section 52-5-5 NMSA 1978 (Repl. Pamp. 1991), does not apply to the appointment of the HCP judge.

**B.** HCP choice:

(1) Emergency care: The provision of emergency medical care shall not be considered a choice of a treating HCP by the employer or worker.

(2) Selection

of HCP:

(a)

The employer shall decide either to select the initial HCP or to permit the worker to select the initial HCP. The decision made by the employer shall be made in writing to the worker. Employer may communicate the decision to select the initial HCP or to permit the worker the selection by any method reasonably calculated to notify workers. The employer may use a wallet card, a poster stating the decision posted with the WCA poster, a flyer inserted semi-annually with pay checks, or any other method employer reasonably believes will be successful in alerting the worker.

(b)

If the decision of the employer is not communicated in writing to the worker, then the medical care received by the worker prior to written notification shall not be considered a choice of treating HCP by either party.

(c)

Medical treatment provided to the worker prior to the employer's written communicated decision to either select the HCP, or to permit the worker to select the HCP, shall be considered authorized health care, the cost of which shall be borne by the employer.

(d)

If a provider not licensed in New Mexico treats a worker, the employer must, upon receipt of the initial billing from that provider, either request approval of the out-of-state HCP pursuant to the act, or immediately notify the worker in writing that the provider is not acceptable pursuant to Section 52-4-1 NMSA 1978 (Repl. Pamp. 1991).

**C.** Referrals by an authorized HCP:

(1) A referral by an authorized HCP to another HCP shall be deemed a continuation of the selection of the referring HCP.

- (2) The 60 day effective period allowed in Subsection B of Section 52-1-49 NMSA 1978 (Repl. Pamp. 1991), is not enlarged by the HCP's referral.
- Notice of change of D. HCP:
- The 60 (1) day period of initial HCP choice shall run from the date of first treatment or examination by, or consultation with, the initial HCP.
- The notice (2) of change of HCP shall provide:

name, address and telephone number

of worker, employer and insurance carrier, if any;

date and county of accident;

nature of injury;

(d)

the names, addresses and telephone numbers of the current and proposed HCPs;

(e)

the signature of the party requesting the change of HCP; and

the following text: "your rights may be affected by your failure to respond to this notice; if you need assistance and are not represented by an attorney, contact an ombudsman of the WCA."

- After 50 days of the initial 60 day period, the party denied the initial selection may give notice of change of HCP.
- Issuance of notice Ε. of change: The party seeking the change of HCP shall issue a notice of change of HCP. A copy of the notice shall be provided to the other party 10 days prior to provision of any medical treatment by the proposed HCP.
- F. Effective date of notice of change:
- The notice (1) of change shall be effective, unless an objection is filed with the clerk within three days from receipt of the notice of change. A copy of the notice of change shall be attached to any objection filed with the clerk. If no objection is filed, the HCP declared on the notice of change form shall be

- designated as the authorized treating HCP and may begin treating the worker 11 days after issuance of the notice of change.
- An (2) objection can be filed after the three day period, but any bills incurred for medical treatment rendered after the effective date of the notice of change and prior to a ruling by the judge on the objection shall be paid by the employer. A party required to pay for medical treatment pursuant to this rule shall not be deemed to have waived any objections to the reasonableness or necessity of the treatment provided.
- Responsibility for G. payment of HCP services:
- The (1) employer shall be responsible for all reasonable and necessary medical services provided by an authorized HCP from the date the notice of change is effective.
- (2) The worker shall be responsible for any medical services rendered by an unauthorized HCP.
- (3) The designation of an authorized HCP shall remain in effect until modified by agreement of the parties or by order of the judge.
- Effective July 1, 2013, all medical services rendered pursuant to recommended treatment contained in the most recent edition of the official disability guidelines<sup>TM</sup> (ODG) is presumed reasonable and necessary; there is no presumption regarding any other treatment.
- H. Reasonable and necessary disputes: Disputes concerning the reasonableness and necessity of prescribed treatment may be brought before the administration pursuant to Section 11 of 11.4.7 NMAC.
- Hearing on I. objection to notice of change: If an objection to notice of change of HCP is filed with the clerk, the objection shall be heard by the judge within seven days from the filing of the objection. The judge may issue a minute order at the conclusion of the hearing on the objection.

- Request for change of HCP: If a disagreement arises over the selection of a HCP, and the parties cannot otherwise agree, a request for change of HCP must be submitted to the clerk. The request for change of HCP may be submitted at any time, including the initial 60 day period.
- K. Request for change of HCP form:
- (1) The request for change of HCP must state the specific reasons for the requested change.
- (2) The request for change of HCP may suggest an alternative HCP's name.
- Burden of proof: L. The applicant requesting a change of HCP must prove the authorized HCP is not providing the worker reasonable and necessary medical care. If the applicant fails to establish the provision of medical care is not reasonable, the request for change shall be denied.
- Hearing on request for change of HCP: The request for change of HCP disagreement shall be heard by the judge within seven days from the filing of the request for change of HCP. The judge may issue a minute order at the conclusion of the hearing on the request for change. [11.4.4.12 NMAC - Rp, 11.4.4.12 NMAC, 1/1/18]

### 11.4.4.13 ADJUDICATION **PROCESS:**

A. Assignment of judge:

- Upon (1) receipt of a timely rejection of a recommended resolution, an application to judge or petition for lump sum payment, the clerk shall assign a judge to the case and shall serve notice on all parties. Pro se parties shall be served by certified mail unless registered with My E-File. This notice shall be considered the initial notice of judge assignment.
- Each party (2) shall have the right to disqualify a judge by filing a notice of disqualification of judge no later than 10 days from the date of filing of the notice of assignment of judge. The

clerk shall assign a new judge to the case and notify all registered parties. A party who has not exercised the right of disqualification may do so no later than 10 days from the filing of the notice of reassignment of judge.

may be taken by any judge on a case until the expiration of the time for all parties to exercise the peremptory right to disqualify a judge. To expedite the adjudication process, the parties may file a joint waiver of the right to disqualify a judge. Such waiver shall forever bar the parties' right to disqualify a judge in that case.

related to the assignment, reassignment, or disqualification of a judge shall be raised by written application to the director, which shall be filed with the clerk.

director may designate an on-call judge for the limited purpose of reviewing and approving lump sum payment petitions on a voluntary walk-in basis. The director shall provide notice to the public about the schedule for any on-call judge availability. Such designation shall not be considered a judge assignment or reassignment under this section if further adjudication action is needed.

**B.** Application to judge:

(1) Unless otherwise provided, all claims under the act shall be initiated by filing a complaint form, and the clerk shall schedule the claim for mediation. A party may file an application to judge, and the clerk shall assign the case to a judge to adjudicate the following limited forms of relief only:

(a)

physical examination pursuant to Section 52-1-51 NMSA 1978;

(b)

independent medical examination pursuant to Section 52-1-51 NMSA 1978;

(c)

determination of bad faith, unfair claims processing, fraud or retaliation;

supplemental compensation order;

(e)

award of attorney fees;

(f)

stipulated reimbursement agreement pursuant to Section 52-5-17 NMSA 1978;

(g)

consolidation of payments into quarterly payments (not a lump sum under Section 52-5-12 NMSA 1978);

(h)

approval of limited discovery where no complaint is pending before the agency, including but not limited to approval of a communication to a treating health care provider when the parties cannot otherwise agree on the form or content; or

(i)

request for release of medical records.

(2) If any claim not enumerated above is raised on an application to judge, the application shall be deemed a complaint and the clerk shall refer it for mediation.

(3) Except for an application seeking relief for the claims enumerated above, an application to judge may not be filed if a complaint has been filed in the same case and the time period for acceptance or rejection of the recommended resolution has not yet expired. Any other claim for relief arising during that time period shall be raised in the mediation process.

(4) Following the rejection of a recommended resolution and during the pendency of a complaint, those claims for forms of relief set forth above shall be sought through motion rather than an application.

(5) Responses to an application to a judge, if any, shall be filed within 15 days of service. A response to application to judge may not raise new claims or issues.

(6) All applications to a judge shall be accompanied by a summons, if one has not previously been issued in the case, and a request for setting. Hearings as necessary may be scheduled by the assigned judge.

**C.** Petition for lump sum payment:

- (1) Parties may request approval of a lump sum payment by filing the WCA mandatory petition form, which shall be signed and verified by the worker or the worker's dependents.
- (2) Petitions under Subsection D of Section 52-5-12 shall also be signed by the employer or its representative or, where applicable, the UEF.
- (3) to lump sum payment petitions filed pursuant to Subsection D of Section 52-5-12 NMSA 1978 shall attend a lump sum payment approval hearing for a determination that the agreement is voluntary, that the worker understands the terms, conditions and consequences of the settlement agreement or any release, and that the settlement is fair, equitable and provides substantial justice to the parties. For all other joint lump sum payment petitions, a hearing may be held at the discretion of a judge pursuant to Sections 52-5-12 and 13 NMSA 1978.
- (4) Any lump sum payment petition filed pursuant to this rule shall comply with Section 52-1-54 NMSA 1978 and counsel for the parties may concurrently seek approval or award of attorney fees, if appropriate, to be heard in the context of the lump sum payment hearing.
- (5) Written responses to the petition, if any, shall be filed within 10 days of service of a petition.
- (6) All petitions shall be accompanied by a request for setting, and a summons, if one has not previously been issued in the case. Such hearings will be promptly scheduled by the assigned judge.
- process for complaints shall commence upon the clerk's receipt of a timely rejection of a recommended resolution. An answer to complaint shall be filed within 20 days of the filing of the initial notice of assignment of judge unless already filed in lieu of the informal response. The answer shall admit or deny each claim asserted in the complaint. Any

affirmative defenses to the complaint shall be stated in the answer.

- E. Amended complaints may be filed during the adjudication process only by leave of the assigned judge or by written consent of the adverse party. Leave shall be freely given when justice so requires. Amended complaints filed during the adjudication process shall not be referred back to the mediation process nor shall a new recommended resolution be issued.
- F. The judge may hold pre-trial conferences as necessary, establish appropriate deadlines, mandate evidentiary disclosures between the parties, approve formal discovery, and otherwise control all other aspects of the adjudication process in order to enable the prompt adjudication of the case.
- **G.** Discovery: Authorized interrogatories, requests for production or inspection, requests for admissions, depositions, and subpoenas shall be governed by the rules of civil procedure of the district courts of New Mexico.
- H. Depositions: Upon the filing of a complaint and by written stipulation of the parties, good cause is presumed and depositions may be taken of the worker, employer representative, authorized HCP, and any provider of an independent medical examination.
- (1) Reasonable notice shall be deemed to be not less than five days prior to the date set for the deposition.
- (2) The original deposition transcript shall be kept by the party who noticed the deposition.
- (3) The parties shall make a good faith effort to obtain a completed and signed form letter to HCP prior to setting the deposition of the HCP.
- (4) Deposition testimony of authorized HCPs shall be admissible in lieu of live testimony.

Depositions of other witnesses identified by the parties may be admissible, if noticed for use at trial, provided that nothing prohibits either

party from issuing a subpoena to order the deposed witness to testify at trial.

- (6) A party intending to use a deposition shall notify the other party of the intended use at least 10 days prior to trial. Any objection to the use of the deposition shall be determined at the adjudication hearing.
- (7) The party that notices a deposition may request the return of the original transcript after final disposition of the case. The clerk may return a transcript or any exhibits tendered to the submitting party or its attorney. If no request for the deposition or exhibits is received, the deposition or exhibits will be destroyed. Notice of intent to destroy exhibits is published in the New Mexico bar bulletin.
- I. Subpoenas: The clerk may issue a subpoena, signed but otherwise blank, to a party requesting it, who shall complete it before service. An attorney authorized to practice law in New Mexico who represents a party before the WCA may also issue and sign a subpoena as an officer of the court on behalf of the WCA.
- **J.** Appointment of interpreter:
- (1) It is the responsibility of the parties to determine if interpretive services are necessary.
- (2) An interpreter may be appointed by the judge, director, or mediator. The interpreter shall be court-certified, except that a non-certified interpreter may serve at mediation conferences.
- (3) The employer shall be responsible for the cost and arrangement of a qualified interpreter for the hearing or mediation conference. This responsibility may fall to the uninsured employers' fund when named as a party.
- **K.** Motions: All motions, except those made in open court, shall be written and comply with the New Mexico district court rules of civil procedure.
  - L. Settlement/pre-trial

conferences: The judge shall have discretion to schedule settlement conferences. A settlement conference facilitated by the assigned judge shall require the consent of all parties either on the record or in writing.

- M. Orders: Proposed orders or other documents requiring a judge's signature shall not be filed with the clerk but shall be submitted directly to the judge.
- **N.** Admissibility of evidence:
- (1) Live medical testimony shall not be permitted, except by an order of the judge.
- (2) A judge may admit the following documentary evidence, including hearsay evidence, provided that the evidence is relevant, has sufficient indicia of reliability and authenticity, and will assist the judge in determining a fact or issue in dispute:

personnel records, payroll records, or other employment files for worker;

pre-injury medical records of treatment received for a period of 10 years prior to the date of injury through the time of hearing on the merits:

(c) form letters approved by the WCA;

records of authorized health care providers and their referrals, including functional capacity evaluations;

reports of independent medical examinations ("IMEs") performed pursuant to the act or as otherwise agreed by the parties;

(f) toxicology or drug and alcohol test reports;

records of the office of medical examiner, including autopsy and toxicology reports; or

(h) records of the New Mexico board of pharmacy prescription monitoring program.

**O.** Continuance of hearing: A judge may continue an

adjudication hearing for good cause shown. All discovery, disclosure, and exchange deadlines shall be extended by a continuance unless otherwise ordered.

- **P.** Trials and other hearings:
- shall appear personally at the adjudication hearing, without the necessity of a subpoena. Parties shall appear personally or through their legal representatives at all other hearings properly noticed, unless excused by a judge.
- (2) Failure to appear at a hearing after proper notice and without good cause may result in the imposition of sanctions.
- (3) The employer shall make all necessary arrangements and pay all costs incurred for telephonic conference calls. The director or judge may appear telephonically for the conference call.
- (4) All hearings shall be recorded by audio tape recording or by any other method approved by the director.
- (5) Prior to commencement of the adjudication hearing, the parties shall confer with the court monitor to ensure that all exhibits are properly marked. Any exhibit to be jointly tendered shall be marked and offered as a joint exhibit. All other exhibits shall be marked by party and exhibit number or letter. Depositions shall be marked as exhibits.
- (6) Under exceptional circumstances and in the interest of justice, a judge has discretion to direct or allow supplementation of evidence within 10 days of the close of the adjudication hearing.
  - Q. Consolidated cases:
    (1) A judge

may order the consolidation of cases when the issues or facts in dispute in the cases are common or when consolidation will expedite resolution of the issues or facts in dispute.

(2) A party may request an order for consolidation of cases by filing a

motion requesting consolidation in each case sought to be consolidated and serving each party and their counsel, if any, for each case sought to be consolidated.

- (3) Motions to consolidate cases will be adjudicated by the final judge assigned to the case with the lowest case number.
- (4) A judge's order of consolidation shall be filed in each consolidated case.
- (5) After consolidation, all pleadings shall only be filed in the case with the lowest case number and the case number of each consolidated case shall appear in the caption of all pleadings.
- (6) All parties of record and their counsel shall have access to view the filed pleadings for each case.
- (7) In the event of an appeal, the notice of appeal shall include the case number for each consolidated case and shall be filed in the case with the lowest case number. The record proper on appeal shall include all pleadings in each of the consolidated cases.
- **R.** Release of medical records:
- (1) A judge shall decide medical record disputes. If no judge has been assigned, the clerk shall appoint a judge upon a party filing an application to judge for release of medical records.
- (2) An application to judge for the release of medical records shall be allowed notwithstanding the provisions of any other rule, and shall be disposed of separate and apart from all rule provisions and procedures pertaining to resolution of other disputes arising from a claim for benefits.
- (3) The judge will determine whether the protected health information in controversy is material to the resolution of any matter presently at issue or likely to be at issue in the administration of the claim and shall order the release of protected health information upon agreement of the parties or a finding of materiality by a preponderance of evidence.

- (4) A bench order or formal order of release of medical records shall have the force of law with respect to the parties and to the HCP or medical facility.
- or medical facility fails to provide records after a judge has ordered the release of records pursuant to this rule, then the party to receive the records may notify the HCP or medical facility through My E-File of the obligation to produce the records and an endorsed copy of the order. If the records are not produced within five days of service of the notice, the payer's obligation to timely pay shall be tolled until the actual production of the records.
- If any judge involved in the adjudication of the case finds that the withholding of records of health information after an order to produce has obstructed the efficient administration or adjudication of a case, then the judge may schedule a hearing to determine if the withholding of records was unreasonable. If the judge finds after notice and an opportunity to be heard that the withholding of records by the HCP or medical facility is unreasonable, the director may find the HCP or medical facility in violation of this rule and assess a penalty pursuant to Section 52-1-61 NMSA 1978 (1990). [11.4.4.13 NMAC - Rp, 11.4.4.13 NMAC, 1/1/18]

## 11.4.4.14 WITHDRAWAL AND SUBSTITUTION OF COUNSEL:

- A. The entry of appearance of an attorney or a firm for a party in a pending case shall not be withdrawn without permission of the judge or by the director if no judge has been assigned to the case. A motion to the judge or application to director requesting withdrawal shall be filed with the clerk and shall indicate whether the client concurs with the withdrawal.
- **B.** A motion to the judge or application to director seeking withdrawal of counsel shall clearly state whether the withdrawing

attorney is asserting a request for attorneys' fees for services rendered. If no statement is made, and if the motion or application to withdraw is granted, the withdrawing attorney is barred from thereafter seeking attorneys' fees for services rendered on the case. A statement asserting a request for attorneys' fees shall serve as notice to the parties and new legal counsel, if any.

- C. When a new attorney assumes a case, a notice of substitution of counsel shall be filed and served on each party. The notice shall contain the new attorney's mailing address, phone number, and e-mail address.
- **D.** The attorney of record shall be subject to notice of hearings or other proceedings until permitted to withdrawal from the case.

[11.4.4.14 NMAC - N, 1/1/18]

## 11.4.4.15 APPROVAL OF ATTORNEY FEES AND LIENS:

- A. Parties may request the award of attorney fees by application to a judge. The application must contain sufficient information to determine if the fee requested is appropriate. The contested application should indicate the date and terms of any offers of settlement made; the present value of the benefits awarded the worker, including, but not limited to medical expenses and past and future weekly benefits; the total number of hours reasonably expended by counsel to secure benefits for the worker; the hourly billing rate of counsel; and any other relevant information for the determination of fees.
- **B.** No attorney fees shall be paid until the case has been settled or adjudged. For purposes of the act, settled or adjudged includes:
  - (1) the entry of

a compensation order; or

- (2) the acceptance by both parties of a recommended resolution; or
- (3) an order granting or denying any petition or application when no other cases are pending before the administration; or

- (4) the WCA has administratively closed the file; or (5) when
- there is a good faith belief that all pending issues or questions have been resolved, whether or not the jurisdiction of the administration has been invoked.
- c. An attorney withdrawing from representation during the pendency of a case and before the case has been settled or adjudged shall assert a request for attorney fees, if any, within the motion to judge or application to director seeking to withdraw as counsel. The request for attorney fees shall not be decided until the case is settled or adjudged.
- **D.** When a subsequent attorney requests attorney fees, the attorney shall give notice to the withdrawn attorney by serving on the withdrawn attorney a copy of all relevant pleadings at the time of filing.
- E. No attorney fee lien shall be filed in a case until a judge has awarded fees pursuant to Section 52-1-54 NMSA 1978.
  [11.4.4.15 NMAC Rp, 11.4.4.14 NMAC, 1/1/18]

### **11.4.4.16 SANCTIONS:**

- A. The judge may sanction any party, attorney, or personal representative for conduct that interferes with the orderly administration of the court or a hearing, including, but not limited to:
- (1) rejecting a recommended resolution without reasonable basis, or without reasonable expectation of doing better at formal hearing;
- (2) failing to obey a lawful order of the court;
- (3) failing to appear for a hearing or deposition; or (4) advancing

a meritless position in order to harass or vex the opposing party.

- **B.** The judge will conduct a separate hearing on the imposition of sanctions according to the procedures in this part.
- C. As a sanction, the judge may do any or all of the

following:

- (1) assess reasonable attorney's fees against a party pursuant to Section 52-1-54 NMSA 1978;
- (2) reduce the fees of an attorney for a party;
- (3) assess prejudgment interest from the date of the recommended resolution in the claim;
- (4) strike a claim or defense;
- (5) limit the evidence which may be introduced;

(6) dismiss an action;

(7) order the suspension or forfeiture of compensation benefits;

(8) assess expenses and costs against a party; or (9) impose a civil penalty pursuant to Sections 52-

civil penalty pursuant to Sections 52-1-28.1, 52-1-28.2, 52-3-45.1 or 52-3-45.2 NMSA 1978.

**D.** For patterns of misconduct beyond a single case, the judge may refer the matter to the WCA enforcement bureau for further investigation, administrative prosecution and imposition of penalties.

[11.4.4.16 NMAC - Rp, 11.4.4.15 NMAC, 1/1/18]

## 11.4.4.17 SEALING OF PUBLIC COURT RECORDS:

- A. Public court records filed with the clerk of court or offered as evidence in an administrative or adjudicative hearing shall not be sealed based solely on the agreement or stipulation of the parties.
- B. The party requesting to seal court records subject to public inspection shall establish the same requirements for sealing court records as set forth in the rules of civil procedure for the district courts of New Mexico.
- C. The order sealing the court records may seal the records from public inspection but shall not prohibit WCA staff from accessing the court record as necessary to enforce the provisions of the act.

  [11.4.4.17 NMAC Rp, 11.4.4.17

NMAC, 1/1/18]

## **HISTORY OF 11.4.4 NMAC:**

**Pre-NMAC History:** The material in this part was derived from that previously filed with the State Records Center:

WCA 86-1, Informal Hearing Procedures, filed 5/26/87. WCD 89-1, Mediation Rules, filed 6/20/89.

WCA 92-2, Workers' Compensation Administration Mediation Rules, filed 2/24/92.

WCA 92.2, Rules Governing Mediation, filed 10/30/92. WCA 93.2, Rule Governing Mediation, filed 10/28/93. WCA 86-2, Formal Hearing Procedures, filed 5/26/87. WCD 89-2, Formal Hearing Rules, filed 6/20/89.

WCA 92.3, Rules Governing Formal Hearings, filed 10/30/92.

WCA 86-7, Attire, filed 5/26/87.

WCD 89-7, Attire, filed 6/20/89.

WCD 89-8, Workers' Compensation

Division Forms, filed 6/20/89.

WCA 91-1, Miscellaneous

Proceedings and Preliminary

Questions of Fact, filed 1/24/91.

WCA 91-1, Miscellaneous

**Proceedings and Preliminary** 

Questions of Fact, filed 5/29/91.

WCA 92.1, Rules Governing

Miscellaneous Proceedings and Preliminary Questions of Fact, filed 10/30/92.

WCA 93.1, Rules Governing Miscellaneous Proceedings and Preliminary Questions of Fact, filed 10/28/93.

### **History of Repealed Material:**

11.4.4 NMAC, Claims Resolution, filed 5/20/1996, repealed effective 10/1/2014.

11.4.4 NMAC, Claims Resolution, filed 10/1/2014, repealed effective 1/1/2018.

## **End of Adopted Rules**

## Other Material Related To Administrative Law

## ATTORNEY GENERAL, OFFICE OF THE

### NOTICE OF PROPOSED FORM

The Attorney General, pursuant to NMSA 1978, Section 57-31-5, is proposing to publish a form Distributed Generation Disclosure Statement that may be used to provide the disclosures required by the Distributed Generation Disclosure Act, Sections 57-31-1 to 57-31-5 NMSA 1978 (2017), for agreements with buyers or lessees. The notice and form will be published in the November 28, 2017, New Mexico Register.

The proposed form is available at the Office of the Attorney General located in the Paul Bardacke Attorney General Complex in Santa Fe located at 408 Galisteo Street, Consumer & Environmental Protection Division; at the Attorney General's Office located in Albuquerque at 201 3rd Street NW, Suite 300; and at the Attorney General's Office located in Las Cruces at 201 North Church Street, Suite 315.

The proposed form is also posted on the Office of the Attorney General's website and may be accessed, free of charge, from the following website: www.nmag.gov.

To request that a copy of the proposed form be mailed to you, please submit your request in writing to:

Office of the Attorney General Consumer Protection Division Attention: Cholla Khoury P.O. Drawer 1508 Santa Fe, NM 87504-1508

You may also request a copy of the proposed form by calling the following telephone number: 1-844-255-9210. There is a \$.25 copying charge per page for written and telephone requests for copies of the proposed form.

You may also request a copy of the proposed form by emailing: ckhoury@nmag.gov, subject line: "57-31-5 proposed form."

Any person who is or may be affected by this proposed form may submit written comments.

Written comments concerning the proposed form may be submitted by mail to:

Office of the Attorney General Consumer Protection Division Attention: Cholla Khoury P.O. Drawer 1508 Santa Fe, NM 87504-1508

The Office of the New Mexico Attorney General will accept written comments for consideration provided on or before December 13, 2017.

## Distributed Generation Disclosure Statement Month /Day/2018

I. Party Information (H.B. 199, Section 3(A)(1-3)		
(Buyer or Lessee)		
Name:		
Address:		
Telephone:		
Email:		
System Installer		
Name:		

## 1145 New Mexico Register / Volume XXVIII, Issue 22/ November 28, 2017

Addre	SS:
Telepl	none:
Email	
State (	Contractor's License:
Maint	tenance Provider (if different from installer)
	<u> </u>
Addre	SS:
Teleph	none:
Email	:
State	Contractor's License:
II.	(Price or Payments) (H.B. 199, Section $3(A)(7)$ , (9)
The To	otal Purchase price including the Cost of Financing: \$
	Projected Cost of Lease or Power Purchase Payments: \$
	Th
III.	(Financing or Leasing) (if applicable) (H.B. 199, Section 3(A)(9)
\$	Total Amount Financed
\$	Payment Amount
%	Annual Percentage Rate
<b>&gt;</b>	Total CostTotal Number of Payments
	Payment Frequency
	Payment Due Date
	1 ayment bue bate
IV.	Fees (H.B. 199, Section 3(A)(8)
A)	\$ Late Fee (Include the circumstances triggering any late fees.) See (Identify
	ge(s) and paragraph(s) of the contract provision(s) that addresses this fee.)
B)	\$Estimated System Removal Fees. See (Identify the page(s) and paragraph(s)
	contract provision(s) that addresses this fee.)
C)	\$ Uniform Commercial Code notice removal and refiling fees. See (Identify
the pa	ge(s) and paragraph(s) of the contract provision(s) that addresses this fee.)
D)	\$ Maintenance Fees. See (Identify the page(s) and paragraph(s) of the contract
	ion(s) that addresses this fee.)
E)	\$ Internet Connection Fees. See (Identify the page(s) and paragraph(s) of the
	ct provision(s) that addresses this fee.)
F)	\$ Automated Clearing House Fees. See (Identify the page(s) and paragraph(s)
	contract provision(s) that addresses this fee.)
G)	\$(List one-time or recurring fees.) See (Identify the page(s) and paragraph(s)
	contract provision(s) that addresses this fee.)
H)	\$(List one-time or recurring fees.) See (Identify the page(s) and paragraph(s)
	contract provision(s) that addresses this fee.)
I)	\$(Add spaces as needed.)
V.	Tax Credits, Rebates and Incentives and Renewable Energy Certificates: The distributed energy system
	ible for the following: (H.B. 199, Section 3(A)(10, 11)
A)	\$ (Identify Each Tax Credit.) (Describe whether, the buyer, lessee, seller or
marke	ter owns the credit, whether the seller or marketer used the credit in determining the price of the system and
descri	be the transferability of the credit.) See (Identify the page(s) and paragraph(s) of the contract provision(s) that
addres	sses this credit.)
B)	\$ (Identify Each Tax Rebate.) (Describe whether, the buyer, lessee, seller or
	ter owns the rebate, whether the seller or marketer used the rebate in determining the price of the system and
	be the transferability of the rebate.) (Describe the ownership and transferability.) See (Identify the page(s) and
paragr	raph(s) of the contract provision(s) that addresses this rebate.)
C)	\$ (Identify Each Tax incentive.) (Describe whether, the buyer, lessee, seller or
	ter owns the incentive, whether the seller or marketer used the incentive in determining the price of the system and
descri	be the transferability of the incentive.) See (Identify the page(s) and paragraph(s) of the contract provision(s) that

address	s this incentive.)
D)	\$ (Identify Each Renewable Energy Certificate(s).) (Describe whether, the
	ssee, seller or marketer owns the certificate, whether the seller or marketer used the certificate in determining the
	he system and describe the transferability of the certificate.) See (Identify the page(s) and paragraph(s) of the
contrac	provision(s) that addresses this fee.)
E)	\$ (Add spaces as needed.)
F)	\$(Add spaces as needed.)
VI.	Tax Obligations – You are required to pay the following tax obligations: (H.B. 199, Section 3(A)(12)
A)	\$Business Personal Property Taxes. See (Identify the page(s) and paragraph(s)
of the o	ntract provision(s) that addresses this tax obligation.)
B)	\$ Gross Receipts Taxes: (Identify the page(s) and paragraph(s) of the contract
provisi	n(s) that addresses this tax obligation.)
C)	\$ Tax Credit(s) or Incentive(s) (Describe Obligations of the power purchaser
or lesse	to transfer tax credits or tax incentives of the distributed energy generation system to any other person.) See
(Identi	the page(s) and paragraph(s) of the contract provision(s) that addresses this tax obligation.)
D)	\$ (In the case of a commercial installation) Change In Assessed Property Taxes
See (Id	ntify the page(s) and paragraph(s) of the contract provision(s) that addresses this tax obligation.)
with th  (Identi: (Identi: the pag B) of the capprov transfe	
	arty Approver Identification (if known):
Name:	
Addres Teleph	
reiepn A)	(Whether the warranty or maintenance obligations related to the distributed energy generation system may be
/	can remark to a third party.) See (Identify the page(s) and paragraph(s) of the contract provision(s) that addresses
soiu oi transfe	
HAUSTE	DHILV. I

- (Notice to the buyer or the lessee of the transferability of any warranty obligations to subsequent buyers or B) lessees.) See (Identify the page(s) and paragraph(s) of the contract provision(s) that addresses transferability.)

### **Performance Guarantees** (H.B. 199, Section 3(A)(6)

(Any performance guarantees that a seller or marketer may include in an agreement.)

### **Design Assumptions** (H.B. 199, Section 3(A)(5)

(The distributed energy generation system design assumptions, including: system size; estimated first-year production; and estimated annual system production decreases, including the overall percentage degradation over the life of the distributed energy generation system.)

### Savings Assumptions (H.B. 199, Section 3(A)(16)

(The assumptions used for any savings estimates that were provided to the buyer or lessee.)

#### XI. Rates Disclosure (H.B. 199, Section 3(A)(17)

Actual utility rates may increase or decrease and actual savings may vary. For further information regarding rates, you may contact your local utility or the Public Regulation Commission. Tax and other state and federal incentives are subject to change.

## 1147 New Mexico Register / Volume XXVIII, Issue 22/ November 28, 2017

## **XII.** Interconnection Disclosure (H.B. 199, Section 3(A)(19)

Interconnection requirements, including time lines, are established by rules of the Public Regulation Commission and may be obtained from either the Public Regulation Commission or the local utility.

### XIII. Right to Rescind (H.B. 199, Section 3(A)(4)

(Buyer or Lessee) shall retain the right to rescind this agreement for a period of (not less than 3 business days) after the agreement is signed.

Signature (H.B. 199, Section 3(A) (Buyer or Lessee)	
Printed Name:	-
Date:	
Signature:	

**End of Other Material Related To Administrative Law** 

## 2017 New Mexico Register

## Submittal Deadlines and Publication Dates Volume XXVII, Issues 1-24

Issue	Submittal Deadline	<b>Publication Date</b>
Issue 1	January 5	January 17
Issue 2	January 19	January 31
Issue 3	February 2	February 14
Issue 4	February 16	February 28
Issue 5	March 2	March 14
Issue 6	March 16	March 28
Issue 7	March 30	April 11
Issue 8	April 13	April 25
Issue 9	April 27	May 16
Issue 10	<b>May 18</b>	May 30
Issue 11	June 1	June 13
Issue 12	June 15	June 27
Issue 13	June 29	July 11
Issue 14	July 13	July 25
Issue 15	July 27	August 15
Issue 16	August 17	August 29
Issue 17	August 31	September 12
Issue 18	September 14	September 26
Issue 19	September 28	October 17
Issue 20	October 19	October 31
Issue 21	November 2	November 14
Issue 22	November 16	November 28
Issue 23	November 30	December 12
Issue 24	December 14	December 26

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