PRACTITIONER'S

MANUAL

An Informational Outline

For New Mexico

New Mexico Board of Pharmacy 5200 Oakland NE Suite A Albuquerque, New Mexico 87113 505-222-9830 800-565-9102

<u>E-Mail: Debra.wilhite@state.nm.us</u> www.rld.state.nm.us/pharmacy

The Prescription Monitoring Program Data Center

NEW! Prescribers, Pharmacists, and other authorized users may now make requests for data from the Prescription Monitoring Program via a secure web page. This web page will assist authorized users in organizing their requests and the reports that are generated by the program. To access the PMP Data Center click here. Or https://www.pmp.state.nm.us/pmpwebcenter. If you are not already a registered user of the PMP Data Center click on the "Not a User? Register to become a User" link on the login screen, fill out the information form and click submit. Your User Name and Password will be emailed to the address listed on your registration. For questions about the PMP Data Center please call 505-222-9830. Access the PMP Data Center. https://www.pmp.state.nm.us/pmpwebcenter.

All statutes and regulations administered and enforced by the NM Board of Pharmacy are available on our web site.

I. CONTROLLED SUBSTANCES

Registration Requirements

Practitioners must obtain a controlled substance registration in order to prescribe and/or order controlled substances. A state controlled substance registration is required (annually) from the New Mexico Board of Pharmacy for each location that controlled substances will be stored, dispensed, distributed, administered, and in which the practitioner practices, performs research, or uses in teaching or chemical analysis. Practitioners who prescribe or order controlled substances, but do not administer or dispense them, at locations other than their principle place of business may do so under the authority of their state controlled substance registration obtained to prescribe controlled substances. http://www.rld.state.nm.us/pharmacy/PDFs/Applications/Prac%20CS%20App%209-07%20_2_pdf

Practitioners must obtain a DEA registration for their principle place of business and for each location as described above (renewed every three years). The DEA will not issue a registration until the Board of Pharmacy has issued a controlled substance registration. https://www.deadiversion.usdoj.gov/webforms/app224Login.jsp

Modification, Transfer, and/or Change of Address of Registration

Modification of a registration to authorize additional controlled substances may be made by filing an application in the same number as an application for a new registration.

In the event of a change in name or address the registrant shall file an application in the same number as an application for modification of a registration, a legal document indicating the change must be submitted. The old registration shall be returned to the Board of Pharmacy. A renewal application for registration will only be sent to the registered address on file with the Board of Pharmacy. It will not be forwarded.

A practitioner who moves to a new physical location must request a modification of the federal registration. A modification of registration can be requested on-line at www.DEAdiversion.usdoj.gov or in writing to the DEA field office responsible for that state. If the change in address involves a change in state, the proper state issued license and controlled substances registration must be obtained prior to the approval of modification of the federal registration. If the modification is approved, DEA will issue a new certificate of registration and, if requested, new Schedule II order forms (DEA Form-222, Official Order Form). A Renewal Application for Registration (DEA Form-224a) will only be sent to the registered address on file with DEA. It will not be forwarded.

Registration under the Controlled Substances Act shall not be transferable.

Termination of Registration

Registration shall terminate if and when a registrant dies, discontinues business or professional practice, has his/her professional license revoked or suspended, no longer possesses a DEA registration, and/or has had his/her DEA registration revoked or suspended, or changes his/her name or address as shown on the registration without notifying the Board of Pharmacy and local DEA office prior to change. In such instances, the registrant or his/her estate shall notify the Board of Pharmacy promptly of such fact and return certificate of registration to the Board within 30 days.

Any practitioner desiring to discontinue business activities with respect to controlled substances must notify the DEA field office (See last page) in writing. Along with the notification of termination of registration, the practitioner should send the DEA Certificate of Registration and any unused Official Order Forms (DEA Form-222) to the nearest DEA field office.

Order Forms

Practitioners must use a DEA form 222 (a triplicate form) in order to obtain Schedule II drugs for office use.

Inventory and Records

Practitioners must inventory all controlled substances, including samples, under their control on May 1 of each year (± 4 days). Practitioners may inventory controlled substances within six months before or after May 1 if they notify the Board of Pharmacy in writing of such date. The specific information required on an inventory is available on the DEA web site listed on the last page.

This site lists the requirements specific for New Mexico. http://www.nmcpr.state.nm.us/nmac/parts/title16/16.019.0020.htm

Every registrant shall maintain the following records:

- A complete and accurate record of each substance (including samples) manufactured, received, sold or delivered.
- Separate records for drugs under Schedules I & II.
- Records of all controlled substances dispensed other than by prescribing or administering.
- All records must be maintained for at least 3 years.

Proper receipt records include the invoices or packing slips from the supplier on which you must record the day received and confirm the order is accurate. These receipts must be maintained in a readily retrievable form.

Typical receipt records include:

- The date received (DEA requires the actual date received to be documented on the distributor/wholesaler's invoice).
- Drug name, strength, dosage form, and amount received.
- Distributor's name, address and telephone number.

Keep dispensing records showing at least the following:

- Date dispensed.
- Name and address of the patient.
- Drug name, strength, and quantity dispensed.

Dispensing Container Label

Practitioners must label the container of a prescription drug, including sample drugs (Provided by Drug Manufacturers) with the following:

- Date of dispensing
- Prescription number, if applicable
- Name and address of dispenser
- Name of patient
- · Name and strength of drug
- Name of practitioner
- · Directions for use and cautionary statements, if any
- The label affixed to the dispensing container of a drug listed in Schedule II, III or IV when dispensed to, or for a patient, shall contain a clear concise warning that it is a crime to transfer the drug to any person other than the patient.

All official compendium requirements for the preservation, packaging, labeling and storage of dangerous drug are applicable.

Sample Drugs

Sample drugs that are prescription drugs (i.e. have the logo "Caution: Federal Law Prohibits Dispensing Without a Prescription" or "Rx Only") are subject to all the record keeping, storage and labeling requirements for prescription drugs.

Disposal of Unwanted or Expired Drugs

A practitioner may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including samples, by transferring them to a registrant who is authorized to receive such materials. These registrants are referred to as "Reverse Distributors." The practitioner should contact the local DEA field office (See last page) for a list of authorized Reverse Distributors. Schedule I and II controlled substances should be transferred via the DEA Form 222, while Schedule III–V compounds may be transferred via invoice. The practitioner should maintain copies of the records documenting the transfer and disposal of controlled substances for a period of three years.

<u>Security</u>

Practitioners must provide effective controls and procedures to guard against theft and diversion of controlled substances. Items for consideration include:

- The quantity of controlled substances handled.
- The extent of unsupervised public access to the facility.
- The adequacy of supervision over employees having access to storage or distribution areas.
- The procedures for handling business guests, visitors, maintenance personnel and non-employee service personnel.
- The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution and disposition of controlled substances in its' operation.
- Keep all prescription blanks in a safe place where they cannot be stolen; minimize the number of prescription pads in use.
- Write out the actual amount prescribed in addition to giving a number to discourage alterations of the prescription order.
- Use prescription blanks only for writing a prescription order and not for notes.
- Never sign prescription blanks in advance.
- Assist the pharmacist when they telephone to verify information about a prescription order; a corresponding responsibility rests with the pharmacist who dispenses the prescription order to ensure the accuracy of the prescription.
- Contact the nearest DEA field office (See last page) to obtain or to furnish information regarding suspicious prescription activities.
- Use tamper-resistant prescription pads.

Theft or Loss Reporting

Report of loss or theft of a controlled substance must be reported to the NM Board of Pharmacy within five days and DEA within one day of becoming aware of that loss. DEA form 106 must be completed by the registrant and forwarded to the NM Board of Pharmacy and DEA.

The Drug Enforcement Administration web site is www.deadiversion.usdoj.gov
Theft or Loss forms and other reporting forms, required by federal law, are available at that site.

DEA Albuquerque District Office

301 Martin Luther King Ave NE Albuquerque, New Mexico 87102 (505) 346-7419

Please report prescription forgeries and all thefts or unexplained losses of controlled substances to the **New Mexico Board of Pharmacy Drug Diversion Unit**.

Albuquerque 222-9830, In-State 1-800-565-9102, Fax 505-222-9845.

New Mexico Controlled Substances

In addition to those substances listed in schedules by the DEA, the following drugs, by Board Regulation, are listed in the New Mexico Controlled Substances Act:

Substance	Schedule
Flunitrazepam (Rohypnol)	C-I
Butalbital (Fioricet)	C-III
Carisoprodol (Soma)	C-IV
Dezocine (Dalgan)	C-IV
Nalbuphine (Nubain)	C-IV
Pseudoephedrine (Sudafed)	C-V

A listing of controlled substances is available on the DEA web site www.deadiversion.usdoj.gov or from the Board of Pharmacy web site www.rld.state.nm.us/pharmacy

II. Prescription Orders

Practitioners may NOT obtain controlled substances for "office use" by prescription. Pharmacies or drug wholesalers must provide you with an invoice that you must file with your controlled substance records.

Every prescription shall contain on its face:

- Name, address, and DEA registration number of the prescriber
- Name and address of the patient
- Name, strength, and dosage form of the drug
- · Quantity prescribed
- · Directions for use
- Date of issue
- Number of refills (if any)
- Practitioners license classification
- Signature of practitioner (written prescriptions only)

Prescriptions may be transmitted directly from the practitioner to the pharmacist or indirectly by a written, signed order. Prescriptions may be faxed to the pharmacy. Prescriptions transmitted through intermediary sources (i.e. nursing agencies, discharge planner, institutional staff) require the pharmacist to contact the prescriber to verify the order. Practitioners may electronically transmit a prescription to the patient's pharmacy of choice if such transmission complies with Board of Pharmacy Regulation 16 NMAC 19.6.23F. The practitioner is responsible for ensuring that the prescription conforms to all requirements of the law and regulations, both federal and state.

Prescriptions for a controlled substances listed in Schedule II shall be written in ink, indelible pencil, or typewritten, zero refills permitted, and manually signed by the practitioner. Exceptions include only:

- Practitioners may not prescribe Schedule II drugs verbally except for emergencies. In such cases, it is the practitioner's responsibility to provide the pharmacy with a written prescription within 7 days. The quantity prescribed is to be only the amount necessary to cover the emergency period.
- A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance.
- A prescription prepared in accordance with 16.19.20.41.A. NMAC written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, or subcutaneous infusion may be transmitted by the practitioner or the practitioner's agent to the Parenteral Products Pharmacy by facsimile.
- The facsimile serves as the original written prescription.

- A prescription prepared in accordance with 16.19.20.41.A. NMAC written for a Schedule II substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription.
- A prescription prepared in accordance with 16.19.20.41.A. NMAC written for a Schedule II narcotic substance for a patient enrolled in a hospice program certified by Medicare under Title XVIII or licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription.

Prescriptions for controlled substances listed in Schedules III or IV may have a maximum of 5 refills within 6 months, and be dispensed only pursuant to:

- A written prescription signed by a practitioner.
- A facsimile of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy.
- An oral prescription made by an individual practitioner and promptly reduced to written form
 by the pharmacist containing all information required for a prescription except the signature
 of the practitioner.

You may NOT issue a prescription for narcotic drugs listed in any schedule to a narcotic dependent person for the sole purpose of continuing dependence upon such a drug. An individual practitioner acting in the usual course of his professional practice may issue a prescription for a controlled substance for a legitimate medical reason. The responsibility of the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

III. PAIN CARE

Pain Care Bill of Rights

As a person with pain, you have the right to:

- have your report of pain taken seriously and to be treated with dignity and respect by doctors, nurses, pharmacists, and other healthcare professionals.
- have your pain thoroughly assessed and promptly treated.
- be informed by your healthcare provider about what may be causing your pain, possible treatments, and the benefits, risks and costs of each.
- participate actively in decisions about how to manage your pain.
- · have your pain reassessed regularly and your treatment adjusted if your pain has not been eased.
- be referred to a pain specialist if your pain persists.
- get clear and prompt answers to your questions, take time to make decisions, and refuse a particular type of treatment if you choose.

Although not always required by law, these are the rights you should expect, and if necessary demand, for your pain care.

How do I talk with my healthcare provider about pain?

- Speak up! Tell your doctor, nurse or social worker that you're in pain.
- Tell your doctor, nurse or social worker where it hurts. Do you have pain in one place or several places? Does the pain seem to move around?
- Describe how much your pain hurts. On a scale from 0 to 10, zero means no pain at all and 10 means the worst pain you can imagine.
- Describe what makes your pain better or worse. Is the pain always there, or does it go away sometimes? Does the pain get worse when you move in certain ways? Do other things make it better or worse?
- Describe what your pain feels like. Use specific words like sharp, stabbing, dull, aching, burning, shock-like, tingling, throbbing, deep or pressing.
- Explain how the pain affects your daily life. Can you sleep? Work? Exercise? Participate in social activities? Concentrate? How is your mood?
- Tell your doctor, nurse or social worker about past treatments for pain. Have you taken medication or had surgery? Tried massage or meditation? Applied heat or cold? Exercised? Explain what worked and what didn't.

American Pain Foundation 201 N. Charles Street, Suite 710 Baltimore, MD 21201-4111

Toll-free information line: 888-615-7246

www.painfoundation.org

New Mexico Boards of Medical Practice, Nursing, and Pharmacy Approved: May 5, 2005

Joint Statement on the Management of Chronic Pain

Pain management is a significant issue in health care today. Estimates of Americans experiencing pain range from 50-75 million persons annually. Thirty to fifty percent of patients undergoing cancer treatment experience pain. The effects of unmanaged pain are serious and wide-ranging and, yet, pain is widely under-treated. Untreated or inadequately treated pain impacts patients' quality of life and increases health care costs. Factors cited in the under-treatment of pain include concerns about causing addiction or tolerance; inadequate knowledge of controlled substances and pain management; fear of scrutiny and discipline by regulatory agencies; inadequate assessment; and patient reluctance to report pain or to take pain medications.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) guidelines on pain management state, "Patients have the *right* to appropriate assessment and management of pain." (Emphasis added). It is, therefore, incumbent upon New Mexico physicians, nurses and pharmacists to work cooperatively and effectively to address the dimensions of pain and to provide maximum pain relief with minimal side effects. Towards that end, and in the interest of public protection, the New Mexico Boards of Medical Practice, Nursing and Pharmacy issue the following joint statement.

To effectively assist patients in the management of chronic pain, health care professionals should, within their scope of practice:

- Consistently and thoroughly assess all patients for pain. If the patient reports untreated or inadequately treated chronic pain, the pain should be evaluated with a complete history and physical with laboratory and diagnostic testing, if indicated;
- Work collaboratively in a multi-disciplinary approach to develop and implement an individualized, written treatment plan utilizing pharmacologic and non-pharmacologic interventions with specific objectives for the patient;
- Regularly evaluate the effectiveness of the treatment plan, using a consistent, developmentally appropriate, standardized pain scale, and make adjustments as needed;
- Document all aspects of pain assessment and care in a timely, clear, consistent, complete and accurate manner;
- Anticipate and effectively manage side effects of pain medications;
- Provide adequate and culturally appropriate information to patients and family members or caregivers to support patients in making informed decisions and participate in the management of their pain;
- Be aware of the risks of diversion and abuse of controlled substances and take appropriate steps to minimize the risks:
- Recognize individuals with chemical dependency may experience pain requiring medications, including opioids, and may require specialized management;
- Consult with, and refer patients to, other providers when appropriate;
- Develop organization-appropriate and evidence-based policies and protocols for pain management;
- Become and remain knowledgeable regarding effective pain management; and
- Comply with all state and federal laws and regulations regarding prescribing, dispensing, and administering legend drugs, including controlled substances.

IV. MONITORING PATIENT CONTROLLED SUBSTANCE USE

New Mexico offers practitioners' possessing DEA and NM controlled substance registrations a secure web based program to access controlled substance prescriptions information on their patients. By registering on-line with the program a practitioner can submit requests for patient reports containing all controlled substance prescriptions dispensed by pharmacies to that patient. These reports can be used to evaluate therapies, identify possible "doctor shoppers", monitor compliance with patient treatment agreements (contracts), and identify possible altered prescriptions.

Registration information is available at: https://www.pmp.state.nm.us/pmpwebcenter

Read the goals of prescription monitoring programs at: http://www.rld.state.nm.us/pharmacy/PDFs/PrescriptionMonitoring/goalsofpmp.pdf