

UNIVERSITY POLICY

Policy Name:	Controlled Substance Policy				
Section #:	100.2.11	Section Title:	Healthcare Compliance Policies		
Approval Authority:	RBHS Chancellor, Executive Vice President for Health Affairs	Adopted:	6/12/2017	Reviewed:	
Responsible Executive:	RBHS Sr. Vice Chancellor of Clinical Affairs	Revised:			
Responsible Office:	Office of the President, Rutgers Health Group	Contact:	rhgboard@rbhs.rutgers.edu		

1. Policy Statement

This policy was established to meet the New Jersey rules for prescribing, administering or dispensing an opioid drug or a Schedule II controlled dangerous substance for pain.

2. Reason for Policy

To ensure compliance with regulations and provide standardization in how Rutgers Health providers prescribe opioid and other Schedule II controlled dangerous substances for the management of pain and screening of patients for compliance and abuse.

3. Who Should Read this Policy

All Rutgers University faculty and staff who prescribe opioids and other Schedule II controlled dangerous substances.

4. Resources

Related New Jersey Statutes:

[N.J.S.A. 45:1-46.1. Practitioners authorized to access prescription monitoring information; Schedule II controlled dangerous substances](#)

[N.J.S.A. 24:21-6 Schedule II](#)

[N.J.S.A. 24:21-2 Dangerous Substances Control Law, Definitions](#)

[NJ ADC 13:35–7.6 Limitations on prescribing, administering, or dispensing of controlled dangerous substances; special requirements for management of acute and chronic pain](#)

New Jersey Register Emergency Rules: <http://www.njconsumeraffairs.gov/bme/Documents/BME-Rule-Text.pdf>

CDC Dose Converter Mobile Application:

<https://www.cdc.gov/drugoverdose/prescribing/app.html>

FDA Opioid Resources:

<https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm>

The New Jersey Prescription Monitoring Program (NJMPMP) website:

<https://newjersey.pmpaware.net/login>

Examples of Opioid Medications:

<http://reference.medscape.com/drugs/opioid-analgesics>

<http://www.globalrph.com/pain2.htm>

Pain Management Agreement (Example)

<http://www.njconsumeraffairs.gov/prescribing-for-pain/Documents/Pain-Treatment-with-Opioid-Medications-Patient-Agreement.pdf>

New Jersey FAQ for prescribers

<http://www.njconsumeraffairs.gov/prescribing-for-pain/Documents/FAQ-for-Practitioners-Licensed-by-BME.pdf>

Rutgers Ernest Mario School of Pharmacy Opioid Toolkit

http://pharmacy.rutgers.edu/content/opioid_abuse_toolkit

5. Definitions for this policy (excerpted from New Jersey Statutes and Regulations)

Acute pain: Pain resulting from disease, accidental or intentional trauma, or other cause, that the practitioner reasonably expects to last only a short period of time. “Acute pain” does not include chronic pain, pain being treated as cancer care, hospice, or other end of life palliative care.

Chronic pain: Pain that persists for three or more consecutive months and after reasonable medical efforts have been made to relieve the pain or its cause and that continues, either continuously or episodically.

Initial Prescription: A prescription issued to a patient who has never previously been issued a prescription for the drug or pharmaceutical equivalent, or has been previously issued a prescription for the pharmaceutical equivalent, but the date on which the current prescription is being issued is more than one year after the date the patient last used or was administered the drug or its equivalent. When determining whether a patient was previously issued a prescription for a drug or equivalent, the practitioner shall discuss or consult with the patient and review the patient’s medical record and the NJ Prescription Drug Monitoring Program (PMP).

Opioid Drug: means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. In our context, this does not apply to the coca derivatives which cannot be prescribed:

- a. Opium, coca leaves, and opiates;
- b. A compound, manufacture, salt, derivative, or preparation of opium, coca leaves, or opiates (this includes most prescription opioids – see [Examples of Opioid Medications](#));
- c. A substance (and any compound, manufacture, salt, derivative, or preparation thereof) which is chemically identical with any of the substances referred to in subsections (a) and (b), except that this shall not include decocainized coca leaves or extracts of coca leaves, which extracts do not contain cocaine or ecgonine.

Pain Management Agreement (also known as a Patient Provider Agreement): Written contract or letter of agreement executed between practitioner and patient, prior to the commencement of treatment for chronic pain using a schedule II controlled substance as a means to:

- a. Prevent possible development of physical or psychological dependence in the patient
- b. Document practitioner and patient understanding of pain management plan

- c. Establish the patient's rights in association with the treatment and the patient's obligations in relation to the responsible use, discontinuation of use, and storage of schedule II controlled dangerous substances, including any restrictions on the refill of prescriptions or the acceptance of schedule II prescriptions from practitioners
- d. Identify the specific medications and other modes of treatment, including physical therapy, exercise or relaxation, or psychological counseling
- e. Specify the measures the practitioner may employ to monitor compliance (random drug screens, pill counts, etc.)
- f. Delineate the process of terminating the agreement, including consequences if the practitioner has reason to believe the patient is not complying with the terms

Practitioners will honor any known current Pain Management Agreements between a patient and another provider.

Palliative care: Care provided to an individual suffering from an incurable progressive illness that is expected to end in death, which is designed to decrease the severity of pain, suffering, and other distressing symptoms, and the expected outcome of which is to enable the individual to experience an improved quality of life. This definition is consistent with the definition of "palliative care" under Department of Human Services' rules concerning decision-making for the terminally ill, set forth at N.J.A.C. 10:48B-2.1.

Practitioner: Include physicians, dentists, nurse practitioners, podiatrists, physician assistants, and certified nurse midwives or any other licensed providers who are currently licensed, registered, or otherwise authorized to prescribe drugs in the course of professional practice, acting within the scope of practice of their professional license or certification.

Schedule II: See definition in [N.J.S.A 24:21-6 Schedule II](#)

6. The Policy

PRACTITIONER EDUCATION

All Rutgers University providers who prescribe medications shall meet the minimum continuing education requirements as required by licensure. The burden will be on the provider to produce documentation of this if needed.

PATIENT APPLICABILITY

This policy applies to all patients, in any age group, where the prescribing of opioid or Schedule II controlled medication is required for pain management. **Exceptions** are for a patient who is currently:

- a. In active treatment for cancer
- b. Receiving hospice care from a licensed hospice or palliative care service
- c. Residing in a long-term care facility
- d. Receiving any medications prescribed for treatment of substance abuse or opioid dependence

PROCEDURE

The steps for prescribing opioid or Schedule II controlled prescriptions for pain are detailed below:

- a. **Check Prescription Monitoring Program (PMP) before every opioid or Schedule II controlled prescription:** <https://newjersey.pmpaware.net/login>
- b. **First/Initial Prescription of an opioid or Schedule II controlled substance prescribed for an individual patient in a course of treatment for acute or chronic pain within the last 12 months:**
 - i. Limit supply to **no more than 5 days** at the lowest effective dose of an immediate release formulation. Prescription must indicate **"Initial prescription for treatment of acute pain"**.
 - ii. Conduct and document a medical history (including patient's experience with non-opioid medication and non-pharmaceutical pain management)

- approaches and substance abuse history), and as appropriate conduct and document a physical examination. Develop treatment plan with particular attention focused on determining the cause of pain. The record must also reflect the complete name of the opioid or Schedule II controlled dangerous substance, the dosage, strength, and quantity of the opioid or Schedule II controlled dangerous substance, and the instructions as to frequency of use, the medical history, the findings on examination, any relevant PMP data, and the treatment plan.
- iii. Discuss with patient or patient's parent or guardian, if patient is under 18 years of age and is not an emancipated minor, the risks associated with the medication being prescribed.
 - iv. Include documentation in patient's medical record about discussion reflecting risks of addiction, physical or psychological dependence, and overdose associated with opioid drugs, the danger of taking opioid drugs with alcohol, benzodiazepines, and other central nervous system depressants, and the requirements for proper storage and disposal.
- c. Second Prescription of an opioid or Schedule II controlled substance prescribed for an individual patient in a course of treatment for acute or chronic pain within the last 12 months:**
- i. Confirm it has been at least 4 days since issuance of initial prescription of the opioid or Schedule II controlled substance via PMP, patient record or any other reliable means.
 - ii. Discuss or consult with patient (in person or by phone).
 - iii. Issue prescription in any quantity not to exceed 30 days.
 - iv. Document rationale for subsequent prescription in chart and document in the medical record the complete name of the opioid or Schedule II controlled dangerous substance, the dosage, strength, and quantity of the opioid or Schedule II controlled dangerous substance, and the instructions as to frequency of use, the medical history, the findings on examination if applicable, any relevant PMP data, and the treatment plan.
 - v. If the patient is under age 18, must discuss and document discussion about risks of medication with parent or guardian.
- d. Third Prescription and all Subsequent Prescriptions of an opioid or Schedule II controlled substance prescribed for an individual patient in a course of treatment for acute or chronic pain within the last 12 months:**
- i. Evaluate patient's physical or psychological dependence and include documentation in the patient's medical record about discussion.
 - ii. Complete pain management agreement with patient. If the patient is under age 18, must discuss and document discussion about risks of medication with parent or guardian.
- e. If an opioid or Schedule II controlled substance is prescribed for three months or more for chronic pain:**
- i. Assess patient for physical or psychological effects and document results.
 - ii. Make reasonable efforts unless clinically contraindicated to either stop the use or decrease the dosage, try other drugs or treatment modalities and document efforts undertaken.
 - iii. **Review, at a minimum of every three months, the course of treatment, any new information about the etiology of the pain, and the patient's progress toward treatment objectives and document this in the chart.**
 - iv. Consider specialist referral (pain management, addiction specialist or other clinical specialist as appropriate).
 - v. Monitor compliance with the pain management agreement and any recommendations that the patient seek a referral, and conduct random urine screen as part of this monitoring.

Examples of text and documentation for prescribing Opioids

[First prescription documentation example](#)

[Second prescription documentation example](#)

[Third and subsequent prescription documentation example](#)

[Chronic pain prescription documentation example \(greater than 3 months\)](#)

[Examples of opioid medications](#)

Section I.

If patient has never received a prescription for an opioid or Schedule II controlled substance for pain or if it has been greater than 1 year since last use/administration, proceed to Section I. If it has been less than a year since the patient's last opioid or Schedule II controlled substance prescription for pain, proceed to Section II.

First Prescription Documentation Example:

___ I have checked the [NJ Prescription Monitoring Program \(PMP\)](#) and have verified that this is the initial prescription for an opioid or Schedule II controlled substance medication this year and there were no aberrant findings.

___ I have conducted and documented a medical history of the patient, including patient's experience using non-opioid medication, non-pharmacological pain management approaches, and substance abuse history as well as the nature, frequency, and severity of any pain. I have performed a physical exam and psychological evaluation along with evaluating the patient's comorbidities and developed a treatment plan with particular attention on determining the cause of the patient's pain and defined objectives by which treatment success is to be evaluated. I have limited the supply of opioids or Schedule II controlled substance to **no more than 5 days** as determined by the dose/frequency. The prescription is written for the **lowest effective dose of an immediate release opioid** and I have indicated on prescription that it is an **"initial prescription for the treatment of acute pain."**

___ I have **documented and discussed** with the patient or patients' parents or legal guardian, if the patient is under 18 years of age and is not an emancipated minor, the reasons why this prescription is necessary and the **risks of the medications** being prescribed. These include but are not limited to: that this medication may be addictive and fatal in overdose, the dangers of taking with alcohol, benzodiazepines, and other CNS depressants; and risks associated with the use of developing a physical or psychological dependence. Alternative therapies have been discussed, which may include Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), such as ibuprofen (Motrin, Advil), or naproxen (Aleve), or acetaminophen (Tylenol). However, given the severity of symptoms, and/or the history of medication sensitivities / allergies, a time limited prescription of an opioid/opioid-like medication is warranted. Other modalities such as heat and cold treatment and topical pain medications such as over-the-counter lidocaine patches or capsaicin cream may help as well.

___ **Safe and Secure Medicine Disposal Communication:** Unused medications that remain in your medicine cabinet are susceptible to theft and misuse by yourself or others. To prevent medications from getting into the wrong hands, New Jersey's Office of the Attorney General and Division of Consumer Affairs urge you to properly dispose of your expired and unwanted prescription medicine at a nearby Project Medicine Drop location. **DROP OFF IS SIMPLE, ANONYMOUS AND AVAILABLE 24 HOURS A DAY - 365 DAYS A YEAR, NO QUESTIONS ASKED.** Simply bring in your prescription and over-the-counter medications and discard them in an environmentally safe manner. Always scratch out the identifying information on any medicine container you are discarding. For a list of Project Medicine Drop locations, please visit <https://www.njconsumeraffairs.gov/meddrop>.

Section II.

This section applies to patients who are receiving a second prescription for an opioid or Schedule II controlled substance for pain within 1 year. If the patient does not meet these criteria, refer to Section I or III.

Second Prescription Documentation Example:

- ___ I have reviewed the [NJ Prescription Monitoring Program \(PMP\)](#) and it has been at least 4 days since the issuance of the initial prescription, and this prescription is for a **maximum of 30 days** supply.

- ___ I have discussed or consulted directly with the patient in person or by telephone. I have considered other non-opioid therapeutic options, but this opioid prescription is necessary and appropriate for the patient's needs. This prescription does not present undue harm or risk of abuse addiction or overdose. I have documented the rationale for this subsequent prescription in the patient's chart.

- ___ I have **documented and discussed** with the patients' parents or legal guardian if the patient is under 18 years of age and is not an emancipated minor, the reasons why this prescription is necessary and the **risks of the medications** being prescribed. These include but are not limited to: that this medication may be addictive and fatal in overdose, the dangers risks of addiction and overdose associated with opioids including dangers of taking with alcohol, benzodiazepines, and other CNS depressants; and risks associated with the use of developing a physical or psychological dependence. Alternative therapies have been discussed, which may include Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), such as ibuprofen (Motrin, Advil), or naproxen (Aleve), or acetaminophen (Tylenol). However, given the severity of symptoms, and/or the history of medication sensitivities / allergies, a time limited prescription of an opioid/opioid-like medication is warranted. Other modalities such as heat or cold treatment and topical pain medications such as over-the-counter lidocaine patches or capsaicin cream may help as well.

- ___ Discharge Instructions: This medication can be addictive, even when taken as prescribed, and fatal in overdose or when taken along with other nervous system depressants such as alcohol or benzodiazepines (such as Valium, Ativan, or Xanax). Take no more than is necessary. Alternatives may include non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen (Motrin, Advil), or naproxen (Aleve), or plain acetaminophen (Tylenol). Other modalities such as ice, heat, compression, or immobilization may help as well.

- ___ **Safe and Secure Medicine Disposal Communication:** Unused medications that remain in your medicine cabinet are susceptible to theft and misuse by yourself or others. To prevent medications from getting into the wrong hands, New Jersey's Office of the Attorney General and Division of Consumer Affairs urge you to properly dispose of your expired and unwanted prescription medicine at a nearby Project Medicine Drop location. DROP OFF IS SIMPLE, ANONYMOUS AND AVAILABLE 24 HOURS A DAY - 365 DAYS A YEAR, NO QUESTIONS ASKED. Simply bring in your prescription and over-the-counter medications and discard them in an environmentally safe manner. Always scratch out the identifying information on any medicine container you are discarding. For a list of Project Medicine Drop locations, please visit <https://www.njconsumeraffairs.gov/meddrop>.

Section III.

Third prescription and all subsequent prescriptions for an opioid or Schedule II controlled substance for pain.

Third Prescription:

___ I have reviewed the [NJ Prescription Monitoring Program \(PMP\)](#) and there were no aberrant findings.

___ I have **documented in the patient's chart** whether the patient is or is not experiencing any problems associated with physical or psychological dependence.

___ I have **documented and discussed** with the patient or patients' parents or legal guardian if the patient is under 18 years of age and is not an emancipated minor, the reasons why the prescription is necessary and the risks of the medications being prescribed. These include but are not limited to: that this medication may be addictive and fatal in overdose, the dangers of taking with alcohol, benzodiazepines, and other CNS depressants; and the increased risks associated with continued opioid use of developing a physical or psychological dependence. Alternative therapies have been discussed, which may include Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), such as ibuprofen (Motrin, Advil), or naproxen (Aleve), or acetaminophen (Tylenol). However, given the severity of symptoms, and/or the history of medication sensitivities / allergies, a time limited prescription of an opioid/opioid-like medication is warranted. Other modalities such as heat or cold treatment and topical pain medications such as over-the-counter lidocaine patches or capsaicin cream may help as well.

___ I have a signed **Pain Management Agreement** with the patient which includes: patient and practitioner understanding of pain management plan; patient's rights in association with treatment; patient's obligations including responsible use, discontinuation of use, storage, disposal, and restrictions on refill or prescriptions from other prescribers; identification of specific medications and non-pharmacological therapies included in treatment plan; measures performed to monitor patient's compliance (e.g., random specimen screens, pill counts); and process for terminating the agreement if patient is not complying with the terms.

___ Discharge Instructions: This medication can be addictive, even when taken as prescribed, and fatal in overdose or when taken along with other nervous system depressants such as alcohol or benzodiazepines (such as Valium, Ativan, or Xanax). Take no more than is necessary. Alternatives may include non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen (Motrin, Advil), or naproxen (Aleve), or plain acetaminophen (Tylenol). Other modalities such as ice, heat, compression, or immobilization may help as well.

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Section IV

Documentation for prescriptions for opioids or Schedule II controlled substances for chronic pain.

For every prescription:

___ I have reviewed the [NJ Prescription Monitoring Program \(PMP\)](#) and there were no aberrant findings.

___ I have been monitoring compliance of the pain management agreement

Every 3 months:

___ I have **documented** my assessment of the patient to determine if they are experiencing physical or psychological effects; the course of treatment, any new information about the etiology of pain, and patient's progress to treatment objectives; efforts to decrease or stop the opioid or Schedule II controlled substance or try medications/modalities to reduce the potential for abuse and development of physical or psychological dependence.

___ I will advise the patient or patient's parent or guardian of the availability of an opioid or Schedule II controlled substance antidote.

Every 12 months

___ I will conduct a random urine screen. I will recommend that the patient seek a referral of a specialist (pain management or addiction specialist) if treatment objectives are not being met.

Examples of Opioid Medications:

<http://reference.medscape.com/drugs/opioid-analgesics>

Generic	Brand	Type of Analgesic
Buprenorphine	Buprenex [®] , Butrans [®]	Short-Acting
Butorphanol	Stadol [®]	
Codeine and Acetaminophen	Capital [®] and Codeine, Tylenol [®] with Codeine No. 3, Tylenol [®] with Codeine No. 4	
Codeine, Butalbital, Acetaminophen, and Caffeine	Fioricet [®] with Codeine	
Codeine, Butalbital, Aspirin, Caffeine	Asacomp [®] with Codeine, Fiorinal [®] with Codeine	
Dihydrocodeine, Aspirin, and Caffeine	Synalgos [®] -DC	
Fentanyl	Abstral [®] , Actiq [®] , Fentora [®] , Lazanda [®] , Onsolis [®] , Subsys [®]	
Hydrocodone and Acetaminophen	Hycet [®] , Lorcet [®] , Margesic H [®] , Maxidone [®] , Norco [®] , Stagesic [®] , Vicodin [®] , Xodol [®] , Zamicet [®] , Zolvit [®] , Zydone [®]	
Hydrocodone and Ibuprofen	Ibudone [®] , Reprexain [®] , Vicoprofen [®]	
Hydromorphone	Dilaudid [®]	
Levorphanol	Levo-Dromoran [®]	
Meperidine	Demerol [®] , Meperitab [®]	
Morphine IR	Morphine IR	
Oxycodone	Oxecta [®] , Roxicodone [®]	
Oxycodone and Acetaminophen	Endocet [®] , Magnacet [®] , Percocet [®] , Roxicet [®] , Primlev [®]	
Oxycodone and Aspirin	Endodan [®] , Percodan [®]	
Oxycodone and Ibuprofen	Combunox [®]	
Tramadol	ConZip [®] , Ultram [®]	
Buprenorphine	Belbuca [®] , Butrans [®]	Extended-Release or Long-Acting
Fentanyl Transdermal System (patch)	Duragesic [®]	
Hydrocodone Bitartrate	Hysingla ER [®] , Vantrela ER [®] , Zohydro ER [®]	
Hydromorphone Hydrochloride	Exalgo [®]	
Methadone Hydromorphone	Dolophine [®] , Methadose [®]	
Morphine Sulfate	Arymo ER [®] , Avinza [®] , Kadian [®] , Morphabond [®] , MS Contin [®]	
Morphine Sulfate and Naltrexone Hydrochloride	Embeda [®]	
Oxycodone	Xtampza [®]	
Oxycodone Hydrochloride	OxyContin [®]	
Oxycodone Hydrochloride and Naloxone Hydrochloride	Targiniq ER [®] , Troxyca ER [®]	
Oxymorphone Hydrochloride	Opana ER [®]	
Tapentadol	Nucynta ER [®]	