THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, and Economic Development

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
Juneau Office

P.O. Box 110806
Juneau, AK 99811-0806
Main: 907.465.2550
Toll free fax: 907.465.2974

# Prescribing and Dispensing Resources, Guidelines, and Recommendations: A Joint Statement

Issued July 22, 2019 (Revised October 16, 2019)

## I. Introduction

This statement is released in response to opioid guidelines, recommendations, and requirements provided by the Centers for Disease Control and Prevention (CDC), Centers for Medicaid and Medicare Services (CMS), the Drug Enforcement Administration (DEA), and provisions under Alaska Statute, AS 08, with the Alaska Department of Commerce, Community, and Economic Development's Professional Licensing Section. The Alaska Board of Pharmacy, the Board of Dental Examiners, the State Medical Board, and the Board of Nursing have contributed to this joint statement.

This document aims to:

- briefly summarize opioid prescribing and dispensing concerns that persist today,
- encourage improved communication between healthcare practitioners and pharmacists through e- prescribing, or other methods, to achieve optimal patient outcomes while reducing risks,
- provide statutory and regulatory expectations for prescribers and pharmacists, and
- distinguish and clarify legal requirements from those that are guidelines or recommendations to support sensible prescribing and dispensing

## II. Prescribing and Dispensing

In 2016, the boards of pharmacy, medicine, nursing, veterinary, dentistry, and optometry made a recommendation to the Alaska State Legislature regarding a maximum Morphine Milligram Equivalent (MME); however, that recommendation was never advanced into law. Despite uncodified MMEs ,healthcare practitioners with DEA authority to prescribed controlled substances must use their professional judgment and comply with applicable statutes and regulations relating to supply limits. The State Medical Board requires, under 12 AAC 40.975(3), that prescribers "comply with the maximum dosage for opioid prescriptions under AS08.64.363; the maximum daily dosage for an initial opioid

prescription issued under AS 08.64.363(a) may not exceed 50 morphine milligram equivalents."

> ***A Shared Commitment:*** *The American Medical Association (AMA) Code of Medical Ethics, Section 10.5, Allied Health Professionals: "Although physicians have overall responsibility for the quality of care that patients receive, allied health professionals have training and expertise that complements physicians'. With physicians, allied health professionals share a common commitment to patient well-being. In light of this shared commitment, physician relationships with allied health professionals should be based on mutual respect and trust."*

Physicians, physician assistants, advanced practice registered nurses, dentists, and optometrists all have similar obligations under AS 08 to exercise professional competence in delivering patient care. Healthcare practitioners should not fear making decisions based on professional judgement after a thorough review of an individual's need for treatment is conducted. In addition, the Alaska Prescription Drug Monitoring Program (PDMP) data should be accessed to determine if a patient has recently been prescribed opioids or other controlled substances. Failure to do otherwise may result in disciplinary action for unprofessional conduct. For physicians and physician assistants, 12 AAC 40.967 addresses matters that may be deemed unprofessional conduct, including behavior that interferes with the provision of patient care, demonstrating gross negligence, or failing to provide necessary continuation of care. For Advance practice registered nurses unprofessional conduct is addressed in AS 08.68.270(7) and 12 AAC 44.770 as acts that place the health, safety, or welfare of a patient at risk.

In addition to the requirement and expectation that healthcare practitioners conduct themselves with professional competence and empathy, all must adhere to laws pertaining to the prescribing, administration, or dispensing of controlled substances, and should consider on an individual basis the circumstances for patients suffering from chronic conditions or needing palliative care.

*Prescribers: Dentists*

Dentists prescribers are encouraged to become familiar with current research on the treatment of acute dental pain as outline below. If a prescriber must deviate from these guidelines and feels it is necessary or appropriate to prescribe an opiate, they should communicate the rationale with the patient and, in certain circumstances, the pharmacist—particularly if more than a seven-day dose or refills is prescribed.

> *"The Board of Dental Examiners stresses that if opioids are prescribed, pain therapy should be coordinated with the patient's other medical providers when possible, especially in cases where there is a history of substance abuse."*

The Number Needed to Treat (NNT) offers a measurement of the impact of a medicine or therapy by estimating the number of patients that need to be treated in order to have an impact on one person. The data below tell us about the NNT as it relates to the number of patients that are helped. A lower number means a more effective treatment.

- Oxycodone 15 mg: NNT is 4.6. Since it is hard to conceptualize 4.6 people, consider that you would have to treat 46 people for 10 to get 50 percent relief of their pain. Thirty-six of those 46 people would not get adequate pain relief. (Gaskell, Derry, Moore, & McQuay, 2009)
- Oxycodone 10 mg + acetaminophen 650 mg: NNT for this combination treatment (Equivalent to two 5 mg Percocet pills) is 2.7. Clearly this is better than oxycodone alone. Acetaminophen adds a significant benefit. (Gaskell et al., 2009)
- Naproxen 500 mg (or naproxen sodium 550 mg): NNT for this is also 2.7. Naproxen is an NSAID. Naproxen sodium is known to many by the brand name Aleve®. (C Derry & Derry, 2009)
- Ibuprofen 200-600 mg + acetaminophen 500 mg: The combination of these two OTC medicines provided the best pain relief of all, with an NNT of 1.6. (CJ Derry, Derry, & Moore, 2013)

The Board of Dental Examiners stresses that if opioids are prescribed, pain therapy should be coordinated with the patient's other medical providers when possible, especially in cases where there is a history of substance abuse.

- The dose and duration should be for as short a time period as possible.
- Prescriptions should be limited to 7 days or less under AS 08.36.355.
- Prescribers must discuss all opioid prescriptions to minors with parent or guardian under AAS 08.36.355.

The Prescription Drug Monitoring Program (PDMP) database must be accessed prior to writing, dispensing, or administering, III or IV prescription for a patient of record or a new patient under AS 17.30.200(k)(4), except in the situations below:

- Dispensing to a patient for an outpatient supply of 24-hours or less at a hospital with an inpatient pharmacy for use after discharge (exempt by AS 17.30.200(u)(2)(A)).
- Dispensing to a patient for an outpatient supply of 24-hours or less at a hospital emergency department (exempt by AS 17.30.200(u)(2)(B)).
- Administering to an inpatient admitted to a healthcare facility (exempt by AS 17.30.200(k)).
- Administering at the scene of an emergency, in an ambulance, or in an emergency department (exempt by AS 17.30.200(k)(4)(A)(iii)).
- Dispensing, prescribing, or administering at a hospice or nursing home that has an inpatient pharmacy (AS 17.30.200(k)(4)(A)(iv)).
- Dispensing, prescribing, or administering immediately before, during, or within the first 48 hours after surgery or a medical procedure (exempt by AS 17.30.200(k)).
- Writing a non-refillable prescription for a controlled substance in a quantity intended to last for not more than three days (exempt by AS 17.30.200(k)(4)(B)).

*Prescribers: Physicians, Physician Assistants, and Advanced Practice Registered Nurses*

While physicians and physician assistants cannot generally issue an initial prescription for an opioid that exceeds a seven-day supply, AS 08.64.363 and 12 AAC 40.975 provide that these healthcare practitioners use their professional judgment when exceeding he limit given the patient's chronic

condition, pain associated with cancer, or palliative pain necessitates a prescription beyond the seven-day supply limit. Prescriptions exceeding the supply limit must be properly documented in the patient's medical record. The same is true for Advanced practice registered nurses under AS 08.68.705 and dentists under AS 08.36.355. The same is also true for optometrists under AS 08.72.276; however, the maximum dosage for an initial opioid prescription is not to exceed four days.

Physicians and physician assistants who prescribe controlled substances must adhere to specific requirements, including but not limited to:

- participation in the state prescription drug monitoring program (PDMP) in advance of prescribing and during ongoing monitoring;
- complying with the maximum weekly and daily dosage requirements for opioid prescriptions under AS 08.64.363;
- practicing pain management with sufficient knowledge, skills, and training, or to refer patients to an appropriate pain management physician;
- practice in accordance with specialty board practice standards; and with the guidelines issued by the Federation of State Medical Boards (FSMB) in their *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*; and with the Centers for Disease Control and Prevention (CDC) *Guideline for Prescribing Opioids for Chronic Pain*;

Advanced Practice Registered Nurses who are authorized to prescribe controlled substances must adhere to specific requirements as well. These include:

- participate in the state prescription drug monitoring program (PDMP) in advance of prescribing and during ongoing monitoring;
- comply with the maximum weekly and daily dosage requirements for opioid prescriptions and other limitations as described under AS 08.68.705;
- follow the regulations for Advanced Practice Registered Nurses outlined in 12 AAC 44.445 Controlled substance prescriptive and dispensing authority

Advanced Practice Registered Nurses who are authorized to prescribe controlled substances must adhere to specific requirements as well. These include:

- participate in the state prescription drug monitoring program (PDMP) in advance of prescribing and during ongoing monitoring;
- comply with the maximum weekly and daily dosage requirements for opioid prescriptions and other limitations as described under AS 08.68.705;
- follow the regulations for Advanced Practice Registered Nurses outlined in 12 AAC 44.445 Controlled substance prescriptive and dispensing authority

In addition, dentists, physicians, physician assistants, and advanced practice registered nurses must adhere to continuing education requirements as follows:

- completion of no less than two hours of education in pain management, opioid use, and addiction prior to initial licensure and for each biennial renewal cycle.
- adherence to other continuing education specifications required by the provider's respective licensing board.

Healthcare practitioners are advised to review the board-issued guidelines regarding controlled substance prescribing, as well as the statutes and regulations. These publications are available on the State Medical and Nursing Board websites.

*Dispensers*

Like healthcare practitioners, pharmacists are obligated to exercise professional competence in delivering patient care under 12 AAC 52.920. In a letter issued to pharmacists dated January 23, 2018, the Alaska Board of Pharmacy provided guidance to its licensees when encountering difficult situations in dispensing controlled substance medications.

## III. Proactive Communication

Pharmacists and healthcare practitioners are vital to improving patient outcomes. Changes in opioid prescribing and dispensing statutes and regulations, as well as the release of new clinical studies, guidelines, or recommendations provide a forum for stronger collegial relationships. Proactive communication among providers is essential for providing comprehensive care.

Considering the CDC guidelines and the changing legal requirements for healthcare practitioners and pharmacists regarding prescribing and dispensing of control substance prescriptions, practitioners are hearing substantially more questions and concerns from pharmacists when filling controlled substance prescriptions. Providers are being asked to provide more information to pharmacists because of the corresponding responsibility placed on pharmacists by the Drug Enforcement Administration (DEA) under Title 21 CFR, Section 1306.04(a):

> ***§1306.04 Purpose of issue of prescription.***
>
> ***(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for 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. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.***

While the pharmacist's role is not to play gatekeeper, this federal regulation places a responsibility on the pharmacist to ensure that the controlled substance prescription is being used for a "legitimate medical purpose." To understand the particular patient scenario, the pharmacist may need to ask the patient and/or practitioner additional questions. This places a heavy emphasis on the collaboration that is needed between patient, pharmacist, and practitioner to ensure not only prescription requirements are met but that best patient improvement and outcomes are placed as the priority. A breakdown in this triad of may result in a pharmacist refusing to fill a prescription for lack of needed information. Collaboration and open communication between patient, pharmacist, and health care provider is necessary to ensure prescription requirements are met and optimal patient care is provided.

> *"[The Alaska Board of Dental Examiners stresses that an] important aspect of the effort to curb opioid addiction and abuse is to promote communication and collaboration between the prescribing dentist and the pharmacist…*
>
> *…the pharmacist should not have to play gatekeeper by turning away patients because of faulty and misguiding prescribing practices of dentists who have not done their due diligence."*

Consultation and collaboration are inherent in the relationships between health care practitioners and pharmacists: The Alaska Board of Pharmacy's regulation, 12 AAC 52.210, outlines essential duties of pharmacists, which includes the duty to consult with a prescriber regarding a patient or prescription. The Alaska Medical Board defines a collaborative relationship under 12 AAC 40.990 as, "a consultative relationship between a physician and non-physician [physician assistant] health care provider which uses their respective areas of expertise to meet the common goal of providing comprehensive care for the patient." Similarly, 12 AAC 40.983 provides for a formal cooperative practice agreement between a prescribing physician and a pharmacist to manage a patient's medication therapy, as prescribed by the physician. This agreement relies upon proactive communication between providers, which is acknowledged and reciprocated by the Alaska Board of Pharmacy, within the context of collaborative practice agreements with practitioners under 12 AAC 52.240.

In a letter of support dated April 29, 2019 and provided to the Board of Pharmacy, The Alaska Board of Dental Examiners "stresses that an important aspect of the effort to curb opioid addiction and abuse is to promote communication and collaboration between the prescribing dentist and the pharmacist. The board feels the pharmacist should not have to play gatekeeper by turning away patients because of faulty and misguiding prescribing practices of dentists who have not done their due diligence." A copy of this letter can be found at pdmp.alaska.gov.

Communication between healthcare practitioners and dispensers can be done through telephone calls, through e- prescribing, or through other secure messaging software. Common questions dispensers may wish to address include dosage amounts, supply limits, or drug interactions. Lack of communication may lead to misunderstandings or assumptions that delay filling the prescription, especially involving controlled substances.

**IV. Requirements vs. Recommendations**

The following links are legal mandates concerning prescribing and dispensing controlled substances:

*Legal References / Requirements:*

- Title 21 Code of Federal Regulations (CFR), Part 1300
- Pharmacist Dispensing: Corresponding Responsibility under 21 CFR 1306.04
- DEA: Pharmacist's Manual
- DEA: Practitioner's Manual
- AS 08: Maximum Dosage of Opioid Prescriptions
- Alaska Professional Licensing Websites: https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing.asp
- March 2017 Alaska Medicaid ICD-10 Diagnosis Code Requirements for Opioid Prescriptions
- Center for Medicare & Medicaid Services: 2019 Final Call Letter (including opioid prescriptions)
- State Medical Board Statutes and Regulations
- Board of Nursing Statutes and Regulations
- Board of Dental Examiners Statutes and Regulations
- Board of Examiners in Optometry Statutes and Regulations
- Board of Pharmacy Statutes and Regulations

The following references and resources are not legal mandates; however, they can aid licensees in supporting safe and legal prescribing and dispensing practices:

*Guidelines / Recommendations:*

- CDC: Determining when to Initiate or Continue Opioids for Chronic Pain
- CDC: Checklist for Prescribing Opioids for Chronic Pain
- December 2016 Joint Committee on Prescriptive Guidelines Report to Alaska State Legislature
- CDC: Information for Providers
- Alaska Emergency Care Providers

**Contact:**

Laura Carrillo, Executive Administrator
Board of Pharmacy
Email: akpdmp@alaska.gov
Phone: 907-269-8404