

INFORMED CONSENT FOR LONG-TERM OPIOID THERAPY FOR PAIN

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Directive establishes policy regarding patient education and informed consent for long-term opioid therapy for pain and policy regarding opioid pain care agreements (OPCA).
- 2. SUMMARY OF CONTENTS:** This is a new VHA Directive that establishes policy on informed consent and patient education prior to the initiation of long-term opioid therapy for pain.
- 3. RELATED ISSUES:** VHA Handbook 1004.01 and VHA Handbook 1004.05.
- 4. RESPONSIBLE OFFICE:** The National Pain Management Program, Office of Patient Care Services (10P4) and the National Center for Ethics in Health Care (10P6) are responsible for the contents of this Directive. Questions may be referred to 202-632-8457.
- 5. RESCISSIONS:** None.
- 6. RECERTIFICATION:** This VHA Directive is scheduled for recertification on or before the last working day of May, 2019.

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DISTRIBUTION: E-mailed to the VHA Publications Distribution List on 5/7/2014.

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1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policy regarding patient education and informed consent for long-term opioid therapy for pain and policy regarding opioid pain care agreements (OPCA). **AUTHORITY:** 38 U.S.C. 7301(b) and 38 CFR 17.32.

2. BACKGROUND:

a. VHA's strategic plan stresses patient-driven health care, defined as "an engagement between a patient and a health care system where the patient is the source of control such that their health care is based in their needs, values, and how the patient wants to live." To achieve this vision, practitioners prescribing long-term opioid therapy for pain must educate patients about the risks, benefits, and alternatives to long-term opioid therapy and engage them in a discussion about a proposed long-term opioid therapy management plan.

b. Under Title 38 Code of Federal Regulations (CFR) 17.32, VHA practitioners are required to obtain signature consent for all diagnostic and therapeutic treatments or procedures that have a significant risk of complication or morbidity. VHA Handbook 1004.01 implements this regulatory requirement and establishes procedures for obtaining and documenting informed consent for all clinical treatments and procedures. According to VHA Handbook 1004.01, practitioners are required to obtain the patient's signature consent for all treatments and procedures that "can be reasonably considered to have a significant risk of complication or morbidity." In addition, VHA Handbook 1004.05 establishes requirements and procedures for using iMedConsentTM to document a patient's signature consent in the electronic health record.

c. Current VHA policy regarding pain management specifies that the safe and effective use of opioid analgesics for the management of pain, particularly complex chronic pain conditions, requires special attention to personal and public health risks. These risks include: side effects of opioids; opioid dependence, tolerance, and addiction; intentional or unintentional fatal overdose; and risks to the public through diversion of prescribed medications. Long-term exposure to opioids increases the risk for developing opioid hyperalgesia, and hypogonadism with concomitant loss of libido.

d. The Department of Veterans Affairs (VA) National Pain Management Program has encouraged documentation of the discussion between the provider and the patient regarding potential risks and benefits of opioids, provider and patient responsibilities related to opioid use, and the parameters for continued opioid use.

e. In recent years, a number of VA practitioners and clinics have used locally created OPCAs to document discussions with patients regarding long-term opioid therapy. A number of benefits have been proposed for OPCAs, including their potential to improve adherence, reduce misuse and diversion, and clarify treatment goals, expectations, and responsibilities. However, other experts have raised concerns about OPCAs, including their use of threatening language and their potential to undermine trust. Poorly crafted OPCAs may potentially harm the patient-provider relationship, lead to practices that are inconsistent with VHA policy, or lead to adverse outcomes.

f. To address this concern, and to meet VA's responsibilities under the 2011 Prescription Drug Abuse Prevention Plan from the Office of National Drug Control Policy, (<http://www.whitehouse.gov/ondcp/prescription-drug-abuse>), the National Pain Management Program and the National Center for Ethics in Health Care have jointly developed, with input from other national program offices and VHA medical facility staff, a patient information guide titled "Taking Opioids Responsibly for Your Safety and the Safety of Others: Patient Information Guide on Long-term Opioid Therapy for Pain," along with a consent form titled "Consent for Long-Term Opioid Therapy for Pain" (see paragraph 5h and Appendix A). These tools are designed to be patient-centered and to help practitioners ensure:

(1) That patients understand the risks, benefits, and alternatives to long-term opioid therapy for pain management;

(2) The appropriate use and dispensing of opioids; and

(3) The fact that VA is authorized to disclose and obtain patient information from state prescription drug monitoring programs (PDMP) to prevent misuse and diversion of prescription medication. *NOTE: Title 38 United States Code (U.S.C.) 5701(l) and 38 U.S.C. 7332(b)(2) authorize VA to share certain patient information with state PDMPs without obtaining the patient's consent. Additionally, when allowed or required by state law, authorized VA employees may query a state's PDMP to monitor a patient's prescription use.*

g. When used together as part of a discussion with the patient or surrogate decision maker, the patient information guide and consent form satisfy VA's legal and policy requirements pertaining to informed consent, while at the same time serving the educational and risk management purposes of an OPCA.

3. POLICY: It is VHA policy that, prior to initiating long-term opioid therapy for pain (see paragraph 6b for definition), VHA opioid prescribers must complete the patient education and informed consent process specified in paragraph 4f of this Directive. **This requirement does not apply to patients receiving short-term opioids, patients enrolled in hospice, or patients receiving long-term opioids for cancer pain, for whom oral consent is sufficient, and specific documentation of consent for opioids is not required.**

4. RESPONSIBILITIES:

a. **National Center for Ethics in Health Care.** The National Center for Ethics in Health Care is responsible for:

(1) Ensuring that the nationally approved consent form titled "Consent for Long-Term Opioid Therapy for Pain" is available and maintained in iMedConsent™ (see paragraph 5c and Appendix A).

(2) Ensuring that the patient information guide "Taking Opioids Responsibly for Your Safety and the Safety of Others" (see paragraph 5f) is available and maintained in iMedConsent™.

(3) Responding to questions from VHA staff regarding the ethics content of the consent form titled “Consent for Long-Term Opioid Therapy for Pain” and the patient information guide titled “Taking Opioids Responsibly for Your Safety and the Safety of Others.”

(4) Ensuring that the consent form titled “Consent for Long-Term Opioid Therapy for Pain” and educational materials are consistent with current standards for ethical practice through periodic updates.

(5) Ensuring the monitoring of provider use of the consent form titled “Consent for Long-Term Opioid Therapy for Pain” for patients receiving chronic opioid therapy for pain.

b. **Office of Patient Care Services.** VHA’s Office of Patient Care Services is responsible for:

(1) Providing clinical content for the consent form titled “Consent for Long-Term Opioid Therapy for Pain” and the patient information guide titled “Taking Opioids Responsibly for Your Safety and the Safety of Others.”

(2) Approving clinical content for the consent form titled “Consent for Long-Term Opioid Therapy for Pain” and the patient information guide titled “Taking Opioids Responsibly for Your Safety and the Safety of Others.”

(3) Responding to questions from VHA staff regarding the clinical content of the consent form titled “Consent for Long-Term Opioid Therapy for Pain” and the patient information guide titled “Taking Opioids Responsibly for Your Safety and the Safety of Others.”

(4) Collaborating with the National Center for Ethics in Health Care to manage updates to the consent form titled “Consent for Long-Term Opioid Therapy for Pain” and educational materials.

(5) Collaborating with Women’s Health Services to assist with expertise on concerns related to pregnancy in women of childbearing age.

c. **VHA Medical Facility Director.** The VHA medical facility Director is responsible for ensuring:

(1) Local policy and procedures, consistent with the requirements detailed in paragraph 4f of this Directive, are developed and published by November 6, 2014.

(2) Practitioners have ready access to printed copies of the patient information guide titled “Taking Opioids Responsibly for Your Safety and the Safety of Others.”

(3) Opioid prescribers have ready access to iMedConsent and printers in relevant patient care areas.

(4) The CPRS progress note title “Consent for Long-Term Opioids for Pain” is established locally by June 6, 2014. This progress note title must be locally linked to the consent form entitled “Consent for Long-Term Opioid Therapy for Pain” that is produced by iMedConsent™.

(5) Locally approved OPCAs are no longer used at the facility.

d. **Chief of Staff.** The Chief of Staff is responsible for:

(1) Informing and educating facility opioid prescribers about the requirements established under paragraph 4f.

(2) Ensuring that all patients on long-term opioid therapy for pain complete the new patient education and informed consent process by May 6, 2015.

(3) Ensuring that all opioid prescribers and health care team members are proficient in the use of iMedConsent™ for documenting signature consent (see VHA Handbook 1004.05).

e. **Nurse Executive.** The Nurse Executive is responsible for:

(1) Informing and educating medical facility nurses who prescribe opioids about the requirements established under paragraph 4f.

(2) Ensuring that all patients who are already on long-term opioid therapy for pain as of May 6, 2014 who receive care from nurses who prescribe opioids complete the new patient education and informed consent process by May 6, 2015.

(3) Ensuring that all nurses who prescribe opioids are proficient in the use of iMedConsent™ for documenting signature consent (see VHA Handbook 1004.05).

f. **VHA Opioid Prescribers.** Prior to initiating long-term opioid therapy for pain, VHA opioid prescribers are responsible for completing the informed consent process specified in VHA Handbook 1004.01 and:

(1) Providing the patient (or in the case of a patient who lacks decision-making capacity, the surrogate decision maker) with a copy of the nationally standardized patient information guide titled “Taking Opioids Responsibly for Your Safety and the Safety of Others” (available through iMedConsent™).

(2) Reviewing and discussing the contents of the patient information guide with the patient, or surrogate.

(3) Obtaining signature consent from the patient, or surrogate, on the nationally standardized informed consent form titled “Consent for Long-Term Opioid Therapy for Pain” (available through iMedConsent™).

(4) Offering the patient, or surrogate, a copy of the signed consent form.

(5) Asking women of childbearing age (age 15-50) about pregnancy status and pregnancy intentions and counseling these patients about preconception care.

(6) For short-term opioids, for Veterans receiving hospice care, and for patients receiving long-term opioids for cancer pain, use of the patient information guide and informed consent form is optional, but the practitioner must discuss opioid risks, benefits, and alternatives as part

of obtaining informed consent for the patient's overall plan of care. Specific documentation of consent for short-term opioids is not required.

(7) Using the nationally standardized patient information guide and informed consent form in place of other forms whenever agency policies or clinical practice guidelines require or recommend the use of OPCAs. If a patient has in place another type of OPCA, such as a locally created OPCA, the opioid prescriber for that patient must ensure that the non-approved OPCA is removed and replaced by the nationally standardized consent form by May 6, 2015. **NOTE:** *Patient-Provider Agreements (PPAs) required by the Food and Drug Administration (FDA) Opioid Risk Evaluation and Mitigation Strategy (REMS) programs may be used in addition to the nationally standardized patient information guide and consent form.*

(8) Ensuring that the patient's, or surrogate's, signature consent for long-term opioid therapy for pain has been obtained and documented in the health record prior to initiating opioids for that purpose.

(9) For patients who are already receiving long-term opioids for pain as of May 6, 2014, VHA prescribers are responsible for completing the patient education and informed consent process by May 6, 2015.

(10) If the signature consent cannot be located in the patient's health record, collaborating with health care team members (such as Patient Aligned Care Team staff) to complete the new patient education and informed consent process established in paragraph 4f(1)-(7).

(11) Completing nationally standardized OPCAs referred to as PPAs when required by FDA Opioid Risk Evaluation and Mitigation Strategy (REMS) programs.

g. **Pharmacy Service.** Each medical facility's pharmacy service is responsible for filling all valid prescriptions based on the procedures outlined in VHA Handbooks 1108.05 and 1108.06. VHA pharmacists are not responsible for ensuring VHA opioid prescribers have met the informed consent requirements outlined in this policy.

h. **Health Care Team Members.** Health care team members, such as Patient Aligned Care Team staff, are responsible for performing, as appropriate to the competency of the team member, elements of the new patient education and informed consent process in collaboration with the opioid prescriber.

5. REFERENCES:

- a. 38 U.S.C. 5701(l).
- b. 38 U.S.C. 7332(b)(2).
- c. Consent Form: "Consent for Long-Term Opioid Therapy for Pain." Available through iMedConsent and in Appendix A.
- d. Institute of Medicine (IOM). "Relieving Pain in America." The National Academies Press, 2011.

- e. International Association for the Study of Pain (IASP). "Part III: Pain Terms, A Current List with Definitions and Notes on Usage." Classification of Chronic Pain, Second Edition, 1994.
- f. Patient Information Guide: "Taking Opioids Responsibly for Your Safety and the Safety of Others." Available through iMedConsent or at: http://www.ethics.va.gov/docs/policy/Taking_Opioids_Responsibly_2013528.pdf.
- g. 21 U.S.C. Section 812.
- h. 38 U.S.C. Section 7331-7334.
- i. 38 C.F.R. 17.32.
- j. VHA Directive 2009-053, Pain Management.
- k. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures.
- l. VHA Handbook 1004.05, iMedConsent.

6. DEFINITIONS:

- a. **iMedConsent™**. iMedConsent™ is a commercially-available software package that has been customized for use within VA. iMedConsent™ supports electronic access, completion, signing, and storage of informed consent forms and educational materials associated with consent forms. VA has purchased an enterprise license for iMedConsent™, see VHA Handbook 1004.05, iMedConsent™, which establishes national policy for iMedConsent™ in VHA.
- b. **Long-term Opioid Therapy for Pain**. Long-term opioid therapy is the medically indicated use of opioids on a daily or intermittent basis for 90 or more calendar days to treat non-cancer pain.
- c. **Opioid**. For the purposes of this Directive, opioids are opiates, opiate derivatives, and chemically equivalent narcotic compounds listed as Schedule II or Schedule III substances in the Controlled Substances Act or superseding controlled substance schedules, see 21 U.S.C. Section 812 at <http://www.deadiversion.usdoj.gov/21cfr/21usc/812.htm>.
- d. **Opioid Pain Care Agreement**. An OPCA is a document describing an exchange of information between a provider and patient regarding the expectations, responsibilities, and obligations of patients to receive opioid therapy. OPCAs may contain a range of information, but generally include provisions advising patients to: take the drugs only as directed; adhere to drug testing; not seek early refills or replacements for lost or stolen drugs; not use illegal drugs; and other provisions as needed. *NOTE: The term OPCA encompasses other documents with similar purposes, such as pain contracts, opioid agreements, opioid contracts, treatment agreements, pain management agreements, patient-provider agreements, and opioid management plans.*
- e. **Opioid Prescriber**. An opioid prescriber is a credentialed health care provider with clinical privileges or who has VHA authorization to prescribe opioids.

f. **Pain.** Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage (see paragraph 5e).

g. **Short-term Opioid Therapy for Pain Management.** Short-term opioid therapy is the medically indicated use of opioids on a daily or intermittent basis to treat a medical condition for less than 90 calendar days.

May 6, 2014

VHA DIRECTIVE 1005
APPENDIX A

DEPARTMENT OF VETERANS AFFAIRS (VA) FORM 10-0431C, CONSENT FOR
LONG-TERM OPIOID THERAPY FOR PAIN

Department of Veterans Affairs (VA) Form 10-0431c, Consent for Long-Term Opioid Therapy for Pain can be found on the VA Forms website at: <http://vaww.va.gov/vaforms> and through iMedConsent. *NOTE: The VA Forms website and iMedConsent are available within VA but are not available to the public.*