

## INFORMED CONSENT FOR LONG-TERM OPIOID THERAPY FOR PAIN

**1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) directive establishes policy requiring patient education and signature informed consent for long-term opioid therapy for pain, and policy prohibiting the use of opioid pain care agreements (OPCA).

**2. SUMMARY OF MAJOR CHANGES:** This directive has been updated to:

a. Clarify that the basic requirements for obtaining informed consent for clinical treatments and procedures found in VHA Handbook 1004.01(2), Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009, apply to providing long-term opioid therapy for pain, including the need to repeat the signature informed consent process in certain circumstances.

b. Specify responsibilities in paragraph 5 for: Executive Director of the National Center for Ethics in Health Care (NCEHC), Assistant Deputy Under Secretary for Health for the Office of Patient Care Services, Chief Officer for Specialty Care Services, Chief Consultant for Mental Health Services, Veterans Integrated Service Network (VISN) Directors, Department of Veterans Affairs (VA) Medical Facility Chief Nursing Officer, and VA Medical Facility Chief of Pharmacy Services.

c. Specify the successor software for iMedConsent™, iMedConsent Web.

d. Remove requirement for VA medical facilities to develop local policy and procedures regarding signature informed consent for long-term opioid therapy for pain.

**3. RELATED ISSUES:** VHA Handbook 1004.01(2), Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009; VHA Handbook 1004.05, iMedConsent™, dated December 10, 2014, VHA Directive 1306(1), Querying State Prescription Drug Monitoring Programs (PDMP); dated October 19, 2016, VHA Directive 2009-053, Pain Management, dated October 28, 2009.

**4. RESPONSIBLE OFFICE:** The National Pain Management Program, Office of Specialty Care Services (10P11), and National Center for Ethics in Health Care (10E1E) are responsible for the contents of this directive. Questions may be referred to NCEHC at 202-632-8457 or [vhaethics@va.gov](mailto:vhaethics@va.gov).

**5. RESCISSIONS:** VHA Directive 1005(1), Informed Consent for Long-Term Opioid Therapy for Pain, dated May 6, 2014, is rescinded.

**6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of May 2025. This directive will continue to serve as national VHA policy until it is recertified or rescinded.

May 13, 2020

VHA DIRECTIVE 1005

**BY DIRECTION OF THE OFFICE OF  
THE UNDER SECRETARY FOR HEALTH:**

/s/ Gerard R. Cox, MD, MHA  
Deputy Under Secretary for Health  
for Organizational Excellence

**NOTE:** *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

**DISTRIBUTION:** Emailed to the VHA Publications Distribution List on May 18, 2020.

**CONTENTS**

**INFORMED CONSENT FOR LONG-TERM OPIOID THERAPY FOR PAIN**

1. PURPOSE..... 1

2. BACKGROUND..... 1

3. DEFINITIONS ..... 2

4. POLICY ..... 3

5. RESPONSIBILITIES ..... 3

6. TRAINING ..... 7

7. RECORDS MANAGEMENT..... 7

8. REFERENCES..... 8

## INFORMED CONSENT FOR LONG-TERM OPIOID THERAPY FOR PAIN

### 1. PURPOSE

This Veterans Health Administration (VHA) directive establishes policy requiring patient education and signature informed consent for long-term opioid therapy for pain. This directive also prohibits the use of opioid pain care agreements (OPCA).

**AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b), 7331, and 38 Code of Federal Regulations (CFR) 17.32.

### 2. BACKGROUND

a. VHA is committed to reducing opioid overdose and opioid use disorder among Veterans. In alignment with the Comprehensive Addiction Recovery Act (CARA) of 2016 (Public Law (Pub.L.) 114-198), VHA's Opioid Safety Initiative (see [https://www.va.gov/PAINMANAGEMENT/Opioid\\_Safety\\_Initiative\\_OSI.asp](https://www.va.gov/PAINMANAGEMENT/Opioid_Safety_Initiative_OSI.asp)) addresses providing safer prescribing and monitoring practices for management of Veterans' chronic pain, and moving towards a more Veteran-centric, biopsychosocial approach to caring for Veterans with chronic pain. In addition, the Department of Veterans Affairs (VA) and Department of Defense (DoD) resource "VA/DoD Clinical Practice Guideline: Management of Opioid Therapy for Chronic Pain," provides evidence based recommendations regarding long-term opioid therapy for patients with chronic pain (see <https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPG022717.pdf>).

**NOTE:** *This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.*

b. To ensure safe, patient-centered care, 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.

c. VHA Handbook 1004.01(2), Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009, establishes procedures for obtaining and documenting informed consent for all clinical treatments and procedures. VHA Handbook 1004.01(2) requires practitioners 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. VHA Handbook 1004.05, iMedConsent™, dated December 10, 2014, establishes requirements and procedures for using iMedConsent™ to document a patient's signature consent in the electronic health record (EHR).

d. In the past, a number of VA opioid prescribers and VA medical facilities used locally created OPCAs, also known as "pain contracts", to document discussions with patients regarding long-term opioid therapy. OPCAs are based on an adversarial rather than therapeutic model, and their use of threatening language has the potential to undermine patient-provider trust. This directive is grounded in a therapeutic approach to treatment decision making based on informed consent.

e. The National Pain Management Program and the National Center for Ethics in Health Care (NCEHC) jointly developed a patient information guide titled “Safe and Responsible Use of Opioids for Chronic Pain: A Patient Information Guide” and an informed consent form titled “Consent for Long-Term Opioid Therapy for Pain” (see <https://www.ethics.va.gov/policy.asp>). These tools are designed to be patient-centered and to help opioid prescribers ensure:

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

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

(3) That patients are aware of VA’s authority to disclose and obtain patient information from State prescription drug monitoring programs (PDMPs) to prevent misuse and diversion of prescription medication. **NOTE:** *38 U.S.C. 5701(l) and 38 U.S.C. 7332(b)(2)(G) 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 are required to query State PDMPs for VHA patients who are receiving prescriptions for controlled substances as outlined in VHA Directive 1306(1), Querying State Prescribing Drug Monitoring Programs (PDMP), dated October 19, 2016.*

f. To further assist with implementation, NCEHC maintains a publicly-facing file, “Frequently Asked Questions VHA Directive 1005: Informed Consent for Long-term Opioid Therapy for Pain” (see <https://www.ethics.va.gov/policy.asp>).

### 3. DEFINITIONS

a. **Electronic Health Record.** Electronic health record (EHR) is the digital collection of patient health information resulting from clinical patient care, medical testing, and other care-related activities. Authorized VA health care providers may access the EHR to facilitate and document medical care. EHR comprises existing and forthcoming VA software including Computerized Patient Record System (CPRS), Veterans Health Information Systems and Technology Architecture (VistA), and Cerner platforms. **NOTE:** *The purpose of this definition is to adopt a short, general term (EHR) to use in VHA national policy in place of software-specific terms while VA transitions EHR platforms.*

b. **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 informed consent forms. VA has purchased an enterprise license for iMedConsent™. VHA Handbook 1004.05 establishes VHA national policy for iMedConsent™. The successor software for iMedConsent™ is iMedConsent Web.

c. **Long-term Opioid Therapy for Pain.** Long-term opioid therapy for pain is the medically indicated use of opioids on a daily or intermittent basis for 90 or more calendar days to treat non-cancer pain.

d. **Opioid.** For the purposes of this directive, opioids are opiates, opiate derivatives, and chemically equivalent narcotic compounds listed in 21 U.S.C. 812 as Schedule II or Schedule III controlled substances.

e. **Opioid Pain Care Agreement.** An OPCA is a document describing an exchange of information between a health care 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 adhere to other provisions as needed. **NOTE:** *The term OPCA encompasses other documents with similar purposes, including pain contracts, opioid agreements, opioid contracts, treatment agreements, pain management agreements, and patient-provider agreements. The use or enforcement of an OPCA is prohibited within the VA health care system.*

f. **Opioid Prescriber.** An opioid prescriber is a credentialed health care provider with clinical privileges or other health care professional whose scope of practice agreement or other formal delineation of job responsibility explicitly authorizes them to prescribe opioids.

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

h. **Surrogate Decision Maker.** The surrogate decision maker (surrogate) refers to an individual or decision-making process authorized to make health care decisions on behalf of a patient who lacks decision-making capacity. **NOTE:** *For further information on surrogate decision makers, see VHA Handbook 1004.01(2).*

#### 4. POLICY

It is VHA policy that, prior to initiating long-term opioid therapy for pain, VHA opioid prescribers must engage Veterans (or in the case of Veterans who lack decision-making capacity, their surrogate decision maker) in an informed consent discussion, including providing patient education materials, to ensure that the Veteran (or surrogate) understands the risks, benefits, and alternatives to the treatment and must obtain signature informed consent from the Veteran (or surrogate). **NOTE:** *This requirement does not apply to patients receiving short-term opioid therapy, patients enrolled in hospice, or patients receiving long-term opioid therapy for cancer pain, for whom oral informed consent is required, and specific documentation of informed consent for opioid therapy is not required.*

#### 5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

(2) Ensuring that each VISN Director has sufficient resources to fulfill the terms of this directive in all the VHA health facilities within that VISN.

(3) Providing oversight of VISNs to ensure compliance with the requirements of this directive.

c. **Deputy Under Secretary for Health for Organizational Excellence.** The Deputy Under Secretary for Health for Organizational Excellence is responsible for supporting the ethical implementation and oversight of this directive across VHA.

d. **Deputy Under Secretary for Health for Policy and Services.** The Deputy Under Secretary for Health for Policy and Services is responsible for supporting the clinical implementation and oversight of this directive across VHA.

e. **Assistant Deputy Under Secretary for Health, Office of Patient Care Services; Chief Officer, Specialty Care Services; and Chief Consultant, Mental Health Services.** The Assistant Deputy Under Secretary for Health for the Office of Patient Care Services, the Chief Officer for Specialty Care Services, and the Chief Consultant for Mental Health Services are responsible for collaborating:

(1) To provide and approve clinical content for the patient information guide titled “Safe and Responsible Use of Opioids for Chronic Pain: A Patient Information Guide” and the informed consent form titled “Consent for Long-Term Opioid Therapy for Pain”.

(2) With the Executive Director, National Center for Ethics in Health Care to manage updates to the patient information guide titled “Safe and Responsible Use of Opioids for Chronic Pain: A Patient Information Guide” and the informed consent form titled “Consent for Long-Term Opioid Therapy for Pain”.

(3) To respond to questions from VHA staff regarding the clinical content of the patient information guide titled “Safe and Responsible Use of Opioids for Chronic Pain: A Patient Information Guide” and the informed consent form titled “Consent for Long-Term Opioid Therapy for Pain”.

(4) With Women’s Health Services to assist with expertise on concerns related to opioid use and pregnancy in women of reproductive potential.

f. **Executive Director, National Center for Ethics in Health Care.** The Executive Director of the National Center for Ethics in Health Care is responsible for:

(1) Ensuring that the patient information guide “Safe and Responsible Use of Opioids for Chronic Pain: A Patient Information Guide” and the informed consent form

titled “Consent for Long-Term Opioid Therapy for Pain” are available and maintained in iMedConsent™ or iMedConsent Web.

(2) Responding to questions from VHA staff regarding the ethics content of the patient information guide titled “Safe and Responsible Use of Opioids for Chronic Pain: A Patient Information Guide” and the informed consent form titled “Consent for Long-Term Opioid Therapy for Pain”.

(3) Ensuring that the patient information guide titled “Safe and Responsible Use of Opioids for Chronic Pain: A Patient Information Guide” and the informed consent form titled “Consent for Long-Term Opioid Therapy for Pain” are consistent with current standards for ethical practice through periodic updates.

(4) Establishing a VA medical facility-level signature monitor for informed consent for long-term opioid therapy for pain and communicating availability of the monitor for use by VA medical facilities to promote quality improvement and a high reliability system.

g. **Veterans Integrated Service Network Director.** The VISN Director is responsible for:

(1) Communicating the contents of this directive to all VA medical facilities across the VISN.

(2) Ensuring that all VA medical facilities in the VISN comply with this directive.

(3) Ensuring that all VA medical facilities have the resources to implement this directive.

h. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring that opioid prescribers have ready access to printed copies of the patient information guide titled “Safe and Responsible Use of Opioids for Chronic Pain: A Patient Information Guide”. **NOTE:** *Copies of the guide may be ordered from the VA Academic Detailing Service SharePoint site at <https://vaww.portal2.va.gov/sites/ad/SitePages/Print%20Requests%20V2.aspx> or downloaded from NCEHC’s Web site at <https://vaww.ethics.va.gov/policy.asp>. These are internal VA Web sites that are not available to the public.*

(2) Ensuring that opioid prescribers have ready access to iMedConsent™ or iMedConsent Web, e-signature pads, and printers in relevant patient care areas.

(3) Ensuring that the electronic health record (EHR) progress note titled “Consent for Long-Term Opioids for Pain” is locally linked to the informed consent form titled “Consent for Long-Term Opioid Therapy for Pain” that is produced by iMedConsent™ or iMedConsent Web.

(4) Ensuring that OPCAs are no longer used at the VA medical facility.



i. **VA Medical Facility Chief of Staff.** The VA medical facility Chief of Staff is responsible for:

(1) Informing VA medical facility opioid prescribers in their respective service line about the requirements established under paragraph 5.k. of this directive.

(2) Ensuring that VA medical facility opioid prescribers, including nurses and pharmacists who prescribe opioids, adhere to the signature informed consent requirements established under paragraph 5.k. of this directive.

j. **VA Medical Facility Nurse Executive, VA Medical Facility Chief Nursing Officer, and VA Medical Facility Chief of Pharmacy Services.** The VA medical facility Nurse Executive, VA medical facility Chief Nursing Officer, and VA medical facility Chief of Pharmacy Services are responsible for informing VA medical facility opioid prescribers in their respective service line about the requirements established under paragraph 5.k. of this directive.

k. **VA Opioid Prescribers.** Prior to initiating long-term opioid therapy for pain, VHA opioid prescribers are responsible for:

(1) Completing the informed consent process in VHA Handbook 1004.01(2).

(2) Providing the patient (or in the case of a patient who lacks decision-making capacity, the surrogate decision maker) with a copy of the patient information guide titled “Safe and Responsible Use of Opioids for Chronic Pain: A Patient Information Guide” (available through iMedConsent™ or iMedConsent Web).

(3) Reviewing and discussing the contents of the patient information guide titled “Safe and Responsible Use of Opioids for Chronic Pain: A Patient Information Guide” with the patient or surrogate.

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

(5) Offering the patient or surrogate a copy of the signed informed consent form.

(6) Asking women of reproductive potential or surrogate about pregnancy status and pregnancy intentions and counseling these patients about preconception care.

(7) Using the patient information guide titled “Safe and Responsible Use of Opioids for Chronic Pain: A Patient Information Guide” and informed consent form titled “Consent for Long-Term Opioid Therapy for Pain” 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 any type of OPCA, such as a locally created OPCA, the VA opioid prescriber for that patient must ensure that the non-approved OPCA is removed and replaced by the VA informed consent form. **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 patient information guide and informed consent form required by this directive. When the State requires a specific informed consent form, the provider and patient must complete both the VA informed consent form (when required by this directive) and the State informed consent form. VA medical facilities may add State informed consent forms for opioids to the iMedConsent™ library. **NOTE:** For short-term opioids, for Veterans receiving hospice care, and patients receiving long-term opioid therapy for cancer pain, use of the patient information guide and informed consent form is optional, but the opioid prescriber 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.*

(8) Ensuring that the patient's or surrogate's signature informed consent for long-term opioid therapy for pain is documented in the EHR prior to initiating opioid therapy for that purpose.

(9) Obtaining a new signature informed consent from the patient or surrogate, on the informed consent form titled "Consent for Long-Term Opioid Therapy for Pain" when:

(a) There is a significant deviation from the treatment plan to which the patient or surrogate originally consented; or

(b) There is a change in the patient's condition or diagnosis that would reasonably be expected to alter the original informed consent. **NOTE:** For further information on when to obtain a new informed consent, see VHA Handbook 1004.01(2).

(10) Determining when to delegate elements of the patient education and informed consent discussion to VA medical health care team members, as appropriate to the competency of the team member.

I. **VA Medical Facility Health Care Team Members.** VA medical facility health care team members, such as Patient Aligned Care Team (PACT) staff, are responsible for assisting VA opioid prescribers to perform elements of the patient education and informed consent discussion when those elements are designated by the VA opioid prescriber and as appropriate to the competency of the team member.

## 6. TRAINING

There are no formal training requirements associated with this directive.

## 7. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Manager or Records Liaison.

## 8. REFERENCES

- a. Pub. L. 114-198.
- b. 21 U.S.C. 812.
- c. 38 U.S.C. 5701(l).
- d. 38 U.S.C. 7301(b).
- e. 38 U.S.C. 7331.
- f. 38 U.S.C. 7332(b)(2)(G).
- g. 38 CFR 17.32.
- h. VHA Directive 1306(1), Querying State Prescription Drug Monitoring Programs (PDMP), dated October 19, 2016.
- i. VHA Directive 2009-053, Pain Management, dated October 28, 2009.
- j. VHA Handbook 1004.01(2), Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009.
- k. VHA Handbook 1004.05, iMedConsent™, dated December 10, 2014.
- l. VA Form 10-0431c, Consent for Long-Term Opioid Therapy for Pain. Available through iMedConsent™ or iMedConsent Web, and at: <http://vaww.va.gov/vaforms>.  
**NOTE:** *This is an internal VA Web site and is not available to the public.*
- m. VA IB 10-791, “Safe and Responsible Use of Opioids for Chronic Pain: A Patient Information Guide.” Available through: iMedConsent or iMedConsent Web, and [https://www.ethics.va.gov/docs/policy/Safe\\_and\\_Responsible\\_Use\\_of\\_Opioids.pdf](https://www.ethics.va.gov/docs/policy/Safe_and_Responsible_Use_of_Opioids.pdf).
- n. VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain. Available at: <https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPG022717.pdf>.  
**NOTE:** *This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973*
- o. VHA Opioid Safety Initiative. Available at: [https://www.va.gov/PAINMANAGEMENT/Opioid\\_Safety\\_Initiative\\_OSI.asp](https://www.va.gov/PAINMANAGEMENT/Opioid_Safety_Initiative_OSI.asp).
- p. Frequently Asked Questions VHA Directive 1005: Informed Consent for Long-term Opioid Therapy for Pain. Available at <https://www.ethics.va.gov/policy.asp>.
- q. Safe and Responsible Use of Opioids for Chronic Pain: A Patient Information Guide. Available at <https://www.ethics.va.gov/policy.asp>.