



## Frequently Asked Questions

### VHA Directive 1005: Informed Consent for Long-term Opioid Therapy for Pain

#### **1. What's new?**

VHA Directive 1005, Informed Consent for Long-Term Opioid Therapy for Pain, was issued May 6, 2014. This new VHA Directive establishes policy regarding patient education and informed consent for long-term opioid therapy for pain.

#### **2. Where can I get a copy of the Directive?**

The Directive is available on the VHA Forms and Publications page at: [http://vaww1.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=3005](http://vaww1.va.gov/vhapublications/ViewPublication.asp?pub_ID=3005) and on the National Center for Ethics in Health Care's intranet page at: <http://vaww.ethics.va.gov/activities/policy.asp>.

#### **3. Why was the Directive published?**

As a part of VA's responsibilities under the 2011 Prescription Drug Abuse Prevention Plan from the Office of National Drug Control Policy, the National Pain Management Program (10P4E) and the National Center for Ethics in Health Care (10P6) collaborated to develop this new Directive to standardize the process for obtaining and documenting the patient's informed consent for treatment with long-term opioids.

#### **4. How does the policy define long-term opioid therapy?**

Long-term opioid therapy is defined as "the medically indicated use of opioids on a daily or intermittent basis for 90 or more calendar days to treat non-cancer pain." See FAQ #9-10 for more information.

#### **5. What are the components of the new informed consent process for long-term opioid therapy?**

VHA opioid prescribers are required to complete the following education and signature informed consent process prior to prescribing long-term opioid therapy:

- a. Reviewing and discussing the contents of the patient information guide titled "Taking Opioids Responsibly" with the patient. A copy of this guide should be provided to the patient. It is available in iMedConsent™ and at this link:

[http://www.ethics.va.gov/docs/policy/Taking\\_Opioids\\_Responsibly\\_for\\_Your\\_Safety\\_and\\_Safety\\_of\\_Others.pdf](http://www.ethics.va.gov/docs/policy/Taking_Opioids_Responsibly_for_Your_Safety_and_Safety_of_Others.pdf)).

b. Obtaining signature consent from the patient on the nationally-standardized VHA informed consent form titled “Consent for Long-Term Opioid Therapy for Pain.”

c. Offering the patient a copy of the signed consent form. (The patient information guide, “Taking Opioids Responsibly” is automatically appended to the signed consent form, making it easy to provide both documents to the patient with one print function).

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

e. For patients currently receiving long-term opioid therapy for non-cancer pain as of May 6, 2014, the patient education and informed consent process must be completed by May 6, 2015.

## **6. Who can obtain signature informed consent for long-term opioid therapy for pain?**

Policy specifies that informed consent must be obtained by the practitioner, defined in VHA Handbook 1004.01, *Informed Consent for Clinical Treatments as Procedures* (paragraph 3, page 2), as:

j. **Practitioner.** A practitioner is defined as any physician, dentist, or health care professional granted specific clinical privileges to perform the treatment or procedure. For the purpose of this Handbook, the term practitioner also includes:

(1) Medical and dental residents, regardless of whether they have been granted specific clinical privileges; and

(2) Other health care professionals whose scope of practice agreement or other formal delineation of job responsibility specifically permits them to obtain informed consent, and who are appropriately trained and authorized to perform the procedure or to provide the treatment for which consent is being obtained.

[http://www1.va.gov/vhapublications/ViewPublication.asp?pub\\_ID=2055](http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2055))

Based on this definition, “perform the treatment or procedure” means to prescribe long-term opioids and thus, only practitioners authorized to prescribe long-term opioids can complete the informed consent process by having a conversation with the patient to:

- ensure that the patient has been informed and educated about the risks, benefits and alternatives,
- ensure that the patient has voluntarily chosen to accept the recommended treatment, and
- obtain the patient’s signature.

(See FAQ #7 for information about the role of staff in supporting the informed consent process).

## **7. What is the role of the Patient Aligned Care Team (PACT) staff in obtaining signature informed consent for long-term opioid therapy for pain?**

Directive 1005 recognizes the important role of the PACT team members and states at para 4h (p. 5): “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.” Prescribers may rely on PACT team members to assist with the patient education and the informed consent discussion. As outlined in FAQ #6, only practitioners authorized to prescribe long-term opioids can complete the informed consent process.

#### **8. When should the informed consent discussion be repeated and a new consent form signed?**

All patients on long-term opioid therapy for non-cancer pain must have completed the new patient education and signature informed consent process by May 6<sup>th</sup>, 2015. Also, all locally created OPCAs must be replaced with the new informed consent form by May 6<sup>th</sup>, 2015. Once patients have completed the signature informed consent process, there are two circumstances under which a new informed consent must be obtained. As stated in VHA Handbook 1004.01, *Informed Consent for Clinical Treatments and Procedures* (para 4, p. 4), a new informed consent must be obtained:

- (1) If there is a significant deviation from the treatment plan to which the patient originally consented; or
- (2) If there is a change in the patient's condition or diagnosis that would reasonably be expected to alter the original informed consent.

#### **9. Do the new informed consent requirements apply to all opioid therapy prescribing?**

No. The requirements do not apply to patients receiving short-term opioids, patients enrolled in hospice, or patients receiving long-term opioids for cancer pain. For these patients, the practitioner must discuss opioid risks, benefits, and alternatives as a part of obtaining oral informed consent for the patient's overall plan of care. Specific documentation of oral informed consent is not required. Use of the patient information guide and consent form is optional for these patients.

#### **10. Directive 1005 states that the new informed consent, “[r]equirement does not apply to patients... receiving long-term opioids for cancer pain”. Does this mean that the new signature informed consent requirements do not apply if the patient has a cancer diagnosis?**

No. The new informed consent requirements do not apply to patients with pain related to cancer and/or cancer treatment, but may apply to some patients with cancer as they may be prescribed long-term opioids for reasons unrelated to their cancer.

#### **11. Does VHA Directive 1005 govern long-term opioid therapy for opioid use disorders?**

No. VHA Directive 1005 establishes policy regarding patient education and informed consent for long-term opioid therapy for pain. It does not establish policy for long-term opioid therapy for other conditions. For information regarding signature consent for other drugs, see VHA Handbook 1004.01, *Informed Consent for Clinical Treatments and Procedures*, Appendix A which provides a list of treatments and procedures requiring signature consent. Number 10 on that list is, “Hazardous drugs (e.g., cancer chemotherapy, methadone for narcotic dependence, buprenorphine, thalidomide, clozapine, Retin A)”. Consent forms for treatments and procedures listed in Appendix A can be found in iMedConsent.

## **12. Who is assigned new responsibilities in the Directive?**

The Directive includes new responsibilities for VHA practitioners who prescribe long-term opioid therapy (e.g., pain management specialists, primary care providers). In addition to VHA opioid prescribers, the Directive also assigns responsibilities to the Facility Director, Chief of Staff, and Nursing Executive.

## **13. What is the new policy regarding Opioid Pain Care Agreements (OPCAs)?**

While some benefits have been proposed for OPCAs, experts have raised concerns about OPCAs, including their use of threatening language and their potential to undermine trust. Poorly crafted OPCAs may harm the patient-provider relationship, lead to practices that are inconsistent with VHA policy, or lead to adverse outcomes. 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. Therefore, locally approved OPCAs may no longer be used within VHA. If a patient has an OPCA in place, the VHA opioid prescriber for the patient must ensure that the non-approved OPCA is removed and replaced by the nationally standardized consent form by May 6, 2015.

## **14. What does Directive 1005 mean when it says, “the non-approved OPCA is removed and replaced by the nationally standardized consent form by May 6, 2015”? Since documents cannot be removed from the electronic health record, how should the requirement be met?**

The statement is not intended to suggest that OPCAs can be “removed” from patient's electronic health records. This statement simply means that by May 6, 2015, the new patient education and informed consent process must be completed for all patients on long-term opioid therapy for non-cancer pain. If an OPCA progress note title is in a CWAD Posting, the only method for removing it from the CWAD section of CPRS is to change the note title. VHA Handbook 1907.01, paragraph 25d suggests changing the note title by adding the term “RESCINDED ....”

## **15. May any OPCAs be used?**

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.

## **16. What are the deadlines for implementation?**

a. Facility Directors are responsible for ensuring that the CPRS progress note title “Consent for Long-Term Opioids for Pain” is established locally by **June 6, 2014**. This should be the local title and the associated standard title in Text Integration Utility, without suffixes or prefixes. iMedConsent Administrators are responsible for assigning this Progress Note Title to the informed consent wizard's document activity profile.

b. Facility Directors are responsible for ensuring that the local policy, consistent with the requirements of the Directive, is developed and published by **November 6, 2014**. The National Center for Ethics in Health Care (NCEHC) has drafted a model Medical Center Memorandum template to assist with this requirement. It is available at: <http://vaww.ethics.va.gov/activities/policy.asp>.

c. The Chief of Staff is responsible for ensuring that all patients on long-term opioid therapy for non-cancer pain have completed the new education and informed consent process by **May 6, 2015**.

d. Opioid prescribers are responsible for ensuring that locally created OPCAs are removed and replaced by the nationally standardized consent form by **May 6, 2015**.

**17. Where can I get a copy of the model Medical Center Memorandum template?**

The Model MCM Template is available on the NCEHC Intranet site at <http://vaww.ethics.va.gov/activities/policy.asp>.

**18. Where can I find the consent form?**

The nationally-standardized informed consent form titled “Consent for Long-Term Opioid Therapy for Pain” is available in iMedConsent. The consent form in iMedConsent is located under the specialties Anesthesia/Pain Management, Neurology, and Physical Medicine and Rehab, and can be added to other specialties locally.

As indicated in VHA Handbook 1004.05, *iMedConsent*, (paragraph 10), iMedConsent must be used to document signature consent for treatments or procedures unless certain exceptions apply. If an exception applies, signature consent must be documented on the nationally approved VHA consent form, 10-0431c, “Consent for Long-Term Opioid Therapy for Pain.” That form can be accessed at <http://vaww.va.gov/vaforms/>.

**19. What are the exceptions to using iMedConsent to complete the Consent for Long-Term Opioid Therapy for Pain?**

VHA Handbook 1004.05, paragraph 10 requires the use of iMedConsent unless:

- a. The patient declines to sign using the electronic signature pad;
- b. There is a temporary system failure that prohibits proper use of the program;
- c. The patient (or surrogate) is giving consent over the telephone, or by fax; or
- d. Use of the program would introduce infection control issues (e.g., patient is in isolation).

As part of full implementation of the Directive by May 6, 2015, facility Directors must ensure that opioid prescribers have ready access to iMedConsent and printers in relevant patient care areas. This will also require facilities to have sufficient electronic signature pads. Until that time, if proper use of iMedConsent is not possible, signature consent must be documented on VHA form 10-0431c, “Consent for Long-Term Opioid Therapy for Pain.”

**20. Should scanned paper “Consent for Long-Term Opioid Therapy for Pain” forms to be attached to the “Consent for Long Term Opioids For Pain” progress note title in CPRS?**

Yes. This note title must be locally linked to the consent form entitled “Consent for Long-Term Opioid Therapy for Pain” whether it is produced by iMedConsent or documented on VHA form 10-0431c. The intent of associating the standardized title with both iMedConsent and scanned versions of this form is to help provide continuity of care

by enabling providers to use remote viewing in order to view these progress notes across the enterprise.

**21. What steps need to be taken to implement the revised policy?**

- a. Carefully read the new Directive.
- b. iMedConsent administrators (e.g., Clinical Application Coordinators, OIT staff) will need to assign the appropriate Progress Note title (“Consent for Long-Term Opioids for Pain” to the informed consent wizard’s document activity profile.
- c. The Facility Director must identify who at the facility is responsible for drafting the facility’s local policy (Local policy, consistent with the requirements of the Directive, must be developed and published by November 6, 2014.)
- d. The Chief of Staff must determine who is responsible for informing and educating facility opioid prescribers about the new requirements of the Directive.

**22. Do professional organizations and others recommend signed informed consent for long-term opioids?**

Yes, for example:

- The Federation of State Medical Boards’ 2013 Model Policy on the Use of Opioid Analgesics recommends the use of “a written informed consent.”
- The HHS/SAMHSA Opioid Overdose Toolkit endorsed by the White House Office of National Drug Control Policy states that “Both patient and physician should sign the informed consent agreement, and a copy should be placed in the patient’s medical record.”
- The National Initiative on Pain Control Treatment Algorithm sponsored by the American Pain Foundation states that “Both patient and physician should sign the informed consent agreement, and a copy should be placed in the patient’s medical record.”
- The Rhode Island Medical Society guidelines for long-term pain management state that “the physician should discuss the risks and benefits of the use of controlled substances with the patient, guardian, or authorized representative. This discussion should be documented and signed by the patient, guardian, or authorized representative.”

**23. Why does VA require signature consent for long-term opioids when other medications have similar risks?**

- VA regulations (38 CFR 17.32) require signature consent for all treatments and procedures that “have a significant risk of complication or morbidity.”
- National program offices determine treatments that meet this standard and the national VA Pain Management office has determined that long-term opioids meet this threshold.
- Many other medications require signature consent.

**24. Is it appropriate to obtain signature informed consent before prescribing tramadol?**

Although tramadol does not fall under the definition of “opioid” in Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain* (it is a Schedule IV, not Schedule II or III drug), practitioners may use the nationally-approved opioid consent



form (“Consent for Long-Term Opioid Therapy for Pain”) to obtain signature consent for tramadol if they think it is appropriate based on the individual patient case and the level of risk/burden of the treatment for that patient (per VHA Handbook 1004.01, *Informed Consent for Clinical Treatments and Procedures*).

**25. Is informed consent required for urine drug testing in the context of long-term opioid therapy for pain?**

Yes, according to VHA regulation (38 CFR 17.32) and VHA Handbook 1004.01, *Informed Consent for Clinical Treatments and Procedures*, all clinical procedures or treatments performed on patients require a provider to obtain informed consent. This standard reflects the ethical principle that patients have a right to determine what is done to their body, and is consistent with VHA’s commitment to patient-centered care based on shared decision making between patients and their providers.

**26. What kind of informed consent is required for urine drug testing?**

Specific oral consent is required. According to VHA Handbook 1004.01, paragraphs 13a(1)(b) and 13c(1), specific tests, including tests used to identify illicit drug use “...are particularly sensitive and may have consequences that the patient might reasonably want to avoid.” For such tests, specifically documented oral consent is sufficient; signature consent is not required.

**27. Must specific oral consent be obtained and documented every time the provider wants to order a urine drug test?**

No. Although practitioners must obtain the patient’s consent for each urine drug test, they cannot realistically get consent at the exact time of urine sampling because practitioners and patients do not meet for an appointment each time urine is collected. In addition, there is often no private space available for a confidential informed consent conversation when a urine sample is requested. The National Center for Ethics in Health Care has determined that it is consistent with ethics and policy to obtain consent for ongoing UDT (initial, periodic, for-cause, and random) if the initial consent for UDT includes discussion and patient understanding that ongoing UDT will be performed while the current long term opioid treatment plan is in place. As part of a review of safe opioid use, a new informed consent discussion for UDT should be completed at least annually, or sooner if the clinical conditions that led to the consent change.

**28. How should oral consent for urine drug testing in the context of long-term opioid therapy for pain be documented in the record?** Simple language can be used to document specific oral informed consent for UDT, such as “Patient consented to ongoing UDT as part of the treatment plan.” This documentation can be done in a progress note, in a note with the order, or in an electronic clinical reminder.

**29. Can oral consent for urine drug testing in the context of long-term opioid therapy for pain be documented in the comment box on the nationally standardized form, “Consent for Long-Term Opioid Therapy for Pain”?**

No. Consent for urine drug testing cannot be documented in the comment box of the consent form. According to VHA Handbook 1004.01, *Informed Consent for Clinical Treatments and Procedures* (paragraph 4, page 4), “VHA does not recognize “general” or “blanket” consent for medical treatment, but requires the patient’s separate consent

for each treatment, procedure, therapeutic course of treatment for a particular problem or condition (e.g., inpatient or outpatient treatment for diabetes), or series of treatments (e.g., cycles of chemotherapy)”.

**30. Even though signature consent for urine drug testing is not required, would it be *inappropriate* to obtain signature consent for urine drug testing?**

Yes. According to VHA Handbook 1004.01, paragraph 13c(2)(a), “The patient’s signature consent must be obtained for treatments and procedures that:

- a. Can be reasonably expected to produce significant pain or discomfort to the patient;
- b. Can be reasonably expected to produce pain or discomfort to the patient that is substantial enough to require sedation, anesthesia, or narcotic analgesia;
- c. Can be reasonably considered to have a significant risk of complication or morbidity;
- d. Require injections of any substance into a joint space or body cavity (excluding the intravascular space); or
- e. Are listed in Appendix A [of Handbook 1004.01].

Although specific tests used to identify illicit drug use are particularly sensitive, they do not meet the risk threshold for the signature consent requirement. In addition, the signature consent process requires a special workflow to obtain the signatures. This workflow involves patient and practitioner access to iMedConsent and the signature pad and, for patients who lack capacity and have no surrogate, involves approval by the attending physician and Service Chief. This workflow burden is justified by the higher risk threshold of those treatments and procedures that require signature consent. The convenience of the provider and ease of locating the consent more quickly in the record are not sufficient to justify this workflow burden.

*For questions regarding this new Directive, please email [vhaethics@va.gov](mailto:vhaethics@va.gov) or call 202-632-8457.*

*Please check the National Center for Ethics in Health Care’s website for future updates to this FAQ document: <http://vaww.ethics.va.gov/activities/policy.asp>.*

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