Frequently Asked Questions


1. What has changed with the release of VHA Notice 2017-38, Amendment of VHA Handbook 1004.01: Removing the Requirement for Specific Documentation of Oral Informed Consent to Tests for Hepatitis B (HBV) Virus and Hepatitis C (HCV) Virus?

When it was issued in 2009, VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, included a requirement that providers specifically document the patient’s (or surrogate’s) oral informed consent for tests for HBV and HCV. VHA Notice 2017-38 removes the requirement for the specific documentation of consent for HBV and HCV. VHA Handbook 1004.01 has been updated to reflect this change.

2. What has NOT changed with the release of VHA Notice 2017-38, Amendment of VHA Handbook 1004.01: Removing the Requirement for Specific Documentation of Oral Informed Consent to Tests for Hepatitis B (HBV) Virus and Hepatitis C (HCV) Virus?

Although specific documentation of the patient’s (or surrogate’s if the patient lacks capacity) oral informed consent to a test for HBV or HCV is no longer required, practitioners who want to recommend an HBV or HCV test continue to have an ethical and professional obligation to engage the patient (or surrogate) in a specific informed consent conversation about the HBV or HCV test.

3. What must a practitioner discuss as part of oral informed consent for an HBV or HCV test?

A practitioner must provide information about the test: what it is, why it’s being recommended, the benefits and potential risks of testing, and the alternatives to testing. A general discussion about a treatment plan or, for example, a blood panel of which the test is a part, is not sufficient.
4. Why was the decision made to remove the requirement for specific documentation of the patient’s (or surrogate’s) oral informed consent to tests for HBV and HCV?

The availability of new, lifesaving treatments for HCV is helping to reduce the stigma associated with an HCV diagnosis, and, for most patients, there is minimal risk of psychosocial harm associated with an HBV diagnosis. This shift, as well as provider concerns about the burden of documentation, was the basis for the decision to remove the requirement to specifically document the patient’s oral consent to the test in question.

5. Does the removal of the specific documentation requirement of oral informed consent to tests for HBV and HCV also apply to documentation of informed consent for HIV, illicit drug use, alcohol intoxication, Methicillin-Resistant Staphylococcus Aureus (MRSA), sexually-transmitted diseases, and inheritable genetic abnormalities?

No. According to VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, tests for HIV, illicit drug use, alcohol intoxication, MRSA, sexually-transmitted diseases, and inheritable genetic abnormalities continue to require specific oral informed consent, including documentation of consent to the test in question. (VHA Handbook 1004.01, paragraph 13a(1)(b), page 7)

“Specific oral informed consent,” also referred to as “specific consent,” is outlined in paragraph 13, of VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures. It is the VA informed consent process for tests that provide information that is particularly sensitive or may have significant consequences that the patient might reasonably want to consider as part of their consent decision. Obtaining specific oral informed consent from the patient (or surrogate if the patient lacks decision making capacity), requires a specific discussion about the test as well as specific documentation of the patient’s (or surrogate’s) consent to the test in the electronic health record. The documentation can be something as simple as “patient consented to X test” written in a progress note or lab order. (See VHA Handbook 1004.01, paragraph 13c(1)(b), page 10).

For questions about VHA Notice 2017-38 or Handbook 1004.01, please contact vhaethics@va.gov.