AMENDMENT OF VHA HANDBOOK 1004.01 REMOVING THE REQUIREMENT FOR DOCUMENTATION OF ORAL INFORMED CONSENT TO TESTS FOR HEPATITIS B (HBV) VIRUS AND HEPATITIS C (HCV) VIRUS

1. PURPOSE: This notice announces an amendment to VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures (August 14, 2009). The amendment removes the requirement established in paragraph 13a(1)(b) for documentation of a patient’s (or surrogate’s if the patient lacks decision making capacity) oral informed consent to tests for hepatitis B (HBV) virus and hepatitis C (HCV) virus. Oral informed consent to these tests is still required, however documentation that the patient (or surrogate) gave oral informed consent to the test in question is no longer required.

2. ORAL INFORMED CONSENT FOR TESTS FOR HBV AND HCV

   a. By VA statute (38 USC §7331) and regulation (38 CFR §17.32), informed consent is required for all treatments and procedures provided in VA.

   b. Informed consent is the process by which the practitioner discloses and discusses appropriate information with a patient so that the patient may make a voluntary choice about whether to accept the proposed diagnostic or therapeutic procedure or course of treatment. Appropriate information is information that a reasonable person in the patient’s situation would expect to receive in order to make an informed choice about whether or not to undergo the treatment or procedure. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, describes the specific oral informed consent requirements for tests whose results predictably may have consequences that the patient might reasonably want to consider as part of their consent decision. At paragraph 13a(1)(b), the Handbook included tests for hepatitis B and hepatitis C among those requiring that the patient’s (or surrogate’s) consent be specifically documented in the electronic health record.

   c. The availability of new, lifesaving treatments for HCV has helped to reduce the stigma associated with an HCV diagnosis, and, for most patients, there is minimal risk of psychosocial harm associated with HBV diagnosis. As a result, documentation of the patient’s consent to tests for these two conditions is no longer warranted. Accordingly, the following amendment was made to VHA Handbook 1004.01 at 13a(1)(b): “Information about certain tests must be considered ‘information that a patient in similar circumstances would reasonably want to know’ because these tests are particularly sensitive and may have consequences that the patient might reasonably want to avoid. These tests include, but are not limited to, specific tests to identify illicit drug use, alcohol intoxication, HIV, Hepatitis C, Hepatitis B, Methicillin-Resistant Staphylococcus Aureus (MRSA), sexually-transmitted diseases, and inheritable genetic abnormalities. For these tests, practitioners must obtain specific consent and follow the informed
consent process as outlined in the remainder of this paragraph. Signature consent is not required; oral consent is sufficient and must be documented in the patient's electronic health record (see subpar. 13c(1))."

d. Health care providers still have an ethical and professional obligation to engage patients in an informed consent conversation about testing for HCV and HBV. The practitioner must discuss specific information about the test, the reasons to obtain the test, the consequences of not being tested, the potential risks of testing, and the alternatives to testing. A general discussion about a treatment plan or, for example, a blood panel of which these tests are a part is not sufficient.

3. RESPONSIBLE OFFICE: The VHA National Center for Ethics in Health Care (10E1E) is responsible for the content of this VHA notice. Questions may be addressed to 202-632-8457.

4. RESCISSION: The VHA Notice will expire on May 31, 2018. However, the amendment information will remain in effect.

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