Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA HANDBOOK 1004.05
Transmittal Sheet
December 10, 2014

iMedCONSENT™

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Handbook sets forth procedures related to the use of the iMedConsent™ software program.

2. SUMMARY OF MAJOR CHANGES: This is a revised VHA Handbook that:

a. Clarifies the medical facility Directors' responsibilities regarding the management of local forms.

b. Adds responsibilities for the National Center for Ethics in Health Care and for the Office of the Deputy Under Secretary for Health for Operations and Management related to implementation of this policy.

3. RELATED ISSUES: VHA Handbook 1004.01 and VHA Handbook 1004.02.

4. RESPONSIBLE OFFICE: The National Center for Ethics in Health Care (10P6) is responsible for the contents of this Handbook. Questions may be referred to 202-632-8457.

5. RESCISSION: VHA Handbook 1004.05, dated March 19, 2009, is rescinded.

6. RECERTIFICATION: This VHA Handbook is scheduled for recertification on or before the last working day of December, 2019.

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Interim Under Secretary for Health

DISTRIBUTION: Emailed to VHA Publications Distribution List on 12/16/2014.

CONTENTS

iMedCONSENT™

PARAGRAPH **PAGE**

iMedCONSENT™

1. PURPOSE: This Veterans Health Administration (VHA) Handbook sets forth procedures related to the use of the iMedConsent™ software program. **AUTHORITY:** 38 U.S.C. 305 and 7331 through 7334, and 38 CFR 17.32.

2. BACKGROUND:

a. VHA is a recognized leader in the use of computer technology to promote and ensure high quality patient care.

b. In February 2004, the VHA National Leadership Board (NLB) mandated national implementation of iMedConsent™.

c. iMedConsent™ is a software package that supports electronic access, completion, electronically captured signature, and storage of documents, such as informed consent forms and advance directives.

d. iMedConsent™ includes an extensive library of patient education documents, anatomical pictures and diagrams, and drug monographs. The nationwide installation of iMedConsent™ was completed in September, 2005.

3. DEFINITIONS:

a. **Additional Information Field.** The additional information field is a content field in the consent form creator portion of iMedConsent™. This field contains facility-determined text that is added to every consent form that is generated using iMedConsent™ at each Department of Veterans Affairs (VA) medical facility. Text that is added to the Additional Information field is not overwritten with the release of national software updates.

b. **Administrative Users.** Administrative users have administrative rights to perform advanced functions in iMedConsent™, such as adding local forms, adding text to locally-controlled fields, and generating specialized usage reports.

c. **Advance Directive.** An advance directive is a written statement by a person, who has decision-making capacity regarding preferences about future health care decisions in the event that individual becomes unable to make those decisions (see VHA Handbook 1004.02, Advance Care Planning and Management of Advance Directives).

d. **Dialog Medical.** Dialog Medical is the vendor of the iMedConsent™ software package.

e. **Electronic Signature Pad.** The electronic signature pad is an electronic device that is used to capture written signatures electronically.

f. **Electronically Captured Signature.** The Electronically Captured Signature is a term used to refer to a written signature captured using an electronic signature pad and affixed to a document. ***NOTE:*** *An electronically captured signature should not be confused*

with an electronic signature which is a computer data compilation of a symbol or series of symbols.

g. **Facility-Specific Procedure Notes Field.** The "Facility-Specific Procedure Note" field is a content field in the consent form creator portion of the iMedConsent™ program. Utilizing this field, iMedConsent™ administrative users may add text to the description of the procedure or treatment described in individual consent forms. Text added to the "Facility-Specific Procedure Notes" field is not overwritten with the release of national updates.

h. **iMedConsent™.** The iMedConsent™ is a commercially-available software package that has been customized for use within the Department of Veterans Affairs (VA). The software supports electronic access, completion, signing, and storage of such documents as informed consent forms and advance directives. VA has purchased an enterprise license for iMedConsent™. The name of the program is sometimes abbreviated as "iMed."

4. SCOPE:

a. iMedConsent™ must be used to generate, sign, and store consent forms for clinical treatments and procedures, except as noted in paragraph 6.a. of this Handbook. Use of the program must be supported in all VA medical facilities, Community-Based Outpatient Clinics (CBOCs), and other VA health care environments with access to VA's Computerized Patient Record System (CPRS).

b. Practitioners must use the Spanish-language translations in iMedConsent™ to facilitate the informed consent discussion when appropriate.

c. Practitioners may utilize the patient education materials, anatomical pictures and diagrams, drug monographs, and forms contained in the iMedConsent™ library, as appropriate.

d. Practitioners may use iMedConsent™ to help Veterans complete VA Form 10-0137, VA Advance Directive: Durable Power of Attorney for Health Care and Living Will.

e. The forms and documents in the iMedConsent™ library must be maintained as described in paragraph 7 of this Handbook.

5. RESPONSIBILITIES:

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

(1) Ensuring that policy and procedures, consistent with this Handbook, are implemented in VA medical facilities by working with National Center for Ethics in Health Care each year to establish appropriate performance tracking and following up on reports of inadequate adherence to this Handbook.

(2) Designating operational policy offices under the Deputy Under Secretary for Health for Operations and Management to coordinate with the Office of Patient Care Services to ensure that consent form content is consistent with VHA policy and practice.

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

(1) Ensuring, through an ongoing review process using subject matter experts and Field Advisory Committees, that the clinical content in the iMedConsent™ system (i.e., consent form information, patient education documents, and pre- and post-operative instructions) is consistent with VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, and any other applicable VHA policies, and reflects current accepted standards of clinical practice.

(2) Submitting content changes to the vendor (Dialog Medical) to be incorporated into the software program.

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

(1) Providing oversight of the iMedConsent™ contract;

(2) Maintaining and updating this Handbook;

(3) Ensuring that the iMedConsent™ software maintains compliance with ethical standards and VHA policies related to health care ethics;

(4) Establishing, interpreting, and communicating standards and guidance for iMedConsent™ usage, including the procedures in this Handbook;

(5) Establishing iMedConsent™ program performance and quality improvement goals, in consultation with the Deputy Under Secretary for Health for Operations and Management;

(6) Identifying, in consultation with the Deputy Under Secretary for Health for Operations and Management, key measures for monitoring adherence to this Handbook on an annual basis;

(7) Collecting quarterly and annual data on identified key measures for iMedConsent™ usage and making data analyses and progress reports available to leaders and the field; and

(8) Reporting inadequate iMedConsent™ usage and policy adherence at the facility and Veterans Integrated Service Network (VISN) level to the Deputy Under Secretary for Health for Operations and Management.

d. **VHA Office of Informatics and Analytics/Health Systems Portfolio Management.** The VHA Office of Informatics and Analytics, Health Systems Portfolio Management (OIA/HSPM) is responsible for:

(1) Acting as a liaison between the National Center for Ethics in Health Care and the VA Office of Information and Technology (OIT);

(2) Designating a primary technical point of contact within the Office of Health Information (OHI) who will act as the primary contact for information technology issues related to iMedConsent™, and who will attend monthly iMedConsent™ point of contact teleconferences; and

(3) Facilitating coordination of business requirements related to software enhancements and new functionalities to the software and compliance with VA technical requirements with OIT and the vendor. This may include coordination with VHA OIA Health Information Governance, Health Care Security Requirements and/or iMedConsent designated Information Security Officer to conduct a security impact analysis of proposed changes or enhancements.

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

(1) Practitioners have the equipment and resources they need to use iMedConsent™ effectively;

(2) Informed consent workflow is examined and reengineered when necessary to comply with this Handbook and VHA Handbook 1004.01;

(3) iMedConsent™ end-users and administrative users are competent in the use of the iMedConsent™ system;

(4) Staff members are made aware that patient education resources are available in iMedConsent™ (including the educational documents, anatomical pictures and diagrams, and drug monographs), which may be accessed and provided to patients, as needed;

(5) Practitioners use iMedConsent™ consistent with this Handbook;

(6) Administrative users maintain forms in the library as directed in this Handbook;

(7) Document processing problems are promptly resolved and/or reported to the vendor, when appropriate;

(8) Administrative users generate regular iMedConsent™ usage reports for Chief of Staff (COS) review;

(10) Facilities do not customize the structure of nationally standardized forms provided in iMedConsent™ by the vendor (e.g., VA Form 10-0137); and

(11) Facilities obtain approval for adding auto-populated text to any nationally standardized form in iMedConsent™. Approval must be obtained from the local forms committee and the appropriate VA Program Office that has primary responsibility for the nationally standardized form.

f. **Facility Chief of Staff.** The facility Chief of Staff (COS) is responsible for ensuring:

(1) Locally-customized forms and data fields contain information that is in compliance with this Handbook, VHA Handbook 1004.01, and any other applicable VHA policies or guidelines;

(2) iMedConsent™ usage reports are reviewed and used to initiate improvement activities, as appropriate; and

(3) All clinical specialties are using iMedConsent™ to document signature consent as stated in this Handbook.

6. INFORMED CONSENT FOR CLINICAL TREATMENTS AND PROCEDURES:

a. iMedConsent™ must be used to document patient consent for treatments or procedures that require signature consent, unless:

(1) The patient declines to sign using the electronic signature pad;

(2) There is a temporary system failure that prohibits proper use of the program;

(3) The patient (or surrogate) is giving consent in a situation not supported by the iMedConsent™ software (e.g. by mail or fax); or

(4) Use of the program would introduce infection control issues (e.g., patient is in isolation).

b. When iMedConsent™ is not used, signature consent must be documented on a nationally approved consent form (see VHA Handbook 1004.01).

c. Workflows associated with the informed consent process and documentation must be examined and reengineered to reflect quality standards for informed consent as stated in VHA Handbook 1004.01. ***NOTE:*** *A guidance document produced to aid in workflow analysis and reengineering to appropriately incorporate the use of iMedConsent™ can be found at: http://vaww.patientdecisions.va.gov/docs/iMed_Analysis.pdf. This is an internal VA Web site and is not available to the public.*

d. iMedConsent™ must not be used to:

(1) Document consent for services provided by Occupational Health.

(2) Document consent for research, except as specifically authorized by the Office of Research and Development.

e. Spanish language translations (consent forms and education documents) are available in iMedConsent™. These materials must be used with Spanish speaking patients (or surrogates) to facilitate the informed consent discussion, when appropriate.

f. A printed copy of the consent form must be offered to the patient or surrogate before and after signatures are obtained.

7. CLINICAL CONSENT FORM ADMINISTRATION IN iMedCONSENT™:

a. Local versions of national consent forms cannot be created in iMedConsent™. Administrative users must ensure that local versions of national consent forms do not exist in their local form library, and must instruct practitioners to use only the nationally-approved consent forms.

b. Facilities may add consent forms to their local library for treatments or procedures that are not included in the iMedConsent™ library. However, copies of locally-created clinical consent forms must be sent to the vendor, Dialog Medical, using the email address content@dialogmedical.com, before the form is added to the local library. If the newly-added form duplicates a form in the national library, or is otherwise inappropriate, the facility will be instructed to delete the form from their library. Once national versions of consent forms are released, facilities must delete any corresponding locally-created consent form and instruct practitioners to use the national form.

c. All locally-added consent forms must be consistent with VHA Handbook 1004.01. Facilities need to determine local procedures for the review and approval of new clinical consent forms that are not included in the standard iMedConsent™ library.

d. Forms used for purposes other than those described in this Handbook and that are not specifically prohibited in this Handbook may be added to the iMedConsent™ library at the local level. All locally added forms must be reviewed and approved by the local forms committee. ***NOTE:*** *The local forms committee make-up varies from facility to facility, but the committee must ensure that this Handbook is followed.*

e. Information added to the Facility-Specific Procedure Notes field must conform to the requirements in VHA Handbook 1004.01. The text on the Facility-Specific Procedure Notes field must not include risks, benefits, or alternatives. Information added to the Facility-Specific Procedure Notes field must be approved by the local Chief of Service. Appropriate content includes logistical information about the treatment or procedure that is relevant to local practice (e.g., directions to the building where the procedure is performed).

f. Text contained in the "Additional Information" field must be approved by the COS or designee. Since this text is added to every consent form, it must only contain information that is relevant to all treatments and procedures performed at the facility. For example, "If you need to cancel or reschedule your treatment or procedure, call 555-1000."

8. ADVANCE DIRECTIVES:

a. Although the use of iMedConsent™ to help patients complete and electronically store advance directive forms is encouraged, it is not mandatory.

b. Practitioners need to print two copies of the completed, signed advance directive for the patient (or more upon request). ***NOTE:*** *Procedures and requirements for documentation*

of advance directives are described in VHA Handbook 1004.02, Advance Care Planning and Management of Advance Directives.

9. OPERATIONAL REQUIREMENTS:

a. iMedConsent™-related equipment (e.g., servers, workstations, signature pads) must be properly configured and maintained.

b. Printers must be available in areas where iMedConsent™ is used so that the documents created, or available in iMedConsent™, can be easily printed for the patient.

c. Various mobile solutions are in use throughout VA for wireless or mobile implementation of iMedConsent™. Each VA medical facility possesses unique characteristics, which make a "single solution" impractical. Specific equipment needs are to be assessed and determined at the facility. Such equipment assessments need to incorporate a user-based evaluation and include simulated "consenting" scenarios in the desired deployment locations. End-user participation in these evaluations is essential to ensure that the equipment is manageable within the context of the informed consent workflow.

d. Except in the simplest of cases, VA staff must not service mobile carts, unless they have received proper training and instruction from the vendor of the devices (e.g., do not add personal electronic signature pads.) ***NOTE:*** *For concerns regarding compatibility of equipment with iMedConsent™ software, VA staff should contact the vendor, Dialog Medical.*

10. CONTACTS:

a. **Technical Issues.** Technical problems or difficulties with the iMedConsent™ software need to be reported to the vendor, Dialog Medical, at 1-800-482-7963 or at enterprise@dialogmedical.com.

b. **Clinical Content Concerns and Requests.**

(1) Concerns related to the clinical content in the iMedConsent™ program and requests for new content need to be reviewed and approved by the relevant Specialty Chief and submitted to the vendor using email (content@dialogmedical.com). Submission must include the name of the document (or proposed name if new content is being requested), the specialty (or proposed specialty), and a description of the concern or new content request.

(2) The vendor, Dialog Medical, evaluates content requests on a 90-day timeframe (estimated) to determine whether content modification or new content is needed. Dialog Medical provides a summary of actions taken in response to any field request to Patient Care Services for review.

(3) Patient Care Services, in conjunction with designated operational policy offices under the Deputy Under Secretary for Health for Operations and Management, is responsible for ensuring that consent form content is consistent with VHA policy and practice.

c. **VHA Policy.** Questions about iMedConsent™ and policy-related requirements need to be sent to vhaethics@va.gov.

d. **Other Resources.**

(1) Electronic Support for Patient Decisions Website: http://vaww.patientdecisions.va.gov. ***NOTE:*** *This is an internal VA Web site and is not available to the public.*

(2) National Center for Ethics in Health Care Website: http://vaww.ethics.va.gov. ***NOTE:*** *This is an internal VA Web site and is not available to the public.*

11. ADMINISTRATIVE FORMS:

a. The use of iMedConsent™ for administrative purposes is encouraged, however it is not mandatory.

b. Administrative forms in iMedConsent ™ must be mapped to a standard national Text Integration Utilities (TIU) note title of "ADMINISTRATIVE NOTE." For information on standardized note titles, see VHA Handbook, 1907.01, Health Information Management and Health Records. Until there is a direct interface to VistA Imaging, these iMedConsent administrative documents must be associated with the administrative note title in order to be filed in the Computerized Patient Record System (CPRS).

12. REFERENCES:

a. 38 CFR 17.32.

b. VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures.

c. VHA Handbook 1004.02, Advance Care Planning and Management of Advance Directives.

d. VHA Handbook 1907.01, Health Information Management and Health Records.