



Privacy Impact Assessment for the VA IT System called:

Clinical Assessment Reporting and Tracking Applications (CART-Apps)

Clinical Systems Design and Evaluation

9 November 2021

System Contacts:

System Contacts

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Abstract

The Clinical Assessment, Reporting, and Tracking Applications (CART-Apps herein referred to as CART) is a joint effort of the VA Office of Organization Excellence, Clinical Systems Design and

Evaluation in close collaboration with the VA National Program for Cardiology. The CART system has been in place since its initial deployment in 2003, identified by OMB Unique Project Identifier: 290001110000000, System Of Record Name: National Patient Databases – VA, System Of Recorded Number: 121VA19, under authority of Title 38, United States Code, Section 501.

The National CART system provides direct clinical support for clinical staff evaluating veterans for, and conducting cardiovascular procedure. The CART application is used by VA Clinicians nationally as a part of their routine clinical care for all Veterans being considered for or undergoing cardiovascular procedures across the VA. CART is used for clinical decision support, quality and patient safety at the point of care and for clinical and quality of care documentation. The CART data is central to quality and patient safety oversight at individual facilities among VISNs and by VACO.

The CART servers are currently hosted at the Rocky Mountain Medical Center in the Continental District. It serves 93 VA Medical Centers in real time across the organization. The CART database contains procedural records of approximately 700,000 veterans who have been seen in a VA cardiac catheterization lab.

Overview

The Clinical Assessment, Reporting, and Tracking Applications (CART-Apps herein referred to as CART) is a joint effort of the VA Office of Organization Excellence, Clinical Systems Design and Evaluation in close collaboration with the VA National Program for Cardiology. The CART system has been in place since its initial deployment in 2003, identified by OMB Unique Project Identifier: 290001110000000, System Of Record Name: National Patient Databases – VA, System Of Recorded Number: 121VA19, under authority of Title 38, United States Code, Section 501.

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The CART servers are currently hosted at the Rocky Mountain Medical Center in the Continental District. It serves 93 VA Medical Centers in real time across the organization. The CART database contains procedural records of approximately 700,000 veterans who have been seen in a VA cardiac catheterization lab. CART transmits an abstract of the procedural data to the Corporate Data Warehouse on a monthly basis. CART receives device data from the Real Time Location Services (RTLS) system. There is no business, technology or SORN changes associated with this PIA.

Section 1. Characterization of the Information

The following questions are intended to define the scope of the information requested and collected as well as the reasons for its collection as part of the program, IT system, or technology being developed.

1.1 What information is collected, used, disseminated, created, or maintained in the system?

Please check any information listed below that your system collects, uses, disseminates, creates, or maintains. If additional SPI is collected, used, disseminated, created, or maintained, please list those in the text box below:

- | | | |
|--|---|--|
| <input checked="" type="checkbox"/> Name | Number, etc. of a different individual) | <input checked="" type="checkbox"/> Previous Medical Records |
| <input checked="" type="checkbox"/> Social Security Number | <input type="checkbox"/> Financial Account Information | <input checked="" type="checkbox"/> Race/Ethnicity |
| <input checked="" type="checkbox"/> Date of Birth | <input type="checkbox"/> Health Insurance Beneficiary Numbers | <input type="checkbox"/> Tax Identification Number |
| <input type="checkbox"/> Mother's Maiden Name | <input type="checkbox"/> Certificate/License numbers | <input checked="" type="checkbox"/> Medical Record Number |
| <input type="checkbox"/> Personal Mailing Address | <input type="checkbox"/> Vehicle License Plate Number | <input checked="" type="checkbox"/> Other Unique Identifying Information |
| <input checked="" type="checkbox"/> Personal Phone Number(s) | <input type="checkbox"/> Internet Protocol (IP) Address Numbers | |
| <input type="checkbox"/> Personal Fax Number | <input checked="" type="checkbox"/> Current Medications | |
| <input type="checkbox"/> Personal Email Address | | |
| <input type="checkbox"/> Emergency Contact Information (Name, Phone) | | |

Patient gender, race and date of birth are used to categorize patients when reporting on information in the CART database and used in calculations on the patient's data.

Patient SSN is used in combination with other keys to identify patients when gathering data from other VA Files/Databases and for patient reporting.

Patients Medical Record Number (VistA legacy field DFN) and the Intergrated Control Number (ICN) are used by the CART to identify patient data that is imported from other VA Files/Databases.

Patient EDIPI to identify for identification in the CERNER EHR.

Patient Record Dates and elements of dates are used on reports generated with CART and stored in the CART database.

Provider ID Numbers, specifically the DUZ field used by VistA Legacy are used to uniquely identify providers at a facility and in reporting

PII Mapping of Components

CART consists of three key components. Each component has been analyzed to determine if any elements of that component collect PII. The type of PII collected by CART and the functions that collect it are mapped below.

PII Mapped to Components

Note: Due to the PIA being a public facing document, please do not include the server names in the table.

PII Mapped to Components

Database Name of the information system collecting/storing PII	Does this system collect PII? (Yes/No)	Does this system store PII? (Yes/No)	Type of PII (SSN, DOB, etc.)	Reason for Collection/ Storage of PII	Safeguards
CARTPro4	Yes	Yes	Patient Name, Social Security Number, Date of Birth, Date of Death, Race, Gender, Integrated Control Number, Data File Number, Veterans Administration Site	Identify patient for medical care	Encrypted drives. Users must have a key to launch the application. No cross-site access. Data is not accessible to end users. Sits behind VA firewall with constant intrusion monitoring in addition to CART specific logs that track user activity.
CART_CART	Yes	Yes	Social Security Number, Date of Birth, Date of Death, Race, Gender, Integrated Control Number, Data File Number, Veterans Administration Site	CARTPRO4 database extract used to perform operational analysis and report aggregate data back to sites and VISNs.	Resides in the Corporate Data Warehouse and relies upon their security and safeguards.
RTLS_1	Yes	Yes	Patient ICN, Site, StartDateTime,	Identify Patient and the devices and implantable	Encrypted drives. Data is not directly accessible

			EndTime, Devices Implanted	devices used during their procedure, to be tracked by lot and serial number.	to end users. Access to data is tightly controlled by an Access Control List. Sits behind VA firewall with constant intrusion monitoring.
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1.2 What are the sources of the information in the system?

Veteran or Primary Subject

Data on veteran’s cardiac conditions, including physical characteristics such as height and weight, history of cardiac conditions, current medications, lab test results, risk factors and co-morbid conditions, and detailed cardiac procedure information are collected from veterans verbally and using cardiovascular diagnostic equipment for the purposes of providing and improving patient care.

Medical Information

Detailed information, including dates and elements of dates, on the patient’s cardiac health, history of cardiac procedures, history of risk factors and co-morbid conditions, history of cardiac related lab tests, cardiac related medication lists, physical characteristics, and procedure notes are all collected and stored in individual data fields in the CART database. This information is used for the purposes of providing and improving patient care.

VA Files/Databases

Data on cardiology related medications, lab test results, procedures, and physical exam history is collected from VistA Legacy and used on CART reports and stored in the CART database. This information is used for the purposes of providing and improving patient care.

RTLS\Devices

Data is sent to CART from RTLS servers. This information includes lot and serial numbers on all devices or piece of equipment used during the procedure. This is used for tracking and reporting to FDA any device failures or to determine if a patient has a recalled device implanted.

1.3 How is the information collected?

Information is collected from the Veteran verbally and/or through VA Files/Databases within the VA intranet.

1.4 How will the information be checked for accuracy? How often will it be checked?

Data is entered and reviewed by the Cardiac clinical staff before submission to the CART system. Once submitted it becomes part of the patients' medical record and a statement of fact. On a monthly basis, feedback reports containing counts of patients entered and procedures performed are provided to each cardiac catheterization laboratory. Each cardiac catheterization laboratory is responsible for reviewing these feedback reports and making corrections. All data imported to the CART system from other VA systems is imported using Synchronist methods. This requires the servers to verify the transmission prior to committing the data to the database.

1.5 What specific legal authorities, arrangements, and agreements defined the collection of information?

CART was mandated for use by VA Directive 2005-062.
Further government identifiers are
OMB Unique Project Identifier: 290001110000000
System Of Recorded Number: 121VA10P2
System Of Record Name: National Patient Databases - VA

1.6 PRIVACY IMPACT ASSESSMENT: Characterization of the information

Privacy Risk: Over collection of PHI\PII.

Mitigation: Access to the system is restricted to cardiac clinical staff and requires a special VistA key to launch the CART application. The data is stored on encrypted drives, in a database behind VA firewalls and not accessible to those outside the VA intranet. Collection of this information is limited to PHI\PII needed to successfully treat the patient and enhance the overall outcome and safety of the treatment. When and where possible, for assessing the patient, information is collected verbally from the patient. Additionally, all data entry is through a set of pre-defined elements.

Section 2. Uses of the Information

The following questions are intended to clearly delineate the use of information and the accuracy of the data being used.

2.1 Describe how the information in the system will be used in support of the program's business purpose.

- Name, SSN, DOB are used to identify the patient.

- Patient gender, race and date of birth are used to categorize patients when reporting on information in the CART database and used in calculations on the patient's data.
- Patient SSN is used in combination with other keys to identify patients when gathering data from other VA Files/Databases and for patient reporting.
- Patients Medical Record Number (VistA legacy field DFN) and the Intergrated Control Number (ICN) are used by the CART to identify patient data that is imported from other VA Files/Databases.
- Phone numbers are used to conduct surveys pre and post procedure.
- Patient EDIPI to identify for identification in the CERNER EHR.
- Patient Record Dates and elements of dates are used on reports generated with CART and stored in the CART database.
- Provider ID Numbers, specifically the DUZ field used by VistA Legacy are used to uniquely identify providers at a facility and in reporting
- Previous Medical records are used to calculate procedure risk factors.
- Current Medications are imported for procedural documentation.

2.2 What types of tools are used to analyze data and what type of data may be produced?

CART creates a patient note which is uploaded to the patients' medical record in Computerized Patient Record System (CPRS). Summary reports are produced based on this data for Clinicians, Sites, VISNs and VACO.

Once reports are uploaded to CPRS by the Attending Physician, they are immediately available to all care providers who have access to the CPRS and the need to know.

2.3 How is the information in the system secured?

All data is stored in a Sequential Query Language database using encryption technology mandated and baselined by VA OIT and only traverses the VA intranet.

2.4 PRIVACY IMPACT ASSESSMENT: Use of the information. How is access to the PII determined? Are criteria, procedures, controls, and responsibilities regarding access documented? Does access require manager approval? Is access to the PII being monitored, tracked, or recorded? Who is responsible for assuring safeguards for the PII?

Cardiac Clinicians who have a need to use the Clinical Assessment, Reporting, and Tracking system are assigned electronic keys that specify their access within the Clinical Assessment, Reporting, and Tracking system. Keys are assigned by their local Automated Data Processing Application Coordinator. In addition, cardiac clinicians are only permitted to view information submitted from the cardiac catheterization lab where they are accessing the Clinical Assessment, Reporting, and Tracking system. Patient information must exist in Veteran Health Information System and Technology Architecture Legacy before it can be added to the Clinical Assessment, Reporting, and Tracking system. When using the Clinical Assessment, Reporting, and Tracking system, you must first launch the Veteran Health Information System and Technology Architecture Legacy Computerized Patient Record System interface; select the patient that will be entered into the Clinical Assessment, Reporting, and Tracking system, and then select the "CART" option for the Tools menu. At this point patient information is passed into the Clinical

Assessment, Reporting, and Tracking system through standard Remote Procedure Call Broker calls. In addition to the protections provided by the Veteran Health Information System and Technology Architecture Legacy system (access logs, warnings on sensitive patients, etc.), the Clinical Assessment, Reporting, and Tracking system maintains a log including the user who accessed the system, the identification of the patient whose data was accessed, the date and time of the access, the duration of the access, and what major activities were performed.

Section 3. Retention of Information

The following questions are intended to outline how long information will be retained after the initial collection.

3.1 What information is retained?

The CART system retains all patient information, including all items listed in 1.1, as part of the patient's permanent medical record.

Name

Social Security Number

Date of Birth

Personal Phone Number

Current Medications

Previous Medical Records

Race/Ethnicity

Medical Record Number

Other Unique Identifying Information

 Patient gender

 Intergrated Control Number

 Patient EDIPI

 Patient Record Dates

 Provider ID Numbers

3.2 How long is information retained?

The CART system retains all patient records indefinitely as part of the patient's permanent medical record.

3.3 Has the retention schedule been approved by the VA records office and the National Archives and Records Administration (NARA)? If so please indicate the name of the records retention schedule.

The CART Program is covered under "National Patient Databases-VA" (121VA10P2). According to 121VA10P2, the following Retention and Disposal must be followed:

Item is covered with GRS 5.1 Item 020 Disposition Instructions: Temporary. Destroy immediately after copying to a recordkeeping system or otherwise preserving, but longer retention is authorized if required for business use. AA-GRS 2016-0016-0002.

[5.1: Common Office Records \(archives.gov\)](https://www.archives.gov)

3.4 What are the procedures for the elimination of SPI?

All records are electronic. In the event a record needs to be purged, only CART personnel with administrative access to the database can remove the record. Backup copies are purged as the backup set is rotated through and overwritten. Currently, that is 42 days. GRS5.1 Item 020 provides for deletion of data files when the agency determines that the files are no longer needed for administrative, legal, audit, or other operational purposes.

3.5 Does the system, where feasible, use techniques to minimize the risk to privacy by using PII for research, testing, or training?

CART testing is completely autonomous and does not use patient data for testing. CART data is not used for research unless an IRB or approved DUA exists. CART uses zzTestPatients' as stored in and access from VistA/CPRS for training.

3.6 PRIVACY IMPACT ASSESSMENT: Retention of information

Privacy Risk: Retention of PII as part of the patient medical record.

Mitigation: Technical controls to safeguard the information include individual access authentication, logging, password protection (content and life restricted), monitoring unsuccessful login attempts, restriction by security keys, file access restriction, session time-outs, and separation of user from data storage devices.

Administrative controls that protect collected information include the use of the Rules of Behavior signed by those with access to the system, VA procedures for establishing user accounts on the VistA hospital information system, and yearly user training on Privacy and IT Security issues.

Section 4. Internal Sharing/Receiving/Transmitting and Disclosure

The following questions are intended to define the scope of information sharing/receiving/transmitting within VA.

4.1 With which internal organizations is information shared/received/transmitted? What information is shared/received/transmitted, and for what purpose? How is the information transmitted?

NOTE: Question 3.10 (second table) on Privacy Threshold Analysis should be used to answer this question.

<i>List the Program Office or IT System information is shared/received with</i>	<i>List the purpose of the information being shared /received with the specified program office or IT system</i>	<i>List the specific data element types such as PII/PHI that are shared/received with the Program Office or IT system</i>	<i>Describe the method of transmittal</i>
CART Coordinating Center	Institutional Review Boards approved Research	Data on cardiology related medications, lab test results, assessments, procedures, and physical exam history	Electronic in bulk. No partner has direct access to CART data. Server to server via VA intranet.
Corporate Data Warehouse (CDW)	National Data Warehouse	Data on cardiology related assessments and procedures	Electronic in bulk. No direct access to CART data. Server to server via VA intranet.
Real Time Location Services (RTLS)	Device lots and serial numbers are received from Real Time Location Services (RTLS) to CART	Patient identifiers and device lots and serial numbers.	Data transmitted on a case by case basis from the Real Time Location Services (RTLS) system to CART. Server to server via VA intranet.

4.2 PRIVACY IMPACT ASSESSMENT: Internal sharing and disclosure

Privacy Risk: Inappropriate sharing of information

Mitigation: All data is shared in accordance with the Data Use Agreement and/or IRB signed between CART and other internal agencies.

Section 5. External Sharing/Receiving and Disclosure

The following questions are intended to define the content, scope, and authority for information sharing external to VA, which includes Federal, State, and local governments, and the private sector.

5.1 With which external organizations (outside VA) is information shared/received? What information is shared/received, and for what purpose? How is the information transmitted and what measures are taken to ensure it is secure?

Data Shared with External Organizations

<i>List External Program Office or IT System</i>	<i>List the purpose of information being shared /</i>	<i>List the specific PII/PHI data elements that are</i>	<i>List the legal authority, binding</i>	<i>List the method of transmission and the</i>
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<i>information is shared/received with</i>	<i>received / transmitted with the specified program office or IT system</i>	<i>shared/received with the Program or IT system</i>	<i>agreement, SORN routine use, etc. that permit external sharing (can be more than one)</i>	<i>measures in place to secure data</i>
N/A				

If specific measures have been taken to meet the requirements of OMB Memoranda M-06-15 and M-06-16, note them here.

5.2 PRIVACY IMPACT ASSESSMENT: External sharing and disclosure

Privacy Risk: Inappropriate sharing of information.

Mitigation: All data is shared in accordance with the Data Use Agreement signed between CART and other external agencies. No PHI\PII is shared by CART with any outside agencies or groups.

Section 6. Notice

The following questions are directed at providing notice to the individual of the scope of information collected, the right to consent to uses of the information, and the right to decline to provide information.

6.1 Was notice provided to the individual before collection of the information? If yes, please provide a copy of the notice as an appendix. (A notice may include a posted privacy policy, a Privacy Act notice on forms, or a system of records notice published in the Federal Register.) If notice was not provided, why not?

All CART data collection is governed by the VA Notice of Privacy Practices Veterans receive every three years.

For non-veterans seeking care at the VA or non-veterans involved in a research protocol a copy is presented to the individual for them to sign and document in the medical record. Consent is given to cover use of all data collected in CART for ongoing patient care and preventive care. Individuals who wish to determine whether this system of records contains information about them should contact the:

Director of National Data Systems (10P2C)
 Austin Information Technology Center
 1615 Woodward Street
 Austin, Texas 78772.

Inquiries should include the person's full name, Social Security number, location and dates of employment or location and dates of treatment, and their return address.

6.2 Do individuals have the opportunity and right to decline to provide information? If so, is a penalty or denial of service attached?

All CART data collection is governed by the VA Notice of Privacy Practices. As CART is the method used to document patient care, the use and therefore the collection of data is mandatory. The document gives the individual the right to restrict certain uses and notifies the individual the VA is not required to agree to the requested restriction.

6.3 Do individuals have the right to consent to particular uses of the information? If so, how does the individual exercise the right?

Consent is given to cover all CART data collected for ongoing patient care and preventive care. A patient can in writing request restriction on certain uses of this data however the VA is not required to agree to the requested restriction.

6.4 PRIVACY IMPACT ASSESSMENT: Notice

Privacy Risk: Individual is not aware of how their information is going to be collected, shared and maintained.

Mitigation: CART relies on the VA Notice of Privacy Practices Veterans receive every three years to inform them of their rights to access, redress and correction of information collected.

Section 7. Access, Redress, and Correction

The following questions are directed at an individual's ability to ensure the accuracy of the information collected about him or her.

7.1 What are the procedures that allow individuals to gain access to their information?

Individuals seeking information regarding access to and contesting of records in this system may write the:

Director of National Data Systems (10P2C)
Austin Information Technology Center
1615 Woodward Street
Austin, Texas 78772

7.2 What are the procedures for correcting inaccurate or erroneous information?

Individuals seeking information regarding access to and contesting of records in this system may write the:

Director of National Data Systems (10P2C)
Austin Information Technology Center
1615 Woodward Street
Austin, Texas 78772

7.3 How are individuals notified of the procedures for correcting their information?

Notification is made through the VA Notice of Privacy Practices Veterans receive every three years. For non-veterans seeking care at the VA or non-veterans involved in a research protocol a copy is presented to the individual for them to sign and document in the medical record.

7.4 If no formal redress is provided, what alternatives are available to the individual?

The CART system does not directly interact with veterans. The VA provides information about Freedom of Information Act (FOIA). The process for release of medical record information is handled by the FOIA/ROI office in each medical center, not by the CART Program Office.

7.5 PRIVACY IMPACT ASSESSMENT: Access, redress, and correction

Privacy Risk: Individuals may not know the proper procedure for accessing and correcting their information.

Mitigation: CART relies on the VA Notice of Privacy Practices Veterans receive every three years to inform them of their rights to access, redress and correction of information collected. If a veteran has a question at the time of service that cannot be answered they are directed to the Privacy Office.

Section 8. Technical Access and Security

The following questions are intended to describe technical safeguards and security measures.

8.1 What procedures are in place to determine which users may access the system, and are they documented?

Users of the CART system are assigned electronic keys that specify their access within the CART system. In addition, users are only permitted to view information submitted from the cardiac catheterization lab where they are accessing the CART system. Physician are granted Read/Write permissions, Fellows Read, and on a case-by-case basis, Write permissions, and Nurses Read permissions.

In addition to the protections provided by the Vista Legacy system (access logs, warnings on sensitive patients, etc), the CART system maintains a log including the user who accessed the system, the ID of the patient whose data was accessed, the date and time of the access, the duration of the access, and what major activities were performed.

By mandate, Information Technology Operations, Back Office Database Team has administrative privileges on CART server through a group account.

8.2 Will VA contractors have access to the system and the PII? If yes, what involvement will contractors have with the design and maintenance of the system? Has a contractor confidentiality agreement, Business Associate Agreement (BAA), or a Non-Disclosure Agreement (NDA) been developed for contractors who work on the system?

Yes. Contracts are reviewed yearly by the CART Program Office and clearance extended or revoked. Contractors perform the application programming and could be employed by ITOP unbeknown to the CART Program Office.

8.3 Describe what privacy training is provided to users either generally or specifically relevant to the program or system?

All users are required to take the privacy and security training and have varied degrees of access based on their background check and level of security. Users sign rules of behavior documents and undergo annual IT security training programs.

8.4 Has Authorization and Accreditation (A&A) been completed for the system?

CART received a full ATO in 2008 and an extension in 2013. The current conditional ATO expires on January 28, 2022 and CART is seeking to extend the ATO. The current FIPPS 199 classification is Very High.

Section 9 – Technology Usage

The following questions are used to identify the technologies being used by the IT system or project.

9.1 Does the system use cloud technology?

No.

9.2 Identify the cloud model being utilized.

N/A

9.3 Does the contract with the Cloud Service Provider, Contractors and VA customers establish who has ownership rights over data including PII? (Provide contract number and supporting information about PII/PHI from the contract)

N/A

9.4 Will the CSP collect any ancillary data and if so, who has ownership over the ancillary data?

N/A

9.5 NIST 800-144 states, “Organizations are ultimately accountable for the security and privacy of data held by a cloud provider on their behalf.” Is this principle described in contracts with customers? Why or why not?

N/A

9.6 If the system is utilizing Robotics Process Automation (RPA), please describe the role of the bots.

N/A

Section 9. References

Summary of Privacy Controls by Family

Summary of Privacy Controls by Family

ID	Privacy Controls
AP	Authority and Purpose
AP-1	Authority to Collect
AP-2	Purpose Specification
AR	Accountability, Audit, and Risk Management
AR-1	Governance and Privacy Program
AR-2	Privacy Impact and Risk Assessment
AR-3	Privacy Requirements for Contractors and Service Providers
AR-4	Privacy Monitoring and Auditing
AR-5	Privacy Awareness and Training
AR-7	Privacy-Enhanced System Design and Development
AR-8	Accounting of Disclosures
DI	Data Quality and Integrity
DI-1	Data Quality
DI-2	Data Integrity and Data Integrity Board
DM	Data Minimization and Retention
DM-1	Minimization of Personally Identifiable Information
DM-2	Data Retention and Disposal
DM-3	Minimization of PII Used in Testing, Training, and Research
IP	Individual Participation and Redress
IP-1	Consent
IP-2	Individual Access

ID	Privacy Controls
IP-3	Redress
IP-4	Complaint Management
SE	Security
SE-1	Inventory of Personally Identifiable Information
SE-2	Privacy Incident Response
TR	Transparency
TR-1	Privacy Notice
TR-2	System of Records Notices and Privacy Act Statements
TR-3	Dissemination of Privacy Program Information
UL	Use Limitation
UL-1	Internal Use
UL-2	Information Sharing with Third Parties

Signature of Responsible Officials

The individuals below attest that the information provided in this Privacy Impact Assessment is true and accurate.

Privacy Officer, Rita Grewal

Information Security Systems Officer, Roland Parten

System Owner, Gregory Noonan

APPENDIX A-6.1

Please provide a link to the notice or verbiage referred to in Section 6 (a notice may include a posted privacy policy, a Privacy Act notice on forms).

The VA Notice of Privacy Practices can be found at this link.

https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=8928