

**TRACKING SYSTEM FOR PATIENTS IDENTIFIED IN THE CREUTZFELDT-
JAKOB DISEASE (CJD) LOOKBACK NOTIFICATION INITIATIVE**

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Directive provides policy for tracking patients identified in the Creutzfeldt-Jakob Disease (CJD) initiative, established in January 1995.
- 2. SUMMARY OF MAJOR CHANGES:** Major changes to this VHA Directive include:
 - a. Updating the name of the VHA Central Office Infectious Diseases Program Office to the National Infectious Disease Service.
 - b. Redefining the responsibilities of the VHA Central Office National Infectious Diseases Service, and eliminating actions for Veteran Integrated Service Networks and VA medical centers.
- 3. RELATED ISSUES:** None.
- 4. RESPONSIBLE OFFICE:** Specialty Care Service (10P4E) is responsible for the contents of this Directive. Questions relating to the Directive are to be directed to the National Infectious Diseases Service at 513-246-0270.
- 5. RESCISSIONS:** VHA Directive 2009-006, dated February 19, 2009, is rescinded.
- 6. RECERTIFICATION:** This VHA Directive is scheduled for recertification on or before the last working day of July, 2019.

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TRACKING SYSTEM FOR PATIENTS IDENTIFIED IN THE CREUTZFELDT-JAKOB DISEASE (CJD) LOOKBACK NOTIFICATION INITIATIVE

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides policy for tracking patients identified in the Creutzfeldt-Jakob Disease (CJD) initiative, established in January 1995, as part of the lookback notification of all Department of Veterans Affairs (VA) patients who may have received certain lots of blood derivatives or blood components produced from donors with CJD.

2. BACKGROUND:

a. In November 1994, the American Red Cross (ARC), Baxter Pharmaceutical Company, and Miles Pharmaceutical Company initiated voluntary withdrawals of certain lots of blood component products based on discussions with the Food and Drug Administration (FDA). The precautions were taken because a frequent ARC volunteer blood donor died of CJD, a rare neurological disorder. Plasma from this donor had been made into nearly 200 lots of derivative blood products. VHA patients were among those in the nation who received these products. Subsequent to this withdrawal, VHA was notified three more times between 1996 and 1998 of potentially CJD-contaminated plasma products that may have been administered to patients.

b. Iatrogenic transmission of CJD from blood components or plasma derivatives has not been reported. *NOTE: This is in contrast to reports of human transfusion transmission of variant CJD, the agent associated with bovine spongiform encephalopathy.* The Centers for Disease Control and Prevention (CDC) characterized the risk of CJD transmission from blood derivative products as “small and immeasurable” and “theoretical.” Notwithstanding the theoretical nature of the transmission risk, VA believed it had an ethical obligation to inform patients of the exposure to potentially contaminated blood components or plasma derivative products while under VA care. In January, 1995, VHA initiated a voluntary lookback notification of all VA patients who may have received certain lots of blood derivatives or blood component products produced from donors with CJD.

c. For the CJD lookback notification, Pharmacy Service in VA Central Office identified VA medical centers known to have received shipments of the potentially contaminated products and sent the list of products to these facilities. The VA medical centers then identified patients who may have received those blood components or plasma derivatives and notified the patients of the exposure and the risks related to the exposure. VHA established a tracking system for individuals who received these products to determine if there was an increase in CJD cases.

3. POLICY: It is VHA policy to track individuals who were identified through the VA CJD lookback notification initiative to determine if there is an increase in CJD cases over time.

4. RESPONSIBILITIES:

a. **VHA Central Office National Infectious Diseases Service Director.** The National Infectious Diseases Service Director is the steward for the CJD lookback database.

b. **VHA Central Office National Infectious Diseases Service.** The National Infectious Diseases Service is the repository for the CJD lookback database and is responsible for:

(1) Updating the status of patients in the CJD lookback database every 2 years (odd years) using the following primary mechanisms:

(a) Using VHA electronic patient records and other available sources (e.g., the Compensation and Pension Record Interchange (CAPRI) system), to collect data and update the CJD lookback database regarding patient information, such as: status of alive, deceased, or unknown; any CJD diagnosis; date and cause of death.

(b) Contacting individual VHA healthcare facilities, as necessary, if further information is needed about specific patients. Any sensitive patient information that is requested will require secure transfer of data using a VA-approved encryption mechanism (e.g., Public Key Infrastructure (PKI) certificate, Rights Management Server (RMS)) in accordance with current VA policy.

(2) Providing a summary report, through Specialty Care Services, to the VHA Assistant Deputy Under Secretary for Health for Patient Care Services no later than 6 months prior to expiration of this Directive or when all patients identified in the lookback are identified as deceased, whichever comes first.