



Billing Code: 5001-06

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD-HA-2012-0148]

Proposed Collection; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs, DoD.

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995*, the Office of the Assistant Secretary of Defense for Health Affairs announces the proposed extension of a public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by **[insert date 60 days from publication of this notice in the Federal Register]**.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd floor, Suite 02G09, Alexandria VA 22350-3100.

Instructions: All submissions received must include the agency name, docket number and title for this Federal Register document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at

<http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Program Manager, Defense Health Information Management System (DHIMS), ATTN: COL Aaron J. Silver, 5109 Leesburg Pike, Skyline 6, Suite 703, Falls Church, VA 22041, or call DHIMS, at (703) 681-7122.

TITLE; ASSOCIATED FORM; AND OMB NUMBER: Enterprise Blood Management System (EBMS); OMB Control Number 0720-TBD.

NEEDS AND USES: EBMS is a family of related automated information systems (AIS) comprised of two separate and distinct commercial-off-the-shelf (COTS) software applications that provides the Military Health System (MHS) with a comprehensive enterprise wide Blood Donor Management System (BDMS) and a Blood Management Blood Bank and Transfusion Service (BMBB/TS).

- The Blood Donor Management System (BDMS) employs two separate COTS software applications, Medware Corporation's LifeTrak Donor™ and LifeTrak Lab & Distribution™. BDMS is a technology modernization effort intended to enhance the DoD's Blood Program capabilities for Donor Centers through the seamless integration of blood products inventory management, transport, availability, and most importantly, blood and blood products traceability from collection to disposition within the electronic health record (EHR).
- The Blood Management Blood Bank Transfusion Service (BMBB/TS) employs two separate COTS software applications, Medware Corporation's HCLL™ (Transfusion) and KnowledgeTrak™ (Learning Management). BMBB/TS is an effort intended to enhance the DoD's Blood Program capabilities for a seamless integration of blood banking and transfusion activities, products inventory management, transport, availability, and most importantly traceability from transfusion to disposition or destruction within the electronic health record (EHR).

EBMS has built-in safeguards to limit access and visibility of personal or sensitive information in accordance with the Privacy Act of 1974. The application will account for everyone that donates blood and receives a blood transfusion in the MHS – Active Duty, Reserves, National Guard, government civilian, contractors and volunteers assigned or borrowed – this also includes non-appropriated fund employees and foreign nationals.

AFFECTED PUBLIC: Contractors, civilian and foreign nationals donating to the Military Health Systems.

ANNUAL BURDEN HOURS: 766

NUMBER OF RESPONDENTS: 4,600

RESPONSES PER RESPONDENT: 1

AVERAGE BURDEN PER RESPONSE: 10 minutes

FREQUENCY: On occasion

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

In order to attain standardization, ensure a safe blood product, and comply with Federal law, all Military blood facilities are licensed and/or registered by the Food and Drug Administration (FDA) and must operate according to Title 21, Code of Federal Regulations, Part 211, Current Good Manufacturing Practices for Finished Pharmaceuticals, Part 610 series, Biologics, and Part 820 series, Medical Devices.

The EBMS Mediware Corporation developed COTS are FDA 510K cleared Medical Devices that provides the Military Health System (MHS) with a comprehensive enterprise wide Blood Donor Management System (BDMS) and Blood Management Blood Banking and Transfusion Service (BMBB/TS) with capabilities to manage blood donors (both in-house and at mobile collection sites), manage blood products both fresh and frozen throughout the collection, processing, testing, storing, and shipping procedures; interface with testing instrumentation for enterprise (Global) results management; shipping blood with in-transit visibility and shipping data transmit and receive; automate, enterprise-wide “lookback” for donors, patients, and products; automated, blood order issue, and transfusion records; manage enterprise inventory (Global), including Theater and VA. It has built-in safeguards to limit access and visibility of personal or sensitive information in accordance with the Privacy Act of 1974. The application will account for everyone that donate blood and receive blood transfusion in the MHS – Active Duty, Reserves, National Guard, government civilian, contractors and volunteers assigned or borrowed – this also includes non appropriated fund employees and foreign nationals.

EBMS is an n-tier enterprise solution. The solution will use COTS products, installed at a Central Server location. EBMS has applicability at the headquarters level allowing Armed Services Blood Program (ASBP) which is delineated in several regulations, including DoDD 6000.12, DoDI 6480.4, and AR10-64 and Service Blood Program Office (SBPO) to use this product to conduct its own day-to-day blood inventory management. This comprehensive tool provides the capability to manage inventory, monitor

adverse trends, review lookback cases, manage donor deferrals and develop standard operation procedure. Deciding to implement EBMS within MHS provides an enterprise solution for transfusion and donor processing that can be applied to enterprise-wide blood inventory, and traceability throughout patient and donor life.

The information in EBMS is personal or sensitive; therefore, it contains built-in safeguards to limit access and visibility of this information. EBMS uses role-based security so a user sees only the information for which permission has been granted. It uses state-of-the-market 128-bit encryption security for our transactions. It is DoD Information Assurance Certification and Accreditation Process (DIACAP) certified having been subjected to and passed thorough security testing and evaluation by independent parties. It meets safeguards specified by the Privacy Act of 1974 in that it maintains a published Department of Defense (DoD) Privacy Impact Assessment and System of Record covering Active Duty Military, Reserve, National Guard, and government civilian employees, to include non-appropriated fund employees and foreign nationals, DoD contractors, and volunteers. EBMS is hosted in a secure facility managed by the MHS Cyber-Infrastructure Services (MCIS).

Dated: November 26, 2012.

Aaron Siegel,
Alternate OSD Federal Register Liaison Officer,
Department of Defense.

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