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TMA Privacy Weekly

TMA Privacy and Civil Liberties Office
2011 DATA PROTECTION SEMINAR



New Developments in the Data Sharing Agreement Program



New Developments in the Data Sharing Agreement Program

Purpose

The purpose of this presentation is to review the role of the TRICARE Management Activity (TMA) Privacy and Civil Liberties Office (Privacy Office) in conducting compliance reviews of requests for data owned and/or managed by TMA and to discuss new developments in our Data Sharing Agreement (DSA) program.



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Objectives

- Upon completion of this presentation, you should be able to
 - Understand the function of the Privacy Office in conducting compliance reviews
 - Discuss the new Data Sharing Agreement Application (DSAA) and new DSAs as well as some enhanced processing changes, which will replace the current process and use of Data Use Agreements (DUAs)
 - Explain when, why, and how a DSA will be used to document compliance with DoD regulations and applicable privacy laws



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Privacy Office

- The Privacy Office conducts reviews of requests for data owned and/or managed by TMA to ensure compliance with regulatory requirements, including:
 - DoD Health Information Privacy Regulation (DoD 6025.18-R), which implements the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule
 - DoD Privacy Program (DoD 5400.11-R), which implements the Privacy Act of 1974, as amended
 - DoD Health Information Security Regulation (DoD 8580.02-R), which implements the HIPAA Security Regulations
- Data access and extractions are handled through separate offices within the Military Health System, but prior approval of the data request is required by the Privacy Office



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Restructure of the DSA Program

- A workgroup was developed within the Privacy Office of regulatory experts, TMA data and system experts, and DSA analysts with three primary goals:
 - Gain clearer and specific information needed for review
 - More closely align the data sharing process with the HIPAA Privacy Rule and DoD 6025.18-R and streamline the analysis of other applicable privacy laws and regulations
 - Enhance regulatory compliance and accountability and create documents that will assist in compliance audits
- Products of the workgroup include a new DSAA, Data Request Templates, new DSAs, and new supporting documents



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Introducing the DSAA

- The **DSAA** is an **application** designed to assist in reviewing a data request for compliance with applicable regulatory requirements and must be initiated by the following:
 - **Applicant:** The individual who will provide primary oversight and responsibility for the handling of the requested data
 - For contract-driven requests, the applicant must be an employee of the prime contractor
 - For projects with more than one prime contractor, a DSAA must be completed by each prime contracting organization that will have custody of the requested data
 - **Government Sponsor:** The point of contact within TMA or the respective Armed Service who assumes responsibility for the contract, grant, project, or Cooperative Research and Development Agreement



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Enhanced Processing Changes in the DSAA

- The DSAA includes the following enhancements:
 - Ten organized sections seeking pinpointed information necessary for conducting a compliance review
 - Development of Data Request Templates for selecting data elements requested from each system owned and/or managed by TMA with a calculator function providing a summary review
 - Avoids current confusion and frustration of data requestors in trying to decide if their request is for protected health information (PHI), a limited data set (LDS), personally identifiable information (PII) excluding PHI, or is “de-identified data” under HIPAA
 - Certification with initials of the applicant and government sponsor; full signatures will only be required on an appropriate DSA once the DSAA is approved



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Data Requests for Research Purposes

- Applicants and government sponsors to a DSAA seeking data for research purposes will be guided if follow-up is needed
 - The DSA team will confirm that research requests have been reviewed by the TMA Health Program Analysis & Evaluation Office or Health Affairs
 - TMA Secondary Officer/Exemption Determination Officer Review
 - Institutional Review Board approval, when required, under the DoD Protection of Human Subjects, otherwise known as the “Common Rule”
 - The DSA team will direct PHI requests to the TMA Privacy Board for a compliance review in accordance with the HIPAA Privacy Rule and DoD 6025.18-R



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New DSAs & Tracking System

- A **DSA** is the **agreement** that will be fully executed by the applicant, government sponsor, and the Director of the Privacy Office *only after* a DSAA is approved
 - An approved DSAA will be incorporated in an executed DSA
 - Applicant will become the “recipient” in the DSA
- A base number is assigned to a DSAA upon submission (e.g., DSAA # 14-737) and the same number is used for the executed DSA once the DSAA is approved and incorporated into the agreement (e.g., DSA # 14-737). All further references will be made to the DSA # (e.g., DSA # 14-737)
 - Supporting templates track modifications (-M), renewals (-R), and extensions (-E) to a DSA



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The Purpose of the DSAs

- The purpose of the DSAs is to:
 - Identify the type of data owned and/or managed by TMA that is required to meet a specific data request
 - Ensure compliance with applicable DoD regulations and privacy laws
 - Set forth permissible uses and disclosures in accordance with regulatory requirements
 - Document the agreed-upon responsibilities of the applicant/recipient and government sponsor
 - Provide clear terms and conditions for approving the data request



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New Types of DSAs

- Four new types of DSAs specific to the type of data requested:
 - DUA for an LDS, a specific type of DSA
 - DSA for PII excluding PHI
 - DSA for PHI
 - DSA for De-identified Data
- Once the DSAA is reviewed by the Privacy Office, the applicant/recipient and government sponsor will be provided with the appropriate DSA for signature, which will incorporate the DSAA and will provide the clear terms and conditions associated with sharing the data



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Retention Date and Expedited Renewal Process

- An executed DSA will remain in force and all data subject to a DSA may be retained for whichever date is the earliest:
 - One year from the effective date of the DSA or
 - The expiration date of the underlying contract, grant, project, or Cooperative Research and Development Agreement that necessitates the applicant/recipient's need for the data
- New expedited renewal process for executed DSAs (which incorporate an approved DSAA)
 - Unlike the current process where a DUA must be completed in full every other year in order to use data for ongoing projects, applicants/recipients and government sponsors in the new process will not be required to complete a new DSAA or execute a new DSA where there are no substantive changes



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New Supporting Documents

- New supporting documents developed to correspond with the new DSAs include:
 - Change of Applicant/Recipient
 - Change of Government Sponsor
 - Addendum for Services
 - Renewal Request
 - Modification Request
 - Extension Request
 - Certification of Data Disposition
 - No-Action Notice



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Transitioning to the DSAA and New DSAs

- The Privacy Office is preparing to launch an updated Web site to begin implementation of its newly restructured DSA program
- The new DSAA will replace the existing PHI, PII and/or LDS DUA and the De-Identified (DIF) DUA
- New supporting documents will replace existing documents that support the DUA (e.g., the Renewal Request Letter and Modification Request Template)
- DUAs submitted and approved under the current DUA process will continue to be valid until they are up for renewal or a modification is required, at which point a DSAA will need to be completed



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Summary

- You should now be able to:
 - Understand the function of the Privacy Office in conducting compliance reviews
 - Discuss the new DSAA and new DSAs as well as some enhanced processing changes, which will replace the current process and use of DUAs
 - Explain when, why, and how a DSA will be used to document compliance with DoD regulations and applicable privacy laws



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Resources

- DoD 6025.18-R, “DoD Health Information Privacy Regulation”, January 24, 2003
- DoD 8580.02-R, “DoD Health Information Security Regulation”, July 12, 2007
- DoD 5400.11-R, “DoD Privacy Program”, May 14, 2007
- Privacy Office Web site:
<http://www.tricare.mil/tma/privacy/default.aspx>
- To subscribe to the Privacy Office E-News, go to:
<http://www.tricare.mil/tma/privacy/maillinglist.aspx>
- E-mail DSA.mail@tma.osd.mil for subject matter questions



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