## PSTT07: Is there a requirement for a standard format for the log files of EHRs to support analysis of access to health information access multiple EHRs or other clinical systems in a healthcare enterprise?

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| # | Comment ID | PSTT07 | Name of Respondent | Organization | Comments |
| 1 | [HHS-OS-2012-0007-0534](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0534) | #2/p.3-4 | Samantha  Halpert | Federation of American Hospitals | * Deferred to comments submitted by the Confidentiality Coalition (#24).
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| 2 | [HHS-OS-2012-0007-0425](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0425) | p. 16 | Willa Fields, Stephen Lieber | HIMSS | * Commenter notes that currently health does not have a codified requirement for centralized, enterprise audit review
* Commented about believing that regulation should dictate “what” is required, but leave the “how” up to product developers and implementers.
* Commented that the Access Report requirement in the draft Accounting of Disclosures rule would require reporting of all accesses to a patient’s data made through the Electronic Health Record (EHR).
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| 3 | [HHS-OS-2012-0007-0412](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0412) | p. 16 | John Travis | Cerner Corp. | * Commented that Integrating the Health Enterprise (IHE) Audit Trail and Node Authentication (ATNA) standard attempts to resolve the problem of having a standard for audit formats.
* Commented about agreeing to a standardized log format, which will then allow the consolidation of all log files, from multiple sources, into a common log file, which can then be used to extract reporting and analytics data.
* Stated that providing the patient with a single report view is very labor intensive without such standardization.
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| 4 | [HHS-OS-2012-0007-0388](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0388) | p. 2 |   | Crowe Horwath LLP | * Commented that the best approach was the use of a security information and event management (SIEM) solution.
* Commented about familiarity with utilizing a Security Information Event Management (SIEM) and suggest the solution to be comma separated values file (.csv) or tab separated values file (.tsv).
	+ Suggested alternate methods of using logging of actions in the Data-Base and using database module readers that would feed into the SIEM solution.
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| 5 | [HHS-OS-2012-0007-0444](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0444) | p. 2 | Kevin Nicholson | National Association of Chain Drug Stores | * Respondent did not comment about a standard format for the log files of EHRs to support analysis of access to health information access multiple EHRs or other clinical systems in a healthcare enterprise.
* Opposed any additional standards on Electronic Health Records (EHRs) related to accounting for disclosures.
* Commented that no new MU requirements of any kind should be implemented based on the proposed changes to the accounting of disclosures rule.
* Commented HHS’s proposed rule failed to balance the patient’s interest in learning how his or her information is disclosed in a way that leverages readily available technology and does not overly burden covered entities and their business associates.
* Provided reasons for not finalizing the proposed rule, such as:
* Under the Privacy Rule, the patient can request and accounting of disclosures back 6 years, but disclosures for Treatment, Payment and Operations (TPO) need not be tracked. Requiring TPO would result in long detailed confusing reports that would be unascertainable by patients and create a significant burden to covered entities.
* HITECH requires practices to account for disclosures for TPO but it also directs the Secretary to determine the administrative burdens to covered entities in providing the accounting.
* HITECH expressly states that the new requirements apply when “a covered entity uses or maintains an electronic health record.” Only then must “disclosures through an electronic health record” be included in an accounting. HITECH Section 13405(c). Later the statute states “Such regulations shall only require such information to be collected through an electronic health record…” the Office for Civil Rights (OCR) is exceeding its authority under the legislation.
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| 6 | [HHS-OS-2012-0007-0376](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0376) | p. 20 | Sarah Cottingham | Telligen Iowa HIT Regional Extension Center | * Commenter currently does not see one.
* Commented that systems should have the ability to generate a common audit log format in order support centralized audit review.
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| 7 | [HHS-OS-2012-0007-0431](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0431) | p. 21 | Susan Turney | Medical Group Management | * Respondent did not comment about a standard format for the log files of EHRs to support analysis of access to health information access multiple EHRs or other clinical systems in a healthcare enterprise.
* Opposed any additional standards on Electronic Health Records (EHRs) related to accounting for disclosures.
* Commented that no new MU requirements of any kind should be implemented based on the proposed changes to the accounting of disclosures rule.
* Commented HHS’s proposed rule failed to balance the patient’s interest in learning how his or her information is disclosed in a way that leverages readily available technology and does not overly burden covered entities and their business associates.
* Provided reasons for not finalizing the proposed rule, such as:
* Under the Privacy Rule, the patient can request and accounting of disclosures back 6 years, but disclosures for Treatment, Payment and Operations (TPO) need not be tracked. Requiring TPO would result in long detailed confusing reports that would be unascertainable by patients and create a significant burden to covered entities.
* HITECH requires practices to account for disclosures for TPO but it also directs the Secretary to determine the administrative burdens to covered entities in providing the accounting.
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| 8 | [HHS-OS-2012-0007-0395](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0395) | p. 28 | Paula Bussard | The Hospital & Health System Association of Pennsylvania  | * Respondent did not comment about a standard format for the log files of EHRs to support analysis of access to health information access multiple EHRs or other clinical systems in a healthcare enterprise.
* Commented that currently there is significant variability in the level of detail captured in the audit trails within the various subparts of the hospital.
* Commented that significant changes to current systems would be required to generate standardized audit logs across the multiple technical systems.
* Referenced experience in undertaking such changes as they require considerable time and effort to design, code and test, and often includes months of staff training and implementation activities that are also dependent on when the hospital falls on the vendors upgrade schedule.
* Commented that Office of the National Coordinator (ONC) take into consideration the effort and time required to implement changes before defining the compliance criteria and deadlines.
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| 9 | [HHS-OS-2012-0007-0382](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0382) | p. 35 | Cheryl Peterson/Karen Daley/Marla Weston | American Nurses Association | * Deferred to ANI’s response on the question.
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| 10 | [HHS-OS-2012-0007-0391](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0391) | p. 4 | Karen Boykin-Towns | Pzfizer Inc | * Respondent did not comment about a standard format for the log files of EHRs to support analysis of access to health information access multiple EHRs or other clinical systems in a healthcare enterprise.
* Commented that the Drug Enforcement Agency (DEA) standards for authentication of any provider who wants to send controlled substances.
* Commented HITPC’s recommendations that EHRs be able to accept two-factor authentication or higher for provider users to remote access PHI in Stage 3.
* Commented if EHR capabilities included DEA authentication requirements, then the redundant, parallel (electronic/paper) work streams could be eliminated.
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| 11 | [HHS-OS-2012-0007-0429](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0429) | p. 7 | Deven McGraw | Center for Democracy and Technology | * Referred to ASTM E-2147-01 as a suitable certification requirement for a certification based requirement for EHR systems.
* Referenced the details defined within around the content and format of system access logs to Patient Health Information (PHI) in EHRs.
* Cited the details defined around the maintenance requirements of keeping a single log of PHI access across and EHR across multiple systems for provision to external parties including, but not limited to, patients.
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| 12 | G:\Meaningful Use\HITPC\Stage\_3\_RFC\Submission | p.1 |   | VA | * Invalid link. Could not view document.
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| 13 | [HHS-OS-2012-0007-0325](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0325) | P.12 | Pamela  Foyster | Quality Health Network | * Should not mandate the format, but it is okay to require the elements.
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| 14 | [HHS-OS-2012-0007-0279](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0279) | p.17 | Yomaris  Guerrero | Boston Medical Center | * Supported the requirement of a format
* Commented that standards should be based on open protocols to allow efficient and cost effective development.
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| 15 | [HHS-OS-2012-0007-0506](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0506) | p.19 | Jamie Ferguson | Kaiser Permanente | * Respondent recommend additional feasibility studies before audit ogs or access reports are mandated under the MU program.
* Stated that the capability to track all needed data and automatically produce access reports, does not exist in their own system, or any other system to their knowledge at this time.
* Presented concern around the Return on Investment (ROI) in terms of value to the patient(s).
* Presented concern around the issue of whether giving individuals many pages listing dates, times, unfamiliar names, but no context for why those instances of access were proper and necessary, will breed distrust and suspicion of EHRs at a time when their adoption is a critical component of improved health care delivery and an important policy goal for this Administration.
* Suggested that additional Feasibility Studies be performed before audit logs or access reports are mandated under MU programs.
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| 16 | [HHS-OS-2012-0007-0525](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0525) | p.2 | David Finn | Symantec Corp. | * Supported the requirement of a format as it would significantly improve ability of covered entities to consolidate and correlate data from disparate systems in a timely and cost efficient manner.
* Stated that this would provide for more comprehensive and accurate analytics as well as advanced user behavior analysis.
* Suggested that a standard retention period also be established.
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| 17 | [HHS-OS-2012-0007-DRAFT-0051](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0051) | p.2 | Peter Alterman | SAFE-BioPharma Association | * No comment.
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| 18 | [HHS-OS-2012-0007-0510](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0510) | p.2 | Kelly Broder | Surescripts, LLC | * Respondent did not comment about a standard format for the log files of EHRs to support analysis of access to health information access multiple EHRs or other clinical systems in a healthcare enterprise.
* Commented that the proposed changes to the HIPAA Accounting of Disclosures rule is the accounting of disclosures proposal to be entirely unworkable.
* Commented to refrain from recommending any changes to the MU standards that are based on the proposed changes to the HIPAA accounting of disclosures rule.
* Commented that the accounting of disclosures proposed rule should be significantly revised (or eliminated), and that the Department should move forward with a new proposal for comment that reflects a better understanding of the current technological environment and is a more realistic balance between burden and benefits.
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| 19 | [HHS-OS-2012-0007-0557](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0557) | p.2 | Heather  Roe Day | WY e-Health Partnership | * Did not directly agree or disagree with the standard.
* Commented that ONC allow and encourage the use of logs already present in the query model HIEs which each across EHR vendor platforms.
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| 20 | [HHS-OS-2012-0007-0565](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0565) | p.21 | Leigh  Burchell | Allscripts | * Agreed that a standard is desirable.
* Were unaware of a standard that is mature enough to meet the stated need.
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| 21 | [HHS-OS-2012-0007-0505](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0505) | p.27 |  Shelly Spiro | Pharmacy e-HIT Collaborative | * Did not see the need for a standard format.
* Were unaware of the existence such a format.
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| 22 | [HHS-OS-2012-0007-0493](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0493) | p.28 | Thomas Merrill | New York City Department of Health and Mental Hygiene | * Supported the requirement of a standard format.
* Suggested an alternative solution – instead of a standard format for all systems, create a standard format that all systems should be able to export into.
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| 23 | [HHS-OS-2012-0007-0274](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0274) | p.28 | Thomson  Kuhn | American College of Physicians | * Supported the requirement for a standard format as it would very useful for capturing compliance at the level of specific events that can then be used for reporting.
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| 24 | [HHS-OS-2012-0007-0486](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0486) | p.3 | Tina Grande | The Confidentiality Coalition | * Respondent did not comment about a standard format for the log files of EHRs to support analysis of access to health information access multiple EHRs or other clinical systems in a healthcare enterprise.
* Commented that no new requirements of any kind should be implemented based on the proposed changes to the HIPAA accounting rule.
* Commented that the proposed changes to the HIPAA accounting rule ignored the fact that the HITECH statute (P.L. 111-5) requires HHS to balance the patient’s interest in learning how his or her information is disclosed in a way that leverages readily-available technology and does not overly burden covered entities (and their business associates).
* Commented that it is inappropriate to make any changes at all to the MU standards that are based on the proposed changes to the HIPAA accounting of disclosures rule.
* Commented that no new requirements should be added to reflect anything about the proposed “accounting of disclosures” rule.
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| 25 | [HHS-OS-2012-0007-0350](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0350) | p.3 | Landon  Combs | Highlands Physicians Inc | * Supported the requirement of a standard with the intent to be able to compare and look up patterns.
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| 26 | [HHS-OS-2012-0007-0315](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0315) | p.33 | Angela  Jeansonne | American Osteopathic Association | * No comment.
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| 27 | [HHS-OS-2012-0007-0568](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0568) | p.34 | Sasha  TerMaat | Epic | * Did not support a standard format.
* Commented that such a format should be evaluated if the recent Office of Inspector General (OIG) survey reveals and “inability to use audit log data” causes major concern.
* Commented that requiring a standard format would impose a burden on vendors and healthcare organizations and pose data conversion risks.
* Noted that if the format is desirable, then it should be in the form of a viewable audit log, and not have to convert raw audit data into a defined format.
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| 28 | [HHS-OS-2012-0007-0212](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0212) | p.35 | Kari  Guida | Minnesota Department of Health | * No comment.
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| 29 | [HHS-OS-2012-0007-0502](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0502) | p.36 | Clara Evans | Dignity Health | * Respondent did not comment about a standard format for the log files of EHRs to support analysis of access to health information access multiple EHRs or other clinical systems in a healthcare enterprise.
* Stated that currently there is significant variability in the level of detail captured in the audit trails within the various subparts of the hospital.
* Commented that significant changes to current systems would be required to generate standardized audit logs across the multiple technical systems.
* Referenced their experience in undertaking such changes as they require considerable time and effort to design, code and test, and often includes months of staff training and implementation activities that are also dependent on when the hospital falls on the vendors upgrade schedule.
* Commenter believes that ONC should take into consideration the effort and time required to implement changes before defining the compliance criteria and deadlines.
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| 30 | [HHS-OS-2012-0007-0343](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0343) | p.39 | Donna  Sledziewski | Geisinger Health System | * Suggested using a SIEM solution.
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| 31 | [HHS-OS-2012-0007-0333](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0333) | P.51 | Koryn  Rubin | American Association of Neurological Surgeons and Congress of Neurological Surgeons | * No comment.
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| 32 | [HHS-OS-2012-0007-0541](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0541) | p.51 | John  Glaser | Siemens Healthcare | * Suggested the development of a standard vocabulary to enable review/analysis /reporting in addition to a standard format.
* Suggested waiting for the finalization of the Accounting of Disclosure final rule and to use it as an input into the definition of a standard format and vocabulary.
* Noted the absence of a mature or dominant standard, despite ASTM E-2147-01 standard specification provided by the American Society for Testing and Materials (ASTM).
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| 33 | [HHS-OS-2012-0007-0145](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0145) | p.54 | Nancy  Payne | Allina Health | * Supported the standard.
* Suggested changes to normalize HIPAA\* and ASTM definition.
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| 34 | [HHS-OS-2012-0007-0295](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0295) | p.7 | Susan  Owens | Memorial Healthcare System | * Did not consider a standard to be feasible to all EHR providers.
* Commented that a format may not be necessary as long as there is defined minimum data set of fields to log.
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| 35 | [HHS-OS-2012-0007-0476](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0476) | p.9 | Anna Roberts | CHITREC (Chicago Health IT Regional Extension Center) | * Did not support a standard.
* Suggested that EHRs maintain a log independently and just provide a way to access them when needed.
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| 36 | [HHS-OS-2012-0007-0520](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0520) | PDF2 - p.79 | Andy Riedel | NextGen Healthcare | * Agreed that a standard is desirable.
* Noted that they are unaware of a standard that is mature enough to meet the stated need.
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| 37 | [HHS-OS-2012-0007-0547](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0547) | tab 3 | Erin  Laney | Intermountain Healthcare | * Supported adoption of standard formats for better integration and reporting.
* Commenter cautioned ONC that the ability of systems, applications, and databases to produce audit data in a standard way is not a technological certainty today and would require a considerable investment by the technology industry to support as a requirement.
* Noted the example of many current vendors of commercial solutions may have some and others very limited audit functionality that is standardized.
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| 38 | [HHS-OS-2012-0007-0535](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0535) | tab 4 | Dan  Rode | American Health Information Management Association | * Did not consider Accounting of Disclosure to be a significant issue based on the last 10 yrs. that HIPAA has been around.
* Suggested that ONC do not spend time on this.
* Suggested and urged the Office for Civil Rights (OCR) to standardize the reporting methodology in the HIPAA privacy rule.
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**Summary**

**Number of Comments:** 32(6 commenters did not provide a response or link was invalid)

## Summary: Commenters generally note that there is no dominant or mature existing standard to meet the stated need. The majority of commenters support a requirement for a standard format for the log files of EHRs to support analysis of access to health information across multiple EHRs or other clinical systems in a healthcare enterprise. Others are neutral or state that the adoption of such a standard presents the need for significant technical changes to existing systems. Other commenters cited specific formats or solutions to meet the need. Some commenters disagree with the need for a standard format, including the burden to healthcare organizations and vendors. Other commenters disagree with the need for MU based standards related to the Accounting for Disclosures rule, in general.

**No existing standard format requirement.** (6)

* *With additional comment*:
	+ No codified requirement for centralized enterprise audit review. (1)
	+ Unaware of any standard format for log files to meet stated need. (3)
	+ Absence of mature or dominate standard. (1)

**Support need for standard format requirement** (14)

* *With additional comment*:
	+ IHE audit trail and ATNA standard attempt to resolve existing issue. (1)
	+ Support of centralized audit review. (1)
	+ Use of ASTM E-2147-01. (1)
	+ Based on open protocols and limit costs. (1)
	+ Improvement of ability to efficiently consolidate and correlate data. (2)
	+ Export into standard format. (1)
	+ Waiting for final Accounting of Disclosure Rule. (1)
	+ Changes to normalize HIPAA and ASTM definition. (1)
	+ Need for significant changes in current system to allow for standard audit log. (1)

**Neutral toward standard format requirement** (8)

* *With additional comment*:
	+ Government should dictate what but not how. (1)
	+ Variability on details captured in audit trail. (2)
	+ Need for significant changes in current system to allow for standard audit log. (2)
	+ Need for additional feasibility studies. (1)
	+ Use of existing audit logs in query model HIEs which reach across EHR vendor platform. (1)
	+ Use of SIEM solution for standard format for log file. (2)
	+ Prescribe standard in HIPAA Privacy Rule. (1)

**Disagree with need for standard format requirement** (6)

* *With additional comment*:
	+ Support for mandating requirement elements. (1)
	+ Burden on health care organizations and vendors. (2)
	+ Support for defining a minimum data set. (1)
	+ Individual EHR system audit logs accessible. (1)
	+ Viewable audit log; no conversion of data into raw format. (1)

**No need for MU based standards related to Account of Disclosures Rule.** (5)

**Appendix:**

**No existing standard format requirement** (#1, #6, #20, #21, #32, #36)

* *With additional comment*:
	+ No codified requirement for centralized enterprise audit review (#2)
	+ Unaware of any standard format for log files to meet stated need (#20, #21, #36)
	+ Absence of mature or dominate standard (#32)

**Support need for standard format requirement** (#3, #4, #6, #11, #13, #16, #20, #22, #23, #25, #32, #33, #36, #37)

* *With additional comment*:
	+ IHE audit trail and ATNA standard attempt to resolve existing issue (#3)
	+ Support of centralized audit review (#6)
	+ Use of ASTM E-2147-01 (#11)
	+ Based on open protocols and limit costs (#13)
	+ Improvement of ability to efficiently consolidate and correlate data (#16, #25)
	+ Export into standard format (#22)
	+ Waiting for final Accounting of Disclosure Rule (#32)
	+ Changes to normalize HIPAA and ASTM definition (#33)
	+ Need for significant changes in current system to allow for standard audit log (#37)

**Neutral toward standard format requirement** (#2, #4, #8, #15, #19, #29, #30, #38)

* *With additional comment*:
	+ Government should dictate what but not how (#2)
	+ Variability on details captured in audit trail (#8, #29)
	+ Need for significant changes in current system to allow for standard audit log (#8, #29)
	+ Need for additional feasibility studies (#15)
	+ Use of existing audit logs in query model HIEs which reach across EHR vendor platform (#19)
	+ Use of SIEM solution for standard format for log file (#4, #30)
	+ Prescribe standard in HIPAA Privacy Rule (#38)

**Disagree with need for standard format requirement** (#12, #21, #27, #34, #35)

* *With additional comment*:
	+ Support for mandating requirement elements (#12)
	+ Burden on health care organizations and vendors (#27, #34)
	+ Support for defining a minimum data set (#34)
	+ Individual EHR system audit logs accessible (#35)
	+ Viewable audit log; no conversion of data into raw format (#27)

**No need for MU based standards related to Account of Disclosures Rule** (#1, #5, #7, #18, #24)