# MU4: Some federal and state health information privacy and confidentiality laws, including but not limited to 42 CFR Part 2 (for substance abuse), establish detailed requirements for obtaining patient consent for sharing certain sensitive health information, including restricting the recipient’s further disclosure  of such information.

# How can EHRs and HIEs manage information that requires patient consent to disclose so that populations receiving care covered by these laws are not excluded from health information exchange?

# How can MU help improve the capacity of EHR infrastructure to record consent, limit the disclosure of this information to those providers and organizations specified on a consent form, manage consent expiration and consent revocation, and communicate the limitations on use and restrictions on re-disclosure to receiving providers?

# Are there existing standards, such as those identified by the Data Segmentation for Privacy Initiative Implementation Guide, that are mature enough to facilitate the exchange of this type of consent information in today’s EHRs and HIEs?

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| # | Comment ID | MU4 | Name of Respondent | Organization | Comments |
| 1 | [HHS-OS-2012-0007-DRAFT-0006](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0006) | 1 |   | Delaware Health Net, Inc | * No comment.
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| 2 | [HHS-OS-2012-0007-DRAFT-0008](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0008) | 4 documents, in folder |   | NORC at the University of Chicago | * Noted that 42 CFR Part 2 applies only when that information is contained in a record held by a federally assisted “program.” Addiction treatment information given in a general hospital, ER, physician office, Federally Qualified Health Center (FQHC), or rural clinic generally would not be protected.
* Commented that 42CFR Part 2 differs sharply from newer laws because it provides no non-discrimination prohibitions or protection against insurance discrimination, disability and life insurance discrimination, and employment discrimination.
* Commented that since the Secretary of HHS has broad authority to prescribe regulations to “carry out the purposes” of the statute and should modify 42 CFR Part 2 regulations to permit an explicit and limited exclusion allowing disclosures of substance use disorder treatment information to healthcare providers and health plans for purposes of treatment, coordination of care, recovery support, quality improvement, disease management, and payment. The only items that can be disclosed without authorization for the limited exceptions are demographic information, diagnosis, medications, laboratory results, and identification of past or current treatment providers.
* Commented that the Secretary should promulgate regulatory interpretations that would prohibit discrimination based on information in substance use disorder program records; limit use in criminal and civil investigations or proceedings; and strengthen civil and criminal sanctions against unauthorized disclosures.
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| 3 | [HHS-OS-2012-0007-0507](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0507) | cell F71 | Sunti Ponkshe | Accenture | * Stated that this is a very important issue.
* Recommended discussion with the American Health Information Management Association (AHIMA), the Health Information Management experts and harmonization of other similar efforts in this area to avoid duplication.
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| 4 | [HHS-OS-2012-0007-0376](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0376) | p. 11 | Sarah Cottingham | Telligen Iowa HIT Regional Extension Center | * Suggested ONC Standardize these types of regulations to be consistent across the states so Electronic Health Record (EHR) Vendors can successfully build these standards.
* Recommended ONC works with the states to see if conformity can be agreed upon.
* Recommended ONC works with the states to establish consistency and that the states work with each other.
* Commented that the Data Segmentation for Privacy (DS4P) pilot was very interesting and that it should be published in Stage 3 recommend that ONC publish the results for the pilot and any proposal for Stage 3.
* Commented that the system has to be able to sequester data by encounter or admission as well as by the other categories that are typically segmented.
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| 5 | [HHS-OS-2012-0007-0412](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0412) | p. 12, 13 | John Travis | Cerner Corp. | * Suggested consideration of some manner of classifying the sensitive data such that disclosure can be effectively managed based on privacy policies applied at the time of disclosure.
* Commented that the Standards and Interoperability (S&I) Framework's DS4P WG has examined leverage of medical code sets that may already codify what is to be disclosed and Health Level 7 (HL7) confidentiality and sensitivity code sets for this classification purpose to codify structured data about to be disclosed in a clinical document for semantically tagging clinical documents and data for purpose of understanding the privacy protection that may be attributed to what is to be disclosed.
* Commented this may support the use of policy decision point business rule engines to examine the content of structured clinical documents based on this semantic tagging for sensitive data at the time of disclosure, and to relate that to policy enforcement point capabilities integrated into disclosure management functions to determine if patient authorization exists for disclosure. This kind of an approach may be workable but is not yet in wide commonplace use.
* Commented that there are multiple areas of requirement here, which suggests that an iterative approach should be used: ONC should consider iterating requirements for consent administration and capture, privacy policy definition and application, authorization capture, semantic tagging of sensitive data, policy decision point abilities and policy enforcement point abilities.
* Suggested that HL7 Sensitivity and Confidentiality code sets and purpose of use kinds of code sets may be a good start.
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| 6 | [HHS-OS-2012-0007-0409](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0409) | p. 14 | William Zoghbi | American College of Cardiology (ACC) | * Commented that reductions in the use of tobacco have contributed significantly to the decrease in morbidity and mortality rates from heart disease. Given the differing requirements for coverage of smoking cessation support across insurance plans and states, the ACC is concerned by the proposed recommendation that health IT be used to generate referrals for patients who need to stop smoking or using tobacco.
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| 7 | [HHS-OS-2012-0007-0425](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0425) | p. 17 | Willa Fields, Stephen Lieber | HIMSS | * Suggested that patient information can be tagged with metadata including special category information and even patient privacy preference information (as previously captured from the patient) using HL7 sensitivity codes. Tagging would be accomplished by the originator of the electronic patient information and would necessarily need to comply with all relevant federal and state laws and regulations.
* Commented that management of patient consent and/or privacy preferences is not something that could easily be captured and maintained in an individual EHR, but rather might require a separate infrastructure or ecosystem that is accessible by providers through an EHR or Health Information Exchange (HIE) and patients alike.
* Commented that the full implementation of such a service or ecosystem would be complex and the interaction with the patient will require a complete set of tools, including training, resources and education regarding the implications of their privacy preference choices. The entirety of this service/ecosystem creation and deployment is likely outside of the scope of the Meaningful Use (MU) program.
* Commented that until such a service or ecosystem is present, it will be difficult to specify a specific MU measure for providers. This approach could simplify the consent process for patients, and also would make it much easier for them to keep track of the permissions they had selected. It also could reduce cost and risk for providers.
	+ Patient records their privacy preferences through a portal or service instead of having to fill out a form each time he/she receives care from a provider.
	+ The portal manages each patient’s preferences, allowing changes by the patient and provides notification to the patient when their permissions needed to be renewed.
	+ Whenever a data holder received a request for an individual’s health information, his/her EHR or the HIE could query the service to determine whether the patient had authorized the requested use or access.
	+ Before any holder of a patient’s information could make it available to another party; the holder would need to query the portal for the permissions currently in effect.
* Suggested that the portal would be responsible for managing permissions, and the holder of information would be responsible for managing data in compliance with the permissions in force at any given time. The service could be accessed using a secure Representational State Transfer (REST) protocol or the eHealth Exchange protocol. Permissions could be exchanged using the Extensible Access Control Markup Language (XACML) standard.
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| 8 | [HHS-OS-2012-0007-0382](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0382) | p. 25 | Cheryl Peterson/Karen Daley/Marla Weston | American Nurses Association | * Recommended working directly with the enforcement bodies (e.g., OCR) to gain their input on disclosure and consent. Seek input from consumer groups and interested consumers directly.
* Suggested evaluating the practicality of developing regional or state-level Certified EHR Technology (CEHRT) criteria for EHR modules that might be regulated at those levels.
* Suggested inviting testimony from large health care systems that have successfully managed consent criteria and variations among those criteria.
* Commented that the ANA supports the ANI’s response to this question.
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| 9 | [HHS-OS-2012-0007-0395](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0395) | p. 26 | Paula Bussard | The Hospital & Health System Association of Pennsylvania  | * Commented that many studies and reports have identified variation in privacy laws across states as a key barrier to information exchange.
* Recommended that HHS works toward a single set of federal privacy laws to facilitate information exchange and improve efficiency, while still protecting privacy.
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| 10 | [HHS-OS-2012-0007-0419](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0419) | p. 47 | James Kaufman | Childrens Hospital Association | * Noted that there are adolescent privacy issues that need to be considered along with these questions.
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| 11 | [HHS-OS-2012-0007-0413](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0413) | p. 7 | John Gilligan | Human Service Center  | * Suggested recognizing Sensitive Health Information through meta tags, leveraging pilots, and developing a method that complies with patient consents.
* Commented that preservation of trust should be a top priority; record patient consent, communicate limitations on use of PHI; communicate restrictions on disclosure and re-disclosure of PHI.
* Commented that the regulations promulgated at 42 CFR Part 2 do not contemplate the electronic exchange of health information enabled by EHR systems and need to be revised. Uniform Privacy Compliance Safe Harbor should be established that would trump any State laws. Standardize approach to regulatory guidance.
* Commented that sensitive data is often mixed with general patient data. Patients should have resources that would make it easier for them to understand how they can use data protections available to them.
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| 12 | [HHS-OS-2012-0007-0393](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0393) | p. 9 | Jennifer Covich Bordenick | eHealth Initiative | * Noted that in 2007, eHI developed the “eHealth Initiative Blueprint: Building Consensus for Common Action” which is a shared vision and a set of common principles, strategies and actions for improving health and healthcare through Health IT and health information exchange. Believes that there continues to be room for progress in these areas: Transparency, Collection and Use of Personal Health Information; Individual Control; Security; Audit; Accountability and Oversight.
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| 13 | G:\Meaningful Use\HITPC\Stage\_3\_RFC\Submission | p.1 |   | VA | * Invalid link. Cannot view document.
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| 14 | [HHS-OS-2012-0007-0557](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0557) | p.1 | Heather  Roe Day | WY e-Health Partnership | * Suggested using the work already done by the HIEs to manage consent for the distribution of sensitive data across data silos. This will happen faster if the work already done is applied.
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| 15 | [HHS-OS-2012-0007-0234](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0234) | p.1 | Aileen  Wehren | Porter-Starke Services Inc | * Commented that all of these suggestions avoid the need for the HIE to manage authorizations and consents however it does slow down information flow because of the added requirement to contact the behavioral health care provider to confirm if a given piece of data can or cannot be sent.
* Suggested ONC consider four options:
	+ Option 1: Requests for behavioral health information are submitted to the HIE, the provider that submitted those data would need to approve the transmission of those data, thus guarding against any change in authorization for disclosures.
	+ Option 2: Assign responsibility for determining the data to be sent to the health care provider. They could filter data by various criteria based upon patient consent. This would still require that Option 1 above be implemented if addictions data are included in the HIE.
	+ Option 3: Restrict the data to be included; not allowing based on diagnoses, medications and laboratory, results that disclose information subject to 42 CFR, thus limiting the amount and type of information in the HIE. Providers would secure consent to include data in the HIE.
	+ Option 4: Stratify data in the HIE so that addictions data are “held separately”. Then implement the processes at the HIE for the data to be released only when the provider/owner of the data approves the release.
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| 16 | [HHS-OS-2012-0007-0236](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0236) | p.1 | Meika  DiPietro | Vermont Department of Health | * Supported the inclusion of a statement on the patient consent form in which the patient will agree to the prescriber/pharmacist having the right to look up controlled prescription information for the patient.
* Supported capacity building for primary care EHR systems to better manage the consents and control the re-disclosure of select types of information.
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| 17 | [HHS-OS-2012-0007-0238](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0238) | p.1 | Kathleen  Connor | Edmond Scientific Company | * Commented that three DS4P pilot teams have already demonstrated the ability to used standard terminologies to "tag" a Meaningful Use (MU) compliant C32 and CCDA in accordance with the HL7 Consent Directive Clinical Document Architecture (CDA).
* Commented that the standards-based semantic labeling (tagging) of clinical facts, which are the discreet elements used to construct a CCDA, with clinical terminologies and provenance is already a MU EHR required capability.
* Commented that the DS4P pilots demonstrate how these "tagged" clinical facts are consumed by the security labeling services or Access Control System Policy Information Point (PIP).
* Commented that the PIP also invokes the governing privacy policies and patient consent directive to control enterprise user access and to construct a CCDA for disclosure, which either redacts, masks, or tags a clinical fact (at the CDA header, section, and entry level) with security labels that tells the receiver how to comply with policies that govern the disclosure.
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| 18 | [HHS-OS-2012-0007-0362](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0362) | p.10 | Chuck  Parker | Continua Health Alliance | * No comment provided.
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| 19 | [HHS-OS-2012-0007-0203](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0203) | p.10 | Robert  Bennett | American Academy of Family Physicians | * Commented about the existence of a distinct need for a robust mechanism of patient consent with some level of adjustable granularity through metadata or similar structures.
* Commented that this will likely require use of role-based certificates for encryption/decryption of data at rest.
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| 20 | [HHS-OS-2012-0007-0279](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0279) | p.11 | Yomaris  Guerrero | Boston Medical Center | * Supported efforts to provide more clarity and efficiency to the process of identifying confidential information at a discrete level.
* Requested clarity on standards to assess the consent levels/fields with in system during visit.
* Suggested consideration for authorized representative specific consent limitations.
* Requested that prior to any measure requiring the exchange of records for specific patient populations, ONC should push for EHR capability to store, validate and exchange these types of consents.
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| 21 | [HHS-OS-2012-0007-0103](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0103) | p.11 (ONC08) | Michael  Lardiere | National Council for Behavioral Health | * Recommended that 42 CFR Part 2 be updated to recognize the evolution and use of technology in healthcare, which was not in place when 42 CFR Part 2 was enacted. Allow a patient to authorize “providers in the HIE involved in my care” to access their records would meet the specificity for the patient as they know who is involved in their care.
* Commented that the Substance Abuse and Mental Health Services Administration (SAMHSA) Consumer Focus Groups clearly indicate that behavioral health consumers want to share their information as long as it is with providers who are involved in their care.
* Suggested certification criteria for EHRs should be enhanced so that any EHR can tag data as being covered by 42 CFR Part 2 and restrict sharing that information based on patient authorization.
* Commented that the work of the Data Segmentation for Privacy Workgroup is a good start and can allow for sharing of sensitive information. Even if the information is only provided as a document with the appropriate Non Re-disclosure Notice affixed to it that will allow 42 CFR Part 2 information to be shared.
* Commented that EHRs as part of their certification criteria must have the capability to receive these documents, tag or flag them in their systems and have the capability to restrict re-disclosure if it is not to an authorized provider.
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| 22 | [HHS-OS-2012-0007-0358](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0358) | p.12 | Katherine  Nordal, PhD. | American Psychological Association | * Same comments as line 21.
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| 23 | [HHS-OS-2012-0007-0574](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0574) | p.1-2 | Alexis  Geier-Horan | American Society of Addiction Medicine | * Stated that the integration of primary and behavioral health care is imperative to the mainstreaming of addiction treatment and to achieving meaningful healthcare reform.
* Commented that addiction patient records are protected by higher standards of confidentiality than even psychiatric records, and far higher than records of general medical encounters.
* Suggested that both behavioral health and primary care electronic health records must be developed with the functionality to manage a behavioral health patient’s consent. Features include:
	+ 1. Free exchange of basic health information, including via sharing of electronic health records or via the placement of basic health information into an electronic health information exchange, should be permitted by the patient’s initial consent for treatment.
	+ 2. Personal health information should not be released outside of the health care system without the explicit written consent of the patient.
	+ 3. Any access to health information obtained in the course of facility inspections and quality assurance activities should be handled only by individuals and entities that agree in writing to avoid any secondary release of this information, and to store and analyze data from health records of patients only after patient identifiers have been removed from the files.
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| 24 | [HHS-OS-2012-0007-0558](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0558) | p.14 | Peter  Basch | MedStar Health | * Stated that they have recently gone thru a system-wide effort with our EHR in understanding how our behavioral health providers can be part of an enterprise’s patient-centric EHR.
* Commented that it is far more difficult than creating a privacy data model, as depending on one’s state / location, the mental health information laws present contradictory requirements -- requirements that are incompatible with Joint Commission standards, MU requirements, and conventional wisdom.
* Commented that the specific issues relate to the definition of specially protected mental health information and requirements for creating and maintaining a complete problem list, medication list, allergy list.
* Suggested that prior to building a consent model to manage information, there needs to be modernization and harmonization of mental health information and substance abuse information laws (state and federal).
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| 25 | [HHS-OS-2012-0007-0263](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0263) | p.15 | Jeff Hummel | MU CoP | * Commented that it is hard to imagine how this could be done without “tagging” sensitive data at the time it is entered. Identifying sensitive data to tag would be almost impossible to automate based on content because primary care includes a large amount of behavioral health and substance abuse over a range of severity. Where to draw the line would be different from patient to patient.
* Suggested release of information could be a two-stage process with the tagged information requiring reauthorization each time any information is released.
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| 26 | [HHS-OS-2012-0007-0556](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0556) | p.15 | Blair w.  Barnhart-Hinkle | Cleveland Clinic | * Agreed with securing the electronic record for these patients and notes that requiring the CEHRT to facilitate this, as a measure of MU is unreasonable.
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| 27 | [HHS-OS-2012-0007-0210](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0210) | p.15 | Linda  Brady | * ADHI
 | * Commented about the necessity of considering the practical ability to work across state lines as consent management decisions are made.
* Commented that the patchwork of state laws throughout the country that currently exists will always be burdensome and difficult to navigate when trying to exchange healthcare information.
* Commented it was time for HIPAA to be the one standard to follow for all healthcare purposes. The patchwork of state laws throughout the country that currently exists will always be burdensome and difficult to navigate when trying to exchange healthcare information. HIPAA should supersede all others when it comes to health care.
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| 28 | [HHS-OS-2012-0007-0493](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0493) | p.16 | Thomas Merrill | New York City Department of Health and Mental Hygiene | * Suggested that states decide whether to require patients to individually opt in, or to set sharing as the default, allowing patients to choose to opt out.
* Commented that it was unclear how this will play out, as information must be transmitted across state lines.
* Commented that given the fragmented landscape, they expect software vendors to focus on nationally applicable functions.
* Suggested a clear role for MU to assist in information management options including recording consent and limiting disclosure.
	+ EHRs must be able to differentiate between sensitive and non-sensitive information, applying both blanket consent and item-by-item flags as appropriate.
	+ EHRs must also be able to alert providers to changes in patient status such as when a patient reaches the age of consent as appropriate.
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| 29 | [HHS-OS-2012-0007-0565](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0565) | p.17 | Leigh  Burchell | Allscripts | * Stated that requirements and expectations for patient consent differ entity-by-entity.
	+ Current state is often an “all or nothing” approach—entire patient record or nothing is shared.
	+ The existing approaches, such as the Data Segmentation for Privacy Initiative, are too granular and unproven to adopt in a single step.
* Suggested that what is needed is a series of interim steps from the current state to the ideal state.
	+ Recommend that segmentation should first cover user-initiated pushes at a document level.
	+ User-initiated pushes can occur from providers that have obtained patient consent, or from the patient themselves through VDT features.
	+ Standards can become more granular over time to place confidentiality flags on individual clinical items and cover other use cases such as query exchanges.
* Commented that the Federal and state variations are quite challenging to manage; does this imply consent for each diagnosis needs to be tracked?
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| 30 | [HHS-OS-2012-0007-0366](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0366) | p.18 | Julie  Clements | American Psychiatric Association | * Strongly believed that EHRs and HIEs must be designed with the capacity to record both the extent of information a patient desires disclosing to his/her health care providers as well as the specific providers who have the patient’s consent to be privy to the specially protected information.
* Commented that several states that have been experimenting with alternative EHR and HIE designs that will allow for the segmentation of data protected by heightened federal privacy laws, like 42 CFR Part 2, while simultaneously allowing patients afforded additional privacy protections.
* Commented that if an EHR system supports the inclusion of psychotherapy notes as defined in federal and state privacy laws, it is imperative that the EHR be designed so as to allow for health care professionals accessing the stored patient information to adhere to all rules governing psychotherapy notes.
* Commented that the HIPAA Privacy Rule is clear that only those psychotherapy notes, which are kept separate from the rest of an individual’s record, are afforded additional protection. How this translates into the EHR platform remains unresolved.
* All psychotherapy notes maintained with other documentation lose any special protection for confidentiality and are not required to be treated differently.
* Offered to be a resource for HITPC as it formulates guidelines for EHRs that address patient privacy and confidentiality laws as well as the appropriate storage and use of psychotherapy notes.
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| 31 | [HHS-OS-2012-0007-0350](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0350) | p.2 | Landon  Combs | Highlands Physicians Inc | * Commented that data release for these sections requires a separate check box to release; check boxes in EHR show which can or can’t be released, notes in chart; chart note when data is released.
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| 32 | [HHS-OS-2012-0007-0307](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0307) | p.2 | Deanna  Triplett | IBHA | * Stated that substance use disorder and mental health care should be integrated more effectively with health care generally.
* Suggested that communication between substance use disorder and mental health care providers and other health care providers must be improved to facilitate such integration.
* Commented that participation in EHRs and HIEs is one very important way to improve communication and integration between substance use disorder and mental health care providers and other health care providers.
* Stated that state and federal laws protecting the confidentiality of “sensitive health information” remain critical for encouraging people with stigmatized health issues to seek and remain in care and for preventing discrimination and other damaging consequences for patients.
* Commented that EHRs and HIEs must have the functional capacity to comply with these vital state and federal confidentiality laws and the capacity to implement patients’ consent choices.
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| 33 | [HHS-OS-2012-0007-0490](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0490) | p.2 | Paul Samuels | Legal Action Center | * Same talking points as #32, plus:
* Suggested EHR/HIEs must have:
	+ Ability to segment or tag data that is protected by 42 CFR Part 2.
	+ Be technologically capable of implementing rules and policies for that segmented or tagged data including:
	+ Determine whether the patient has consented to disclosure.
	+ Disclose that tagged data only for the providers whom the patient has provided consent and for the purposes and amount listed on the consent form.
	+ Ensure that notice prohibiting redisclosure accompanies those tagged disclosures.
	+ Implement revocation and expiration of patient consent.
* Commented that the HITPC should recommend standards and certification criteria that promote the development and require adoption of technological capabilities that would enable EHR systems to comply with state and federal confidentiality laws.
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| 34 | [HHS-OS-2012-0007-0274](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0274) | p.20 | Thomson  Kuhn | American College of Physicians | * Commented granular consent appears harder and harder to accomplish the deeper you dig into the granularity and expand the complexity of the workflows.
* Suggested a better approach is to focus on identification and punishment of inappropriate use of patient data across the healthcare system.
* Suggested we need to redraft HIPAA to clearly define what consent is required, what is opt-in and what is opt-out.
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| 35 | [HHS-OS-2012-0007-0347](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0347) | p.25 | Jeffery  Smith | College of Healthcare Information Management Executives | * Stated that the lack of consistent policies across the country with respect to patient consent and the exchange of information complicates this matter.
* Stated that failure to share sensitive information could have very serious consequences for patient health and safety, especially if unaccompanied by some workable exceptions in emergencies.
* Commented that there is also much uncertainty regarding the relative responsibilities of hospitals and HIEs (e.g., redaction of patient records).
* Urged more study of how HIEs might efficiently handle sensitive patient data.
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| 36 | [HHS-OS-2012-0007-0272](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0272) | p.26 | Kim  Johns | Deaconess Health System | * Stated that they do not have an answer on how to best exclude this information to the exchanges.
* Stated that its organization currently struggles with how to limit the disclosure of patient information to HIEs if a patient chooses not to share their information.
* Believed that the Electronic Medical Records (EMR) vendors will have to develop better tools for meeting the needs of those patients who have select to be excluded from data sharing.
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| 37 | [HHS-OS-2012-0007-0321](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0321) | p.26 | Linda  Fishman | American Hospital Association | * Same comments as in #9.
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| 38 | [HHS-OS-2012-0007-0568](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0568) | p.26-27 | Sasha  TerMaat | Epic | * Commented that attempts to segment a patient’s record will result in missed expectations for patients, liability for providers, and overall reduced confidence in interoperability. The significant safety risks of data segmentation are not fully understood.
* Suggested that the best course to further interoperability at this time is for patients to authorize the sharing of their information or for patients to indicate they do not wish their record to be shared and to transport their records between providers themselves via Personal Health Records (PHRs).
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| 39 | [HHS-OS-2012-0007-0315](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0315) | p.27 | Angela  Jeansonne | American Osteopathic Association | * No comment.
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| 40 | [HHS-OS-2012-0007-0212](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0212) | p.28 | Kari  Guida | Minnesota Department of Health | * Stated that Minnesota is currently completing a study in health records access and patient consent. We would be willing to share the findings in March 2013.
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| 41 | [HHS-OS-2012-0007-0218](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0218) | p.28 | Wende  Baker | Electronic Behavioral Health Information Network (eBHIN) | * Commented that their Network is currently managing consents via an Opt-in/Opt-out participation-setting template that is embedded in the record access workflow. The default is to opt-out. This is a manual process but is part of the data entry process in the EHR so does not create an administrative burden.
* Stated that the eBHIN Regional Health Information Organization (RHIO) has established practices that are largely manual to manage all of these required elements. This is achieved through technical architecture, participation agreements and policies and procedures. Data segmentation is urgently needed to automate what is now a cumbersome and time consuming process.
* Stated that unfortunately, data segmentation is not yet available via the vendor market. Providing standards and potentially development code to decrease vendor and stakeholder investments would speed adoption.
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| 42 | [HHS-OS-2012-0007-0505](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0505) | p.29 |   | Pharmacy e-HIT Collaborative | * Supported the data segmentation for privacy that are mature enough to facilitate the exchange of this type of consent information in today’s EHRs and HIEs.
 |
| 43 | [HHS-OS-2012-0007-0310](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0310) | p.29 | Joe  MacDonald | Mercy Health System | * Stated the importance of the ability to automatically populate a referral form for specific purposes, including a referral to a smoking quit line.
 |
| 44 | [HHS-OS-2012-0007-0229](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0229) | p.3 | Kathleen  Aller | Recommind, Inc. | * Believed that the ONC and the S&I Frameworks program should be actively involved in establishing and promoting standards for consent management, but Stage 3 is too early to formally require standards that are still in their infancy.
 |
| 45 | [HHS-OS-2012-0007-0540](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0540) | p.3 | Ann  Berkey | McKesson Corporation | * Stated that the HITPC should support efforts to advance policies and standards to guide health information exchange and public health requirements anticipated for future stages.
	+ ONC should engage stakeholders, incl. OCR, CDC, State and local agencies, patient advocates, and the provider and vendor community, in a collaborative effort to address the barriers to information exchange.
	+ Policies that result from this collaboration should guide the application of technology. Through RelayHealth and other systems, McKesson facilitates the exchange of health information in a secure environment.
* Supported the continued efforts of the S & I framework and certain public/private initiatives to move states towards the use of common exchange standards.
	+ We strongly endorse the use of shared services for patient identity, consent management and provider authentication and identity management, and will work closely with other stakeholders who share similar perspectives.
	+ We encourage the HITPC to drive further adoption of Direct within Stage 3and address the standards and policy gaps in the near-term to enable the widespread adoption of health information exchange in future stages.
* Strongly recommended uniform national privacy and security standards for clinical care that supersede state authority and geographical boundaries to ensure the portability and interoperability of patient information.
* Supported education programs to improve awareness and understanding among consumers and private sector entities about protections for personal health information, the appropriate uses of health information and the privacy and security obligations associated with good data stewardship.
 |
| 46 | [HHS-OS-2012-0007-0497](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0497) | p.3 | Mark Callahan | The Mount Sinai Medical Center | * Commented that their state requires consent from both the sender and receiver for every piece of data that is exchanged. Varying state requirements make it very difficult to segregate Mental Health data in an EHR.
* Strongly believes that the population of patients they serve needs to be actively involved in the discussion as well as provided greater education.
 |
| 47 | [HHS-OS-2012-0007-0170](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0170) | p.3 | Karl Auerbach, MD, MS, MBA, FACOEM | American College of Occupational and Environmental Medicine (ACOEM) | * Suggested that an EHR system must have robust messaging capability including “message wrappers” to enable credentialing of message recipients. This would also address patient consents for record release to outside message recipients.
* Commented that to facilitate information transfer between the patient-centered medical home and other loci of care (i.e., workplace), the EHR must be able to exchange a minimum set of occupational health data with the PHR.
* Stated that to take account of the confidentiality requirements imposed by the Americans with Disabilities Act (ADA) and GINA (Genetic Information and Non-Disclosure Act), the EHR must have adjustable information “firewalls” to allow users with varying levels of credentialing to view different fields.
 |
| 48 | [HHS-OS-2012-0007-0499](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0499) | p.3 | Tine Hansen-Turton | National Nursing Centers Consortium | * Appreciated that ONC seeks achievable objectives in increasing the level of certain Stage 2 measures for Stage 3.
* Suggested that ONC not rush Stage 3 implementation.
 |
| 49 | [HHS-OS-2012-0007-0249](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0249) | P.3 | David  Litts | National Action Alliance for Suicide Prevention | * Commented that many states have mental health privacy rules that preclude the sharing of mental health information without consent while many EHR systems do not have the capacity to manage these consents or to control the re-disclosure of select types of information as required.
* Stated that the inability of many EHR’s to properly manage consents for protected information prevents the efficient integration of primary care and behavioral health care.
* Commented that the inability for providers to responsibility share information regarding mental health status and acute suicide risk puts lives in jeopardy.
* Recommended that all certified EHR’s be required to have the capacity to manage patient consents to control the re-disclosure of select types of information.
 |
| 50 | [HHS-OS-2012-0007-0373](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0373) | p.3 | Sabra  Rosener | Iowa Health System | * Stated that software developers have not yet built solutions that are well-tailored to specifically address the requirements of these laws.
* Commented that industry would benefit from discussion and clarification on the topic, particularly given the focus on improving patient outcomes through coordination of care to address all of a patient’s conditions.
* Commented that the current situation is impacting the way health care providers structure EHR systems forcing our outpatient mental health clinic to build its EHR database as a stand-alone database separate from the general hospital and clinic EHR databases in order to meet heightened privacy requirements for mental health records.
 |
| 51 | [HHS-OS-2012-0007-0351](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0351) | p.30 | Jonathan  Kimerle | SSM Health Care | * No comment.
 |
| 52 | [HHS-OS-2012-0007-0343](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0343) | p.30 | Donna  Sledziewski | Geisinger Health System | * Commented that to be truly useful, all of the clinical information needs to reside in the exchange. Access to a complete record is essential for high quality care.
 |
| 53 | [HHS-OS-2012-0007-0502](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0502) | p.34 | Clara Evans | Dignity Health | * Stated that many studies and reports have identified variation in privacy laws across states as a key barrier to information exchange.
* Stated that Dignity Health has first-hand experience within their own system, which exists across three states with varying consent policies.
* Urged the HITPC to recommend that HHS work toward a single set of federal privacy laws. Having the same laws in place across the country would facilitate information exchange and improve efficiency, while still protecting privacy.
 |
| 54 | [HHS-OS-2012-0007-0588](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0588) | p.38 | Gregory  Rivas | UC Davis Medical Center | * Suggested HHS allow organizations to create their own measurements based on specialty or patient population.
 |
| 55 | [HHS-OS-2012-0007-0536](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0536) | p.4 | David  Harlow | Society for Participatory Medicine | * Stated that centralized consent should be enabled.
 |
| 56 | [HHS-OS-2012-0007-0541](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0541) | p.40-41 | John  Glaser | Siemens Healthcare | * Commented that EHRs need to have the ability to flag the patient's consent at some level -- Consent might include allowing certain clinical documents to be shared with an HIE, with certain provider types and preventing the sharing of certain treatments/procedures.
	+ This level of documentation in the EHR needs to appropriately designate patient consent for data sharing – indicating whether a clinical document can be posted to an HIE and how the document can be shared within the HIE.
* Commented that the industry needs to come to consensus on how and where the management/control of consents occurs, i.e., from the EHR or the HIE, if the EHR should be controlling what is sent to the HIE based on the patients’ consent, and how to ensure that appropriate mechanisms are implemented to ensure that the HIE honors any constraints that might be imposed by the patient.
* Recommended the following steps to expedite the industry adoption of methods for managing consent for sharing health information:
	+ Identification and classification of the data and sensitivity at a data level. The DS4P initiative designed to address this requirement is currently under way.
	+ Establishing industry code sets that would cover standard consent policies, which could be adopted and implemented by both the EHR and HIE vendors. This would provide a set of standards for defining what to display and what is permitted to be exchanged against which all EHR and HIE vendors can code.
	+ Updates to CFR to address electronic collection of consent; with patient signature capture.
* Believed that the existing approaches such as the DS4P are too granular and unproven to be adopted in a single step in Stage 3.
* Suggested that what is needed is a series of interim steps from the current state to the ideal state. Confidentiality flags should be tracked at a clinical document level first and then over time as DS4P evolves, additional use cases to track confidentiality flags at more granular levels within the document can be addressed.
 |
| 57 | [HHS-OS-2012-0007-0145](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0145) | p.43, p.56 | Nancy  Payne | Allina Health | * Commented that patient consent will need to be an integral part of the infrastructure for information exchange either via HIE or EHR to EHR. Notes that consent must be incorporated into initial consent for treatment, and treated as a baseline hurdle before any exchange occurs. This will require vendor development work.
* Stated that while the work of the DSPI group is laudable, the fundamental 'miss' in their work is in a key process step in most of the use case work flows they created - the issue of what data is tagged as requiring consent for release/disclosure – without 'rules' that are consistent for this step, everything else can't happen - the additional requirements for consent registries and repositories are also extremely challenging, requiring major development of EHR systems and/or new, linked systems to perform that work.
 |
| 58 | [HHS-OS-2012-0007-0333](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0333) | P.44 | Koryn  Rubin | American Association of Neurological Surgeons and Congress of Neurological Surgeons | * No Comment.
 |
| 59 | [HHS-OS-2012-0007-0280](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0280) | p.5 | Paula  Theriault | Eastern Maine Health Care Systems | * Stated that current laws do create risks to patients within our system due to restrictions for 42 CFR part 2 and Maine Law.

This is a social and political issue.* Stated that at a minimum, there should be mechanisms for sharing medication information.
 |
| 60 | [HHS-OS-2012-0007-0295](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0295) | p.5 | Susan  Owens | Memorial Healthcare System | * Commented that this is a complex issue that requires legal consideration.
 |
| 61 | [HHS-OS-2012-0007-0345](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0345) | p.5 | Steven B.  Kelmar | Aetna | * Believed that EHRs should be able to record and manage patient consent, limit the disclosure of sensitive information to specified providers and organizations, and communicate the limitations on use and restrictions on re-disclosure to receiving providers.
* Believed that the need for strong privacy protections must be balanced with the need for simple, straightforward electronic processes that are easy for patients and providers to understand.
* Suggested that electronic consent processes should clearly identify how and when information can be shared, and consent standards should be readily consumable by receiving systems.
* Suggested that the Voluntary Universal Healthcare Identifier (VUHID) is one possible solution to not only operationalize the meaningful use standards, but also ensure the proper and appropriate identification of patients.
 |
| 62 | [HHS-OS-2012-0007-0346](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0346) | p.5 | American Academy of Dermatology Association |   | * No comment.
 |
| 63 | [HHS-OS-2012-0007-0566](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0566) | p.5 | Lena  O'Rourke | Futures Without Violence | * Commented that as sensitive health information changes hands, patients may lose control over who has access, when, and for what purposes. While electronic health records and health information technology clearly offers a unique and critical opportunity for responding to domestic violence, the widespread use, disclosure and sharing of health information can put victims at risk.
* Commented that efforts to improve the health care system's response to victims of domestic violence need to address the unique safety and privacy needs of victims of domestic violence.
* Stated that advocates, state and federal policy makers, administrators, providers, and survivors must work together to protect patient privacy while still promoting domestic violence identification, documentation and Coordinated response.
 |
| 64 | [HHS-OS-2012-0007-0311](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0311) | p.6 | Bruce  Wacker | Adventist Health System | * Suggested that a mechanism to confirm patient acceptance of the referral be developed and that the measure not be tied to patient participation in the program to which they were referred.
 |
| 65 | [HHS-OS-2012-0007-0476](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0476) | p.6 | Anna Roberts | CHITREC (Chicago Health IT Regional Extension Center) | * Commented that EHRs and HIEs could better manage information that requires consent if fields for Specially Protected Health Information (SPHI) were standardized. This should be a part of the certification criteria.
	+ EHRs could then track consent and block SPHI elements from being shared without permission.
	+ Having a standardized list of SPHI would put the work on the vendor rather than on the provider, and will allow for straightforward sharing/blocking that can be tracked.
* Suggested that an additional piece of managing this data could come from patients themselves through the patient portal.
	+ The portal could give patients the ability to view exchanges of their information (like an audit trail), receive notifications of information pending release via the HIE, and allow them to approve/disapprove release of that information.
	+ A potential downside to this is that patients may not know the ramifications of having certain pieces of information shared.
 |
| 66 | [HHS-OS-2012-0007-0251](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0251) | p.6 | Michael  Moran | Breaking Free, Inc | * Suggested HHS must address the issue of using tagging to determine what constitutes specially-protected health information and uniformly defining data elements and consent procedures.
* Noted that attention must be given to developing technologies and methodologies that provide direct patient control of data sharing preferences.
* Suggested that Preservation of Patient Trust is a top priority. Consideration should be given to the creation of a uniform national rule.
* Suggested making development of EHR infrastructure that has the capacity to manage patient consent a primary focus of data segmentation efforts.
* Commented that providers should have access to treatment information about their patients in order to facilitate their care, including reducing risks associated with conflicting prescriptions and providing the ability to share toxicology results.
* Commented that providers will consider information disclosed as part of the provider’s “designated record set” as defined by HIPAA and thus no longer concerned about re-disclosure risk.
* Commented that the regulations promulgated at 42 CFR Part 2 do not contemplate the electronic exchange of health information, thus creating a “digital divide” that grants physical medicine patient populations greater rights and treatment opportunities than those rights afforded the behavioral health care population.
* Suggested consideration creation of a “safe harbor” for uniform privacy compliance.
* Supported the development of national standards for behavioral health elements to facilitate data quality and specificity.
 |
| 67 | [HHS-OS-2012-0007-0459](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0459) | p.6 | Phillip Eaton | Rosecrance | * Same comments as in #66.
 |
| 68 | [HHS-OS-2012-0007-0277](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0277) | p.6 | Marvin  Lindsey | Community Behavioral Healthcare Association of Illinois | * Same comments as in #66.
 |
| 69 | [HHS-OS-2012-0007-0523](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0523) | p.6 | Timothy Sheehan | Lutheran Social Services of Illinois/Community Behavioral Healthcare Association of Illinois | * Same comments as in #66.
 |
| 70 | [HHS-OS-2012-0007-0494](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0494) | p.6 | Kate Mahoney | PEER Services | * Same comments as in #66.
 |
| 71 | [HHS-OS-2012-0007-0515](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0515) | p.6, 7 | Sara Howe | Illinois Alcoholism and Drug Dependence Association | * Same comments as in #66.
 |
| 72 | [HHS-OS-2012-0007-0482](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0482) | p.7 | Robert Morrison | National Association of State Alcohol and Drug Abuse Directors | * Recommended that certification criteria for EHRs be enhanced so that any EHR can tag data as being covered by 42 CFR Part 2 and restrict sharing that information based on patient authorization.
* Suggested that the work of the Data Segmentation for Privacy Workgroup is a good start and can allow for sharing of sensitive information.
* Commented that perhaps the information could be provided as a document with the appropriate Non-Redisclosure Notice affixed to it that would allow 42 CFR Part 2 information to be shared.
* Commented that EHRs as part of their certification criteria must have the capability to receive these documents, tag or flag them in their systems and have the capability to restrict redisclosure if it is not to an authorized provider.
 |
| 73 | [HHS-OS-2012-0007-0452](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0452) | p.7 | Mark Fluery | American Association for Cancer Research | * Commented that not only will recording differential consent for different subsets of data within an EHR be important, but it will also be important to have the capability to modify consent over time, since increasingly patients are given the option to withdraw or modify original consent agreements later. This is especially relevant for genomic sequence data.
 |
| 74 | [HHS-OS-2012-0007-0296](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0296) | p.7 | Harrison  White | Gateway Foundation | * Same comments as in #66.
 |
| 75 | [HHS-OS-2012-0007-0304](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0304) | p.7 | Harriet  Sadauskas | Association House of Chicago | * Same comments as in #66.
 |
| 76 | [HHS-OS-2012-0007-0474](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0474) | p.7 | Brusce Jefferson | The Thresholds | * Same comments as in #66.
 |
| 77 | [HHS-OS-2012-0007-0498](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0498) | p.8 | Michael Morris | Software and Technology Vendors Association (SATVA) | * Recommended adoption of a CDA being self-contained and includes in machine and human readable format all the information required for a recipient to legally administer the disclosure, that information would be available for any CCDA maintained in an HIE’s document repository.
	+ Limiting disclosures to specified list of providers.
	+ Enhancing the current functionality of BH EHRs to only create disclosures based upon consent has been demonstrated in the SATVA interoperability demonstration for more than a year.
* Stated that SATVA has addressed in depth the ability to communicate limitations on use and re-disclosure to recipient providers.
	+ A recipient’s right to use the disclosed information does not expire upon the expiration or revocation of the consent. The only possible right that would expire or could be revoked would be the right for re-disclosure of ultra-sensitive information – which they would not have in any case if SATVA’s proposal was adopted.
	+ If the recipient was fully aware of their rights for rediscovery of disclosed information, and especially if there was MU Stage 3 functionality designed to support reconciliation of information rediscovered form the patient as discussed above, the need to sequester data in the recipient EHR would be dramatically reduced.
* Stated that if the SATVA recommendation of providers that maintained a mix of “HIPAA Only” and ultra-sensitive information sending self-sequestered disclosures was adopted, the recipient provider could reconcile only the “HIPAA Only” disclosure and sequester the other(s).
* Believed that “on ramp” interoperability for 42 CFR Part 2 compliant disclosures, and for most disclosures to which state privacy laws apply, can be performed today using a specific implementation of the DS4P IG so long as every received disclosure was exposed to a human to determine the limitations on reconciliation. The same approach provides the on ramp capabilities such that EHR vendors can utilize the machine readable code to make all operations “hands free”. The additional suggestions included in this document for MU Stage 3 would clearly provide for “hand free” ultra-sensitive interoperability in a Direct environment.
 |
| 78 | [HHS-OS-2012-0007-0312](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0312) | p.9 | Blair  Childs | Premier healthcare alliance | * Stated that variation of privacy laws across states is a barrier to effective health information exchange.

Encourages the federal government to work to address this variation to enable better health information exchange across state lines. |
| 79 | [HHS-OS-2012-0007-0301](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0301) | p.9 | Paul Kleeberg | REC | * No comment.
 |
| 80 | [HHS-OS-2012-0007-0538](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0538) | p.9-13 | Renee  Popovits | Substance Abuse Workgroup, Illinois Health Information Exchange Legal Task Force | * Same comments as in #66.
 |
| 81 | [HHS-OS-2012-0007-0553](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0553) | p.9-16 | Renee  Popovits | Popovits & Robinson | * Commented that one issue that will need to be addressed is the use of codes to determine what constitutes specially-protected health information. The SAMHSA/Veteran’s Administration Pilot is currently approaching this issue by segmenting items element by element and applying tags required by program policy.
* Commented that there should also be sufficient flexibility embedded in the technology that allows for future technological advances and variations in systems.
* Suggested that the ONC’s Data Segmentation Implementation Guidance provides an excellent framework for addressing the technological methodology for managing information and the consent process.
* See also comments in #66.
 |
| 82 | [HHS-OS-2012-0007-0520](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0520) | PDF2 - p.76 | Andy Riedel | NextGen Healthcare | * Same comments in # 29.
 |
| 83 | [HHS-OS-2012-0007-0547](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0547) | tab 2 | Erin  Laney | Intermountain Healthcare | * Same comments as #9.
 |
| 84 | [HHS-OS-2012-0007-0535](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0535) | tab 2 | Dan  Rode | American Health Information Management Association | * Suggested standardizing these types of regulations to be consistent across the states so EHR Vendors can successfully build these standards.
* Recommended ONC works with the states to see if conformity can be agreed upon.
* Recommended ONC work with the states to establish consistency and that the states work with each other.
* Commented that the AHIMA finds the DS4P pilot very interesting and we think it should be published in Stage 3 recommend that ONC publish the results for the pilot and any proposal for Stage 3.
 |
| 85 | [HHS-OS-2012-0007-0579](http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0007-0579) | x | Doreen  Espinoza | UHIN | * Unable to locate relevant comments at the link provided.
 |

**Summary**

**Number of Comments:** 74 (11 commenters did not provide a response or link was invalid)

**Summary:**

**A. How can EHRs and HIEs manage information that requires patient consent to disclose so that populations receiving care covered by these laws are not excluded from health information exchange?**

* Many comments indicated support for a metadata tagging approach to enable this type of consent management. (6)
* Several comments indicated that data segmentation capabilities that would allow managing consent of sensitive health information currently exist and have been demonstrated:
* Data Segmentation for Privacy Initiative
* VA/SAMHSA
* SATVA

However, other commentators stressed that segmentation capabilities required to enable this type of consent management are not existent in the vendor market currently. (3)

* One commentator who felt this was not feasible stated it was better to focus on identifying and punishing inappropriate use of data.
* Another commented that an easier way to accomplish this is to give patients control of their data via PHR.

# B. How can MU help improve the capacity of EHR infrastructure to record consent, limit the disclosure of this information to those providers and organizations specified on a consent form, manage consent expiration and consent revocation, and communicate the limitations on use and restrictions on re-disclosure to receiving providers?

A number of comments supported the idea of creating or promoting standards to improve the capacity of EHR infrastructure to accomplish this and to which EHRs can build. (4)

Also, a number of comments specifically supported creating standardized fields for specially protected health information. (10)

Several comments recommended that all certified EHRs be able to manage patient consent and control re-disclosure. (2)

Several comments recommended that a system also be able to do the following:

* Modify consent over time. (4)
* Sequester by encounter/admission.
* Allow for various levels of credentialing.
* Confirm patient acceptance of a referral.
* Use a patient portal to enable patient to track and approve/disapprove release of information.
* Apply privacy preferences at time of disclosure.

# C. Are there existing standards, such as those identified by the Data Segmentation for Privacy Initiative Implementation Guide, that are mature enough to facilitate the exchange of this type of consent information in today’s EHRs and HIEs?

Many comments pointed to segmentation-related initiatives that they considered promising:

* S&I Framework’s Data Segmentation for Privacy Initiative (DS4P WG). (4)
* HL7 confidentiality and sensitivity code sets for semantically tagging for privacy protection. (3)
* SAMHSA/VA pilot is segmenting items and applying tags.
* eHI developed the “eHealth Initiative Blueprint: Building Consensus for Common Action.”
* work already being done by some states and some HIEs. (2)
* Voluntary Universal Healthcare Identifier (possible solution to operationalize MU standards and ensure patient ID).

Regarding comments related to the Data Segmentation for Privacy pilot as a model, many noted that the pilot is a good start and provides a good framework (6), while several felt the pilot is too granular and not proven (2) or should address rules re: what data is tagged.

**Other comments:**

Addressing Legal Challenges:

Many commentators noted the challenge of navigating conflicting state and federal laws, and a number of these recommended or supported attempts to harmonize state and federal laws to better enable exchange of information. (7)

* Related recommendations included creating a “safe harbor” to trump state laws (8) and creating a uniform national rule on patient trust. (6)

Additionally, some specifically recommended modifying 42 CFR Part 2, including modifications to permit limited disclosures or to prohibit discrimination based on the use of that type of information. (4)

Patient Trust:

A number of comments noted that patient trust is top priority (8) and several commented on the importance of protecting sensitive information in order not to discourage treatment.

Education:

Several comments noted that any solution will likely be complex and there is a definite need for patient education, including educating patients on consent. (4)

Next Steps:

Several comments recommended an iterative approach. (2)

A number of comments recommended working with various stakeholders, including states, enforcement bodies, OCR, CDC, local agencies, patients, patient advocates, providers, vendors.

*Additional issues noted in the comments:*

* Issues related to minors should be considered.
* Need capacity building for primary care EHRs to handle this.
* Need to look at authorized representatives.
* Need to consider psychotherapy notes.

Some comments noted dangers associated with segmentation.

* Liability.
* Can’t share information re: acute suicide risk.
* Need all information in the exchange to ensure quality of care.

**Appendix:**

*How can EHRs and HIEs manage information that requires patient consent.*

Many comments indicated support for a metadata tagging approach to enable this type of consent management. (5, 7, 11, 17, 19, 25).

Several comments indicated that data segmentation capabilities that would allow managing consent of sensitive health information currently exist and have been demonstrated:

* DS4P (77)
* VA/SAMHSA (81)
* SATVA (77)

However, other commentators stressed that segmentation capabilities required to enable this type of consent management are not existent in the vendor market currently. (41, 49, 50)

* One commentator who felt this was not feasible stated it was better to focus on identifying and punishing inappropriate use of data (34) and another commented that an easier way to accomplish this is to give patients control of their data via PHR (38)

*How can MU help improve the capacity of EHR infrastructure to record consent.*

A number of comments supported the idea of creating or promoting standards to improve the capacity of EHR infrastructure to accomplish this and to which EHRs can build (4, 41, 44, 45)

Also, a number of comments specifically supported creating standardized fields for specially protected health information (5, 65, 66 – 71, 80, 81)

Several comments recommended that all certified EHRs be able to manage patient consent and control re-disclosure (49, 72)

Several comments recommended that a system also be able to do the following:

* Modify consent over time (73 - 76)
* Sequester by encounter/admission (4)
* Allow for various levels of credentialing (47)
* Confirm patient acceptance of a referral (64)
* Use a patient portal to enable patient to track and approve/disapprove release of information (65)
* Apply privacy preferences at time of disclosure (5)

 *Are there existing standards?*

Many comments pointed to segmentation-related initiatives that they considered promising:

* S&I Framework’s Data Segmentation for Privacy (DS4P WG) (5, 17, 45, 56)
* HL7 confidentiality and sensitivity code sets for semantically tagging for privacy protection (5, 7, 17)
* SAMHSA/VA pilot is segmenting items and applying tags (81)
* eHI developed the “eHealth Initiative Blueprint: Building Consensus for Common Action” (12)
* work already being done by some states and some HIEs (14, 30)
* Voluntary Universal Healthcare Identifier (possible solution to operationalize MU standards and ensure patient ID) (61)

Regarding comments related to the Data Segmentation for Privacy pilot as a model, many noted that the pilot is a good start and provides a good framework (4, 21, 22, 42, 72, 81), while several felt the pilot is too granular and not proven (29, 82) or should address rules re: what data is tagged (57).

*Addressing Legal Challenges:*

Many commentators noted the challenge of navigating conflicting state and federal laws, and a number of these recommended or supported attempts to harmonize state and federal laws to better enable exchange of information. (9, 24, 27,45, 53, 78, 83)

* Related recommendations included creating a “safe harbor” to trump state laws (11, 66 – 71, 80) and creating a uniform national rule on patient trust (66 – 71, 80)

Additionally, some specifically recommended modifying 42 CFR Part 2, including modifications to permit limited disclosures or to prohibit discrimination based on the use of that type of information. (2, 11, 21, 22)

*Patient Trust:*

A number of comments noted that patient trust is top priority (11, 66 – 71, 80) and several commented on the importance of protecting sensitive information in order not to discourage treatment

*Education:*

Several comments noted that any solution will likely be complex and there is a definite need for patient education, including educating patients on consent. (7, 11, 45, 46)

*Next Steps:*

Several comments recommended an iterative approach (5, 56)

A number of comments recommended working with various stakeholders, including states, enforcement bodies, OCR, CDC, local agencies, patients, patient advocates, providers, vendors

*Additional issues noted in the comments:*

* Issues related to minors should be considered (10)
* Need capacity building for primary care EHRs to handle this (16)
* Need to look at authorized representatives (20)
* Need to consider psychotherapy notes (30)

Some comments noted dangers associated with segmentation

* Liability (38)
* Can’t share information re: acute suicide risk (49)
* Need all information in the exchange to ensure quality of care (52)