Netsmart

January 31, 2023

U.S. Department of Health and Human Services
Office of the Secretary
Office for Civil Rights (OCR)
Substance Abuse and Mental Health Services Administration (SAMHSA)
Attention: Lester Coffer, OCR

RE: **Confidentiality of Substance Use Disorder (SUD) Patient Records Notice of Proposed Rulemaking (NPRM), Docket No. HHS-OCR-2022-0018**

Dear Secretary Becerra and Assistant Secretary Delphin-Rittmon,

Netsmart appreciates the opportunity to comment on the proposed modifications to 42 CFR Part 2 outlined in the NPRM. As a leading supplier of clinical and management information systems to behavioral health and substance use treatment providers nationwide, we believe our experience provides us with a pragmatic, on-the-ground perspective of this area of regulation, and we are grateful for the ability to share that insight.

Netsmart is highly supportive of aligning 42 CFR Part 2 requirements with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of treatment, payment, and health care operations as outlined in Sec. 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act. As written, subsection (b)(1)(B) now permits a covered entity, business associate, or Part 2 program to use or disclose the Part 2 records for TPO, following written consent. Any information so disclosed may then be redisclosed in accordance with the HIPAA regulations. We believe this NPRM is a step in the right direction related to implementation of the statute.

We have provided comments below on several sections of the NPRM. In this introduction, I call your attention to an important area of focus to assuring fully informed diagnosis and treatment and reducing patient risk and unintended medical errors for persons with a substance use disorder (SUD) or with a history of SUD treatment.

More than 10 years ago, SAMHSA issued grants to five states to test the viability for SUD patient data to be transmitted and utilized by providers in Health Information Exchanges (HIEs). The grant requirements related to data segmentation, purging, accounting for disclosures and other areas would have necessitated massive re-designs of the HIEs, which typically operate with more limited financial, operational and customer services capabilities

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than mental health and substance use treatment facilities or hospitals. In the end, all the states dropped out of the pilot because they did not have resources to do the necessary upgrades.

This resulted in a two-tier, inequitable healthcare delivery system that discriminated against persons with SUD issues even if they wanted to share their data. It was far easier for HIEs to simply deny access to patients with SUD data subject to Part 2 protection than to rebuild their systems and hire customer support personnel for this population, and in the end most HIEs and non-Part 2 providers did just that - they stopped accepting data that was subject to 42CFR protections. The inequity: Persons with diabetes and other acute care illnesses and medical conditions could receive fully coordinated care using a HIE to share their data, but persons with a SUD diagnosis were left outside looking in on the benefits of this integrated care model.

We made strides in the ensuing decade to more closely align Part 2 with HIPAA and rectify this inequity and stigma, while also retaining patient privacy and anti-discrimination protections. However, I am concerned that some of the requirements in the NPRM will set us back a decade or more. Classifying HIEs as an intermediary, with the associated accounting for disclosure requirements, will likely cause them to deny access to people with a SUD diagnosis because of concerns about potentially violating the Part 2 statute which now have stronger legal ramifications if violated than they did 10 years ago.

In today's networked world, a majority of the communications between providers and HIEs and within HIEs are computer-to- computer – automatic. For example, with Carequality, one of the nation's largest and most widely adopted interoperability frameworks, a provider can enter a zip code for a patient that has given consent, and the system will query all EHRs on the framework for information on that patient before they appear for an appointment and, assuming the patient has given consent at the queried provider, the data will be automatically shared. For example, if I were in Los Angeles, the transaction may look like this:

- LA County Substance Use Prevention and Control (SAPC) queries the local HIE (HIE 1)
- That query is passed on to Commonwell (HIE 2)
- Commonwell queries the Carequality network (HIE 3)
- Carequality queries the Statewide Health Information Network for New York (SHI-NY) (HIE 4) to get my local health records

One provider initiated this entire transaction, with patient consent, releasing data to another provider to enable integrated care. The initiating provider was not likely aware of how the data transits the network, just like most people do not know the route of an internet data packet or how a cell phone call is routed from carrier to carrier. In the case of HIEs, they are all subject to HIPAA, Business Associate Agreements (BAAs) and other healthcare security requirements -- but 42 CFR Part 2 is not one of them.

In a centralized HIE model, a provider sends patient data from its EHR to the HIE, which in turn provides authorized access to that data to the patient's other treating providers if the patient has consented. At that point, the data is now stored in multiple EMRs. HIEs cannot track when the data is redisclosed in order to provide an accounting back to the patient. In a federated model comprised of provider EHRs, HIEs, and national frameworks, the ability to track and audit Part 2 records differently than other health records would be a significant, if not insurmountable challenge. The system works under the assumption that the originating provider and receiving provider have consent or TPO relationships and are working in a HIPAA environment.

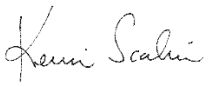
Under the NPRM, each of these networks would have to provide an accounting, but none of them have patient-facing customer service departments. If they were to return data, it would be volumes of very technical IP addresses that would be useless to the average consumer.

In fact, auditing Part 2 data differently than non-Part 2 data would significantly hinder this goal described in the NPRM: *"The expanded ability to use and disclose Part 2 records would facilitate greater integration of SUD treatment information with other PHI. The Department believes this change would improve communication and care coordination between providers and with other elements of the health care system, such as the ability of payers to share SUD treatment claims information with alternative payment model providers for population health management and enhance the ability to comprehensively diagnose and treat the whole patient."*. In fact, I believe it would stop the sharing of data for consumers with SUD issues that we have worked for 10 years to enable.

It would also be counterproductive to ONC's initiative to advance a nationwide data sharing network. And, most significantly, it would continue to prevent fully informed diagnosis and treatment of persons with a SUD or history of SUD treatment.

Netsmart hopes you take both this historical context, current-day considerations, and our comments below into account as you develop the Final Rule. We express our support and appreciation for the hard work and dedication of you and your staff behind the preparation and creation of the NPRM. Please do not hesitate to contact me at (516) 241-2575 if I can provide any additional information or clarification to our comments.

Sincerely,



Kevin Scalia
Executive Vice President
Netsmart

§ 2.16—Security for Records & Notification of Breaches

Summary of Proposed Language:

The NPRM applies the HITECH Act breach notification provisions that are currently implemented in the Breach Notification Rule to breaches of records by Part 2 programs and retitles the provision to include breach notification to implement CARES Act provisions.

The NPRM also clarifies that formal policies and procedures designed to reasonably protect against unauthorized uses and disclosures of patient identifying information must address all issues regarding paper and electronic records listed in this part. In addition, the NPRM applies the provisions of 45 CFR part 160 and subpart D of part 164, which require notification in the case of a breach of unsecured protected health information, in the same manner as the provisions apply to covered entities regarding breaches of unsecured protected health information.

For both paper and electronic records, the NPRM specifies that de-identified patient identifying information must be rendered in accordance with the requirements of HIPAA at 45 CFR 164.514(b), "such that there is no reasonable basis to believe that the information can be used to identify a particular patient as having or having had a substance use disorder."

PUBLIC COMMENT:

Netsmart recommends the Department create a regulatory definition of "lawful holder" and use that mechanism to further expand exceptions for the re-disclosure of Part 2 records. We recommend HHS, OCR & SAMHSA align the definition of "lawful holder" to the suggestions put forth by the Partnership to Amend 42 CFR Part 2.

In particular, the definition of "lawful holder" should provide for a safe harbor from the imposition of civil or criminal monetary penalties under the Breach Notification Rule for the unintentional redisclosure of Part 2 records by lawful holders that would have otherwise been a compliant disclosure of PHI under HIPAA TPO.

We recommend that HHS, OCR & SAMHSA align the breach notification requirements for Part 2 programs with the requirements in the HIPAA Breach Notification Rule at 45 CFR §§ 164.400-414.

Additionally, we recommend complete alignment with the HIPAA de-identification standard, as applicable at 45 CFR § 164.514 (b). Due to the technology implications of having Part 2 data subject to the HIPAA breach notification rule, we recommend an extended timeframe for compliance with the breach notification rule. Part 2 programs have not previously been required to comply, and the implementation of net new policies and procedures is a time-consuming and extensive process.

§ 2.19—Disposition of Records by Discontinued Programs
Summary of Proposed Language: The NPRM adds an exception to clarify that when a part 2 program discontinues operations or is taken over or acquired by another program, it must remove patient identifying information from its records by either destroying its records or sanitizing them such that patient identifying information is non-retrievable, unless: 1) The patient gives written consent to a transfer of the records, 2) There is a legal requirement that the records be kept for a period specified by law, or 3) A newly proposed program is transferred, retroceded, or reassumed pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA) and its implementing regulations. Updates the language of the regulation to specify that all records in "non-electronic (e.g., paper) form" must be sealed and labeled in envelopes.
PUBLIC COMMENT: Netsmart supports the updates to this section and emphasizes the importance of maintaining patient confidentiality and privacy. Many operators of Part 2 programs are diverse service providers that utilize a single EHR across both Part 2 and non-Part 2 programs. Purging data from only Part 2 programs, or any other individual program, is currently technologically challenging. Current systems do not support this requirement, and there is no way to eliminate data from one program for a particular patient or subset of patients. This requirement would require EHRs to be redesigned. Netsmart recommends alignment with the HIPAA privacy & security rules. The HIPAA Security Rule requires that covered entities implement policies and procedures to address the final disposition of electronic PHI and/or the hardware or electronic media on which it is stored, as well as to implement procedures for removal of electronic PHI from electronic media before the media are made available for re-use. See 45 CFR 164.310(d)(2)(i) and (ii).

§ 2.24—Requirements for intermediaries (Redesignated and proposed heading).
Summary of Proposed Language: Moves and redesignates current section § 2.13(d)) and retitles this section as "Requirements for intermediaries" to clarify the responsibilities of recipients of records received under a consent with a general designation, such as health information exchanges, research institutions, accountable care organizations, and care management organizations.

Intermediaries, upon request, must provide to patients who have consented to the disclosure of their records a list of persons to which the records have been disclosed. The section also prescribes the form of the patient request and the intermediary's response.

PUBLIC COMMENT:

The current regulation ensures that a patient has the right to receive a list of Part 2 disclosures from an intermediary. However, the scope of disclosures from an intermediary will likely be much broader with the proposed rule, given that a single consent for TPO would be implemented, and therefore, there will be a long list of entities that will need to be disclosed. Even sophisticated intermediaries such as HIEs find the accounting of disclosures incredibly burdensome, and patients need more information. With the expanded TPO flexibility, the accounting of disclosures could become overwhelming and inevitably hinder care coordination.

Further, as noted in our cover letter, placing these requirements on HIEs will likely make HIEs unwilling to participate in the exchange of Part 2 data altogether. We note that today, the HIPAA accounting of disclosures requirement provides an exception for disclosures related to TPO, among other items. However, we recognize there are proposed updates to the accounting of disclosures requirement within the HITECH Act forthcoming. We recommend alignment regarding treatment of Part 2 and non-Part 2 data. We advise that due to the potential refusal by HIEs to deal in Part 2 data that intermediaries should be carved out from the accounting of disclosures requirement. If included, we recommend HHS, OCR & SAMHSA provide robust guidance related to an intermediary's duties regarding the accounting of disclosure requirement. Further, we recommend that they be responsible for accounting for the first disclosure of data only (i.e., their own transmissions of data, not subsequent disclosures or redisclosures by other entities).

§ 2.25—Accounting of disclosures (proposed heading)

Summary of Proposed Language:

A newly proposed section. A Part 2 program must provide to a patient, upon request, an accounting of all disclosures made with consent under § 2.31 in the six years prior to the date of the request. This section also states that a Part 2 program must provide a patient with an accounting of disclosures of records for treatment, payment, and health care operations only where such disclosures are made through an electronic health record, and that a patient only has a right to receive an accounting of these disclosures during the three years prior to the date on which the accounting is requested. This proposed right to an accounting of disclosures of records mirrors the standard in the Privacy Rule at 45 CFR 164.528.

PUBLIC COMMENT:

Netsmart recognizes the value of providing an accounting for both TPO disclosures and non-TPO disclosures. Netsmart notes that except for disclosures made by intermediaries, the existing Part 2

regulation does not include a right for a patient to obtain an accounting of disclosures of Part 2 records. HHS, OCR & SAMHSA have preemptively included updates not yet proposed or finalized with respect to the accounting of disclosures requirement in the HITECH Act. The first paragraph of the section, (a), would generally require an accounting of disclosures made with patient consent, and the second paragraph, (b), would limit the requirement with respect to disclosures made with consent for TPO purposes, which would only be required for TPO disclosures made from an electronic health record system. We ask HHS, OCR SAMHSA consider the significant cost & time associated with updating the accounting of disclosures requirement to apply to Part 2 programs, and provision due time to implement the proposed updates. We agree that the proposed changes to the accounting of disclosures requirement should align with future changes proposed for non-Part 2 data.

We ask HHS, OCR & SAMHSA provide clear guidance pertaining to the expectations related to providing data within the lookback period. Would the accounting have a retrospective application or a go-forward application…meaning would Part 2 programs only be required to provide an accounting from the date the proposed regulation becomes final? If adopted, Netsmart recommends no retrospective application of the accounting of disclosures requirement for Part 2 programs.

§ 2.31—Consent Requirements

Summary of Proposed Language:

The required elements of the written authorization forms for Part 2 records have been modified to more closely track the core elements of a written authorization form under HIPAA, at 45 CFR 164.508(c). Several of the proposed changes to the language do not substantively change the requirements, but merely align the wording of similar requirements under HIPAA (e.g., changes related to identity of the discloser, description of information to be disclosed, the right to revoke consent, and the expiration of consent).

For example, the wording is modified to clarify the limits on a patient's ability to "pull back" Part 2 information from a covered entity, business associate, or Part 2 program once it is disclosed, in alignment with the Privacy Rule. Thus, once a Part 2 program discloses a record for TPO purposes to a Part 2 program, covered entity, or business associate with prior written consent, a revocation would only be effective to prevent additional disclosures to those entities. It would not prevent a recipient Part 2 program, covered entity, or business associate from using the previously disclosed record for TPO, or redisclosing the record in the same manner as permitted by the Privacy Rule.

More substantive updates, which align with updates proposed elsewhere in the Part 2 rules, include that the written authorization contain the following:

- Where applicable, language indicating a single patient consent is meant to apply for all future uses and disclosures for TPO;
- Where the disclosure is for TPO – a statement that the patient's record may be redisclosed in accordance with HIPAA, except for uses and disclosure for civil, criminal, administrative, and legislative proceedings against the patient;
- A description of purpose statements sufficient for relaying (i) when a patient initiates the consent and elects not to provide a statement of purpose, (ii) when a patient provides consent once for all TPO uses and disclosures; and (iii) when the patient consents to uses or disclosures for fundraising.
- Statements around (i) the potential for the records to be redisclosed and no longer protected by Part 2, and (ii) the consequences of refusal to sign the consent.

Where "disclosure" is referenced, the language is updated to refer to "use and disclosure" to align with HIPAA and clarify that disclosures and uses are subject to the rules.

The proposed rule also includes wording changes for defined terms and phrases of art, which were updated for alignment with HIPAA. The proposed rule:

- replaces the term "individuals" with the term "persons";
- replaces the phrase "individual or entity" with the term "person" (which by definition would include both individuals and entities);
- where disclosure is referenced, also refers to "uses" to clarify that disclosures and uses are subject to the rules.

PUBLIC COMMENT:

The new flexibility to share TPO with consent is a step in the right direction. However, the continued need for providers to segment Part 2 records is inconsistent with HIPAA and will likely continue to have a chilling effect on the ability and willingness of providers to treat persons who have an SUD disorder or history of SUD treatment. We urge that SAMHSA specify in the Final Rule that there is no requirement for data segmentation or segregation after written consent is obtained and Part 2 records are transmitted to a health information exchange or other care management entity that is a business associate of a covered entity covered by the CARES Act consent language.

Further, we recommend when a patient revokes a consent, that revoked consent should prevent continued sharing of their data. It should NOT require Covered Entities, Business Associates & Intermediaries that already have authorized access of the Part 2 data to have to remove that data from their system. With a revoked consent, no new data should be shared. With regards to oral consent, the Cares Act (Sec. 3221) specifies written consent only: ''It shall be permissible for a patient's prior written consent to be given once for all such future uses or disclosures for purposes of treatment, payment, and health care operations, until such time as the patient revokes such consent in writing." We are unaware of Part 2 programs that accept or rely on oral consent, and

we do not recommend oral consent as a standard. Electronic signature or attestation should be supported to capture and maintain consent. EHR and HIE solutions share data systematically and can account for electronic consent provisions, especially in an ever-growing virtual care delivery model.

To be consistent with other proposed changes, we also recommend that intermediaries be included in the list of entities where revocation of consent only affects additional disclosures. The sentence would be modified to read: "Thus, once a Part 2 program discloses a record for TPO purposes to a Part 2 program, Covered Entity, Business Associate or Intermediary with prior written consent, a revocation would only be effective to prevent additional disclosures to those entities."

We encourage HHS, OCR, and SAMHSA to offer subsequent guidance on the best way to flag a revocation within electronic health records and highlight technological advancements that can help make this more seamless.

§ 2.33—Uses and Disclosures Permitted With Written Consent (Proposed Heading)

Summary of Proposed Language:

Currently Section 2.33 allows disclosure with the written consent of the patient, and if the patient consents to disclosure of their records for payment or health care operations, allows a lawful holder to further disclose those records as necessary for its contractors, subcontractors, or legal representatives to carry out the payment or operations specified in the consent, on behalf of the lawful holders. It includes a list of examples of permissible payment or operations activities. All such redisclosures must be pursuant to a written contract binding the contractor, subcontractor, or representative to Part 2. The proposed rule identifies how a recipient may further disclose records related to treatment, payment, and health care operations (TPO).

Specifically, the Department proposes to create two categories of redisclosure permissions. The first category would apply to Part 2 programs, covered entities, and business associates that have received a Part 2 record with consent for TPO. These entities would be permitted to redisclose the records for uses and disclosures as permitted by the Privacy Rule (subject to the limitations of proposed subpart E of Part 2 pertaining to legal proceedings). Thus:

- 1 - Where disclosed for TPO activities to a program, covered entity, or business associate, the recipient may further use or disclose of the records as permitted under HIPAA.

The second category of redisclosure permissions would apply to lawful holders that are NOT business associates, covered entities, or Part 2 programs and have received Part 2 records with written consent. For payment and health care operations purposes, this category would permit the

recipient to redisclose the records for uses and disclosures to its contractors, subcontractors, and legal representatives to carry out the intended purpose, also subject to the limitations of proposed subpart E of part 2 pertaining to legal proceedings. However, for treatment purposes, a lawful holder under this provision would not be permitted to redisclose Part 2 records it receives before obtaining an additional written consent from the patient. Thus:

- 2 - Where disclosed with a consent given once for all future TPO to a Part 2 program that is NOT a covered entity or business associate, the recipient may further disclose only as consistent with the consent.
- 3 - Where disclosed for payment or operations activities to a lawful holder that is NOT a covered entity, business associate, or Part 2 program, the recipient may further use or disclose those records as necessary for its contractors, subcontractors, or legal representatives to carry out the payment or health care operations specified in the consent, on behalf of the lawful holders.

Thus, the proposed rule would prohibit redisclosure for the purposes of treatment by a provider that is not a Part 2 program, covered entity, or business associate (under 2.33(b)(3)), while allowing redisclosure for the purposes of treatment by a provider that is a Part 2 program, covered entity, or business associate (under 2.33(b)(1)).

The proposed rule would also exclude covered entities and business associates from the requirements for a written agreement between a lawful holder and redisclosure recipient, because these entities are already subject to the HIPAA requirements for business associate agreements. The proposed update removes the current list of permitted "payment or health care operations activities" for which a disclosure must be limited. These examples of "payment or health care operations" are likely eliminated to better align with the interpretation of "TPO" under HIPAA. Where "disclosure" is referenced, the language is often updated to refer to "use and disclosure" to align with HIPAA and clarify that disclosures and uses are subject to the rules.

PUBLIC COMMENT:

This answer is predicated on the final definition of a lawful holder. Under the currently proposed language, a lawful holder would not be permitted to redisclose Part 2 records it receives before obtaining an additional written consent from the patient. This scenario will pose significant challenges as once Part 2 data is received it is difficult to partition that data from the full medical record and then require specific consent to share the Part 2 data. This is especially challenging in an opt out data sharing model.

Netsmart notes there will be an inherent technology tax in requiring Part 2 providers to respond to electronic data request queries with a consent status of the patient as well on ongoing updates of consent. Alternatively, HIEs will have to partition Part 2 data and have a second set of consent rules to manage both Part 2 and non-part 2 data.

Therefore, we reiterate the final rule should support the coordination of care via the sharing of SUD data and other health care data amongst health care providers, Health Information

Exchanges, and IT developers. Putting granular consent rules around Part 2 data and additional redisclosure requirements will require both providers and HIEs to segment sensitive data and limit the use. Much more significant is the negative impact on patients. For example, this will diminish the ability of a provider to leverage technology in order to drive clinical decision support through medication reconciliation in an integrated care model.

We request that once disclosed to a HIPAA entity under a TPO consent, a covered entity or business associate may redisclose the data for any purpose permitted by HIPAA. If the recipient is neither a HIPAA-covered entity, a business associate, nor a Part 2 program, then the recipient could redisclose the information so long as the redisclosure was consistent with the terms of the consent.
We note that in a federated HIE model, the consent to share data is at the provider level, not the HIE level. This means that before a provider's EHR responds to an inbound query for Part 2 data, the responding provider should attest they have an active consent on file to share that data with the query initiator. In a centralized model, the HIE needs to ensure patient consent is up to date in order to redisclose Part 2 data to another provider requesting the information. In this case, the provider accessing the data must send a consent attestation.

We recommend that audit logging and reporting for Part 2 data mirror the requirements in HIPAA to support disclosure management. Putting additional auditing requirements on Part 2 data will provide challenges to HIEs and national frameworks such as Carequality and Commonwell. Auditing and disclosure logging should be consistent between Part 2 and non-Part 2 data and not require additional technology considerations to segment the disclosures.

§ 2.52—Scientific Research (Proposed Heading)

Summary of Proposed Language:

Section 2.52 permits Part 2 programs to disclose patient identifying information for research, without patient consent, under limited circumstances. The proposed rule changes the standard required for including Part 2 de-identified aggregate data in research reports, to mirror the HIPAA de-identification standard more closely.

Instead of requiring that the information be "rendered nonidentifiable such that the information cannot be re-identified and serve as an unauthorized means to identify a patient, directly or indirectly, as having or having had a substance use disorder", the proposed rule requires that ". . . patient identifying information has been de-identified in accordance with the requirements of the Privacy Rule at 45 CFR 164.514(b) such that there is no reasonable basis to believe that the information can be used to identify a patient as having or having had a substance use disorder."

The proposed rule also includes wording changes for defined terms and phrases of art, which were updated for alignment with HIPAA.
The proposed rule:

- replaces the term “individuals” with the term “persons”.
- replaces the phrase “individual or entity” with the term “person” (which by definition would include both individuals and entities);
- where disclosure is referenced, also refers to “uses” to clarify that disclosures and uses are subject to the rules

PUBLIC COMMENT:

Netsmart supports the disclosure of de-identified information for scientific research purposes, and the alignment with the HIPAA de-identification standard. However, the language quoted in the proposed rule “such that there is no reasonable basis to believe that the information can be used to identify a patient as having or having had a substance use disorder” is not the HIPAA de-identification standard. Netsmart recommends full alignment with the HIPAA de-identification standard as currently written.

§ 2.54—Disclosures for Public Health (Proposed Heading)

Summary of Proposed Language:

The current Part 2 regulations do not permit the disclosure of Part 2 records for public health purposes. The proposed rule adds permissible disclosure for public health purposes without patient consent, provided that the information is de-identified in accordance with the HIPAA standard for de-identification. Once the de-identified information is disclosed to the public health authority, Part 2 no longer applies to those de-identified records.

PUBLIC COMMENT:

Netsmart supports the disclosure of de-identified information for public health purposes, and the alignment with the HIPAA de-identification standard. However, as previously mentioned, the language quoted in the proposed rule “such that there is no reasonable basis to believe that the information can be used to identify a patient as having or having had a substance use disorder” is not the HIPAA de-identification standard. Netsmart recommends full alignment with the HIPAA de-identification standard as currently written.

Effective and Compliance Dates
Summary of Proposed Language: The proposed effective date of a final rule would be 60 days after publication and the compliance date would be 22 months after the effective date. Entities subject to a final rule would have until the compliance date to establish and implement policies and practices to achieve compliance.
PUBLIC COMMENT: Netsmart recommends a phased implementation timeline. The compliance timeline should correlate directly to the amount of EHR redesign required based on the Final Rule.