

21st Century Cures Act and Data Segmentation An Update—July 20, 2022

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- I have no conflicts of interest to disclose.
- I am participating in several groups which are working toward implementing the provisions of the Cures Act in clinical practice.
- I am a co-author of an AAP Policy Statement and Technical Report on Adolescent Confidentiality (in development.)

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Goals

- Review the impact of the 21st Century Cures Act on clinical pediatric practice and data management
- Understand what you ARE and ARE NOT required to do
- Recognize some potential pitfalls in handling sensitive patient data in daily practice
- Understand the need to be sure your EHR is “Cures Act Compatible”
- Develop a set of “asks” to discuss with your EHR vendor to assure compliance

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21st Century Cures Act

- Enacted 2016, compliance dates (various components) during 2021
- Wide-ranging law to support medical innovation, device and drug development and IT improvements
- **IMPACT ON PROVIDERS:** The Information Blocking Rule—meant to encourage seamless sharing of health information to streamline care, achieve savings and improve outcomes
- **OPEN NOTES:** Requires sharing of DIGITAL health information--direct impact on providers
- **Enforcement:** Office of the National Coordinator for Health IT (ONC)
- **Specific pediatrics concerns:** Adolescent confidentiality and maternal information in a newborn's chart

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Open Notes

- Open Notes is administrative; it requires sharing of clinical information, but does not specify how sharing is accomplished.
- Open Notes, and the sharing of clinical information, has been found to increase patient understanding of and participation in their care, yet adolescent confidentiality remains a concern¹
- “Clinicians must ensure that confidential information is properly protected and ensure that the adolescent’s rights are respected”²

¹Chethan Sarabu, Natalie Pageler and Fabienne Bourgeois. Pediatrics October 2018, 142 (4) e20180601; DOI: <https://doi.org/10.1542/peds.2018-0601>

²Fabienne C. Bourgeois, Catherine M. DesRoches and Sigall K. Bell. Pediatrics June 2018, 141 (6) e20172745; DOI: <https://doi.org/10.1542/peds.2017-2745>

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The ONC Information Blocking Final Rule

- Definition: Any activity by IT provider, health information system or provider which is likely to interfere with access, exchange or use of Electronic Health information (EHI)
- Implications for practice: Must share all EHI with the patient/representative, *in a form requested by them*
- Not required pre-emptively, but “promptly” upon request
- Options: Portal, disc/drive, printed
- Enforcement by ONC
- Penalties TBD at this time

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<https://www.healthit.gov/curesrule/final-rule-policy/information-blocking>

<https://www.healthit.gov/sites/default/files/cures/2020-03/InformationBlockingExceptions.pdf>

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Implications for Adolescent Care

- Transition from dependency towards independence
- Unique situation for pediatrician: Two clients for one encounter
 - Parent: Often paying for care, has responsibility for most care decisions
 - Adolescent: Encouraging independence and participation, minor-consented care
- Need to balance sometimes competing and conflicting interests of parent and adolescent patient
 - By Federal and state law, adolescent has right to consent for care in certain situations without parental involvement
- Challenge: Segmenting data when appropriate to preserve these rights

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Implications for Adolescent Care

- Some situations are clear, and all notes should be shared
 - Encounters for most medical conditions—acute/chronic illness
- Some are equally clear, and all information must be kept confidential (unless sharing permitted by adolescent)
 - Substance abuse care at federally-assisted programs (CFR42 part 2)
 - Subject to state laws, care for reproductive health issues—includes STDs
 - Generally DOES NOT include gender-affirming care
 - Mental health care
- Generally would fall under the “Privacy Exception”—specific consent

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Implications for Adolescent Care

- But many situations are not so clear-cut
- Multiple issues addressed at a single visit
 - Segmentation of EHI data into sharable and confidential silos
 - Easy in theory—automated, manual
 - If shared via portal, who has access? Adolescent (patient), parent (proxy)
 - “Curious” gaps in portal information
 - Medication history
 - Lab results in portal
 - Screenings, SDOH issues
- IT problem to solve, but provider has ultimate responsibility

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Implications for Adolescent Care

- But it gets even more complicated once data leaves your EHR (HIPAA Redux)
- Consultants
 - Do they need all EHI data?
 - Will they observe confidentiality?
 - Is their EHR able to deal with segmentation flags in received data?
 - Who is responsible in the event of a breach of confidentiality?
- Pharmacy
 - Can often deduce nature of condition from a prescription
 - Notifications from pharmacy—who gets them for different prescriptions

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Implications for Adolescent care

- Payers—The ULTIMATE practical aspect
- Medicaid—may actually be easiest to address (no EOB)
- Private insurance
 - Interests of the person buying the insurance (consumer law)
 - Confidentiality interests of the patient receiving care
 - Individual payer policies and capabilities



An EOB sent to someone without access to the medical record can trigger a demand for the record, which is protected

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Implications for THE PROVIDER OF Adolescent Care

- Interests of patient and parent are not always aligned
 - Especially fluid as an adolescent matures
 - Interests of the adolescent patient should be primary at all times
- Subject to several laws which may not appear to be consistent
 - HIPAA—protecting PHI, IT must be secure
 - Cures Act—information usually must be shared, IT must facilitate sharing
 - Consumer and business law

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Implications for THE PROVIDER OF Adolescent Care

- Some of these issues can be managed by the provider
 - Office policies are critical for Cures Act compliance
 - Data segmentation can be done manually, but at what cost?
 - This would ideally happen in the background, but rules must be developed
 - Think about every piece of data entered, and where it might end up
 - Managing patient expectations
 - EHI sharing should be a cooperative endeavor with patients and families

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Practical Issues 2022

- *State-by-State Variability in Adolescent Privacy Laws*
- Constitutional right to privacy—no longer exists (SCOTUS, Dobbs 2022)
- Back to state control and regulation
- No two states have identical regulations regarding these topics (clinicians often winging it)
- Adolescent encouraged to share confidential information
- Risks in sharing
- Open Notes—increases access and sharing of EHI, but also increases risks

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Practical Issues 2022

- Clinicians have an obligation to follow the law
- Clinicians have an equal (stronger?) ethical obligation to protect their patients and their privacy
- And sometimes that ethical obligation is legally mandated (OPMC)
- Sometimes these obligations align, but when they do not, the clinician is on shaky ground
- Further variability in adolescent ability to consent for certain types of care
- But ability to consent does not always come with protection of health information generated
- Asking an adolescent to share confidential information without necessarily being able to control where that data ends up
 - Data crossing to different jurisdictions
 - Variation among institutional policies even within the same jurisdiction

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Practical Issues 2022

- *Protecting the Privacy of Reproductive Health Information After the Fall of Roe v Wade*
- Just relating to abortion restrictions, new state regulations may clash with protection of PHI in three ways
 - Use of a patient's records—HIPAA is not complete protection
 - Facility records subject to reporting and FOIA requests—incriminate institutions and clinicians
 - Individual's online activity may provide incriminating evidence
- Protecting PHI
 - Avoid sharing too much information online
 - Documenting less rather than more
 - Permitted vs. mandated release of information/physician-patient privilege
- Finally, broader Federal health information privacy laws are urgently needed

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Practical Issues 2022

- ***Adolescent Consent and Confidentiality: Complexities in Context of the 21st Century Cures Act***
- Reality of what we can do in an EHR today
 - Best practices
 - Cures Act
 - HIPAA
- Uniform guidelines about the type of information that should be protected for adolescents
- Eliminate state-to-state variability and risk of disclosure
- Harmonize state laws with professional guidelines and obligations
- Granular segmentation of data to facilitate both sharing and protection where appropriate
 - Support ongoing efforts to develop segmentation policies and protocols
 - Work with EHR/IT developers to implement data segmentation in a clinically meaningful manner
- Maximize the benefits of Open Notes while preserving confidentiality for adolescents

English and Ford, <https://publications.aap.org/pediatrics/article/149/6/e2022056414/187002/Adolescent-Consent-and-Confidentiality>

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In Summary....

- Reviewed things you need to know about sharing PHI
- Discussed risks and benefits of sharing of adolescent PHI
- Discussed the current state of the art
- Reminder to consider not just your data, but where that data might travel, and what the regulations governing confidentiality might be in a new location
- And, finally, a brief examination of the new situation regarding a patient's right to confidentiality, and the impact on all patients, but especially our adolescent patients