

NATIONAL COUNCIL for Mental Wellbeing

Healthcare Confidentiality It's Unspeakably Complicated

July 2023

1

My Background

- Distinguished Professor of Science, MIMH
- Medicaid Director
- Practicing Psychiatrist
- Previously - MO Department of Mental Health Medical Director - 20 years

TheNationalCouncil.org

NATIONAL COUNCIL for Mental Wellbeing

2

Introduction

This presentation focuses on ways Protected Health Information (PHI) can be disclosed to the benefit of the individual. Sometimes, covered entities interpret HIPAA too narrowly, to the detriment of the individual. It is often vital to get information to the parties who need it. How to do so, without violating HIPAA How to do so, without violating HIPAA, 42CFR part 2, or ONC/CMS Interoperability is the focus of this presentation.

TheNationalCouncil.org

NATIONAL COUNCIL for Mental Wellbeing

3

Disclaimer

None of the information presented should be construed or relied upon as legal advice.

TheNationalCouncil.org

NATIONAL COUNCIL for Mental Wellbeing

4

Brief History - HIPAA

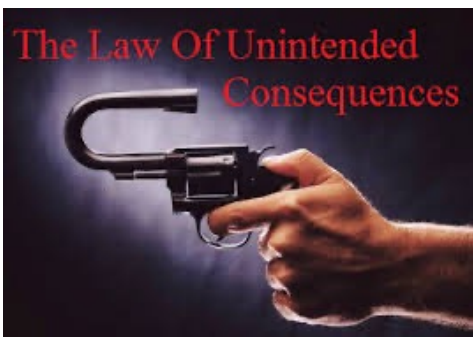
- HIPAA was enacted as the Kennedy-Kassebaum Bill of 1996
 - Intended as "administrative simplification"
 - Proposed rule issued 1999
 - Final rule issued 2002
 - Revised and updated 2013 and 2016
 - New Revised Rule is pending final Publication

TheNationalCouncil.org

NATIONAL COUNCIL for Mental Wellbeing

5

The Law Of Unintended Consequences




NATIONAL COUNCIL for Mental Wellbeing

6

Brief History – 42 CFR part 2

- 42 CFR Part 2 was enacted as the Drug Abuse Office and Treatment Act of 1972
 - Intended to encourage people to seek treatment
 - Regulations – Effective August 1, 1975
 - First revised and updated 1983
 - Revised and updated 2017, 2018, and July 2020 now in force
 - New Proposed rule closed final comments and is now pending final publication




TheNationalCouncil.org

7

Brief History ONC/CMS Interoperability

- Requirements set by 21st-century cures act enacted by Congress 2016
- Two Final interoperability rules released 2020
 - Office of the National Coordinator (ONC) - *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule* - Regulates IT requirements and funding
 - CMS - *The Interoperability and Patient Access final rule (CMS-9115-F)*
- Intended to give patients access to their health information and move the healthcare system toward greater interoperability
- Requirements phased-in over three years 2022 to December 2023




TheNationalCouncil.org

8

Consolidated Recent History

- HIPAA - Revised and updated 2013 and 2016
- 42CFR part 2 - Last revised and updated July 2020
- ONC/CMS Interoperability - Substantial requirements came into effect April 2021 and October 2022
- Coming Attractions
 - Anytime now – Office of Civil Rights (OCR) releases new proposed impending HIPAA regulations
 - Anytime now - SAMHSA releases new proposed and pending 42 CFR part 2 regulation
 - December 31, 2023 - ONC interoperability requires full export capability of all EHI
- Additional Issues
 - None of the above includes any state specific confidentiality requirements
 - When was the last time you organization updated its confidentiality policies, procedures, forms, and training?



TheNationalCouncil.org

9

Informed Consent Warning

TheNationalCouncil.org

NATIONAL COUNCIL for Mental Wellbeing

10

HIPAA Allows Sharing PHI

- For the Purposes of:
 - Treatment
 - Operations
 - Payment
- Absent Patient Consent
- Over Patient Objections

TheNationalCouncil.org

NATIONAL COUNCIL for Mental Wellbeing

11

Treatment

- Authorizations are not needed to use or disclose PHI for treatment purposes.
- Treatment, by design, is broadly defined.
- Treatment covers the coordination or management of health care among providers or a third party "related service".


TheNationalCouncil.org

NATIONAL COUNCIL for Mental Wellbeing

13

Treatment


- Treatment includes not just health care, but, also, "related services."
- "Related services" can include social, rehabilitative or other services associated with health care.
- DHHS believes disclosures for treatment purposes are appropriate for timely and quality treatment.


TheNationalCouncil.org

14

Treatment

- Treatment can only be provided to an individual or particular patient.
- PHI about a prospective patient to a health care provider may be disclosed.
- Minimum necessary disclosure does not apply to treatment.
- Treatment does not generally apply to psychotherapy notes.



TheNationalCouncil.org

15

Treatment

The following, when undertaken on behalf of a single consumer (not a population) are treatment activities:

- Case management;
- Care coordination;
- Disease management;
- Health promotion; and
- Outreach programs.



TheNationalCouncil.org

16

Surprising Truth about Sharing PHI for Treatment, Health Care Operations, and Payment

- Individuals have the right to request restrictions on how a covered entity will use and disclose PHI about them for treatment, health care operations, and payment.
- A covered entity is not required to agree to an individual's request for restriction, but is bound by any restrictions to which it agrees. (45 CFR 164.522(a))

TheNationalCouncil.org




17

Health Care Operations

The following, when population-specific rather than individual-specific are health care operations activities:

- Case management;
- Care management;
- Disease management;
- Health promotion; and
- Outreach programs.

TheNationalCouncil.org




20

Proposed Updates to HIPAA Pending Final Publication

- Allowing patients to inspect PHI in person and take notes or photographs of their PHI.
- Changing the maximum time to provide access to PHI from 30 days to 15 days.
- A definition has been added for electronic health records.
- The definition of healthcare operations has been broadened to cover care coordination and case management.
- The addition of a minimum necessary standard exception for individual-level care coordination and case management uses and disclosures, regardless of whether the activities constitute treatment or health care operations.
- Covered entities will be permitted to make certain uses and disclosures of PHI based on their good faith belief that it is in the best interest of the individual.
- Wording change to expand the ability of a covered entity to disclose PHI to avert a threat to health or safety when harm is "seriously and reasonably foreseeable." (currently it is when harm is "serious and imminent.")

TheNationalCouncil.org




35

Proposed Updates to HIPAA Pending Final Publication

- Restricting the right of individuals to transfer ePHI to a third party to only ePHI that is maintained in an EHR.
- Confirming that an individual is permitted to direct a covered entity to send their ePHI to a personal health application if requested by the individual.
- A pathway has been created for individuals to direct the sharing of PHI maintained in an EHR among covered entities.

TheNationalCouncil.org




36

Proposed Updates to HIPAA Pending Final Publication

- Stating when individuals should be provided with ePHI without charge.
- HIPAA-covered entities will be required to post estimated fee schedules on their websites for PHI access and disclosures.
- HIPAA-covered entities will be required to provide individualized estimates of the fees for providing an individual with a copy of their own PHI.

TheNationalCouncil.org



37




Why it was Time to Change 42 CFR Part 2


Separate is Never Equal

39

42 U.S. Code § 290dd-2 - Confidentiality of records

- The original Federal Statute behind 42 CFR part 2
- Short and Simple – only 474 words!
- Only 2 Requirements stricter than HIPAA
 - Patient Consent required for all releases of identifiable patient information for treatment except in a medical emergency
 - Prohibits use of patient information for criminal charges or investigation unless there is a substantial risk of death or bodily harm

TheNationalCouncil.org




40

42 CFR Part 2 is Much More restrictive than Federal Statute Requires

- Consent for a specific purpose
- Consent to a specific organization
- Consent must be time limited
- Consent is limited to minimum necessary for the specific purpose
- Prohibits Re-disclosure

TheNationalCouncil.org




41

HIPAA is Much Broader

- Allows Disclosure for
 - Treatment
 - Operations
 - Payment
- Allows Disclosure without Consent

TheNationalCouncil.org



42

Disadvantages Persons with Substance Abuse Disorder

- Have to anticipate what care they will need from who in the future
- Must constantly update expiring consents
- Do not get extra attention and supports
 - That providers give to any patient with a known chronic disorder
 - That Health Care systems arrange for high risk and high utilized patient groups

TheNationalCouncil.org

NATIONAL COUNCIL for Mental Wellbeing

43

Disadvantages Substance Use Treatment Providers

- Expense of constantly updating and re-doing consents
- Expense of EMR that can track and manage the complicated 42 CFR Part 2 consent requirements
- Public relations cost of being seen as non-responsive and obstructive by other Health care Providers

TheNationalCouncil.org

NATIONAL COUNCIL for Mental Wellbeing

44

Keeps SUD Treatment System Small and Isolated

- General Health Care Providers
 - Less likely to add SUD treatment
 - Less likely to partner or do projects with SUD treatment providers
- Health Information Exchanges all say they will work out later how to manage 42 CFR part 2 and just exclude SUD treatment
- Excludes SUD providers and conditions from care coordination and care management initiatives

TheNationalCouncil.org


NATIONAL COUNCIL for Mental Wellbeing

45

Increases Overdose Deaths

- Methadone is reported by the Centers for Disease Control and Prevention to be involved in 30 percent of prescription overdose deaths
- CDC also reports that the death rate from methadone overdoses was 6 times higher in 2009 than in 1999.
- While buprenorphine abuse and overdose deaths are much rarer, they are rapidly increasing in number.

TheNationalCouncil.org




46

Prescription Drug Abuse

- Prescription drug abuse in general has become a national epidemic.
- While individuals who have received specialized substance abuse treatment are less likely to abuse prescription medications than substance abusers who have not received treatment, they remain more likely to abuse prescription medications.
- Some persons who have received specialty substance abuse treatment relapse to prescription drug abuse and
- Some subsequently die of prescription drug overdoses.

TheNationalCouncil.org




47

False Promise of Magical IT Solutions and “Segmented Consent”

- IT vendors wanting new contracts say it’s “do-able”
- Nobody has done yet
- IT Experts who are not vendors looking for contracts say “Sure, We can do anything....given enough time and money”
 - Who loves SUD treatment enough to give that money?
 - Who has put their initiatives on hold to give the SUD field time to catch up?
 - We will be Billions of dollars short and decades late
- Even if it gets built where are the staff to help patients continuously update their consents? Will Treatment providers re-contact all previous patients for every new regional project and annually to get new consents?

TheNationalCouncil.org




48

42 CFR Part 2 Makes SUD Patients and Providers Miss Out On

- The better Electronic Medical Records
- Health Information Exchanges
- Prescription Drug Monitoring and Improvement Systems
- Care Coordination
- Population Management

TheNationalCouncil.org




49

Separate is Never Equal

- Any health information privacy requirements related to substance abuse treatment that differ from the privacy requirements related to general medical care will :
 - Always be a barrier to increasing access to substance abuse services
 - Always be a barrier to the coordination of substance abuse services with the rest of healthcare
 - Always be a barrier to providing high-quality substance abuse treatment in general medical care treatment settings.
- make it much less likely that persons with substance abuse disorders will receive the additional attention and time required to support continuing remission and identifying early recurrence that is routinely provided for persons with other chronic medical conditions.

TheNationalCouncil.org




50

42 CFR Part 2 Discriminates Against Persons with SUD and SUD Treatment Providers

- Persons with SUD can't get the same coordination of care, early interventions, protection from medical risks, and extra condition specific supports as a person with Diabetes
- SUD providers end up excluded from the new data driven healthcare world – You're invisible and unworkable if you can't show and share data

TheNationalCouncil.org



51

Fear of 42 CFR part two Penalties is Greatly Over Exaggerated

- No published reports of a federal penalty under 42 CFR part two for releasing SUD treatment information to another provider.
- After 20 years of asking I'm unable to locate any clinic or individual who received a penalty or consequence through the federal penalty process.
- Do you know anyone who has received a 42 CFR part two federal penalty?
- Can a violation of the old regulation be prosecuted since the current statute no longer supports those terms or penalties?

TheNationalCouncil.org



52

42 CFR part 2 Penalty

- **Subsections 2.3, 2.4, and 2.5**
- Violations handled by the local United States District Attorney
- Fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense.
- Because there is a criminal penalty for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute

TheNationalCouncil.org



53

District Attorneys Must Prioritize


- Too Many reports to pursue them all
- There are only 93 DAs and 350 Assistant DAs
- They must be selective in which cases to investigate and prosecute
- Common Reasons not to prosecute
 - Weak or insufficient evidence
 - Prioritization of Federal resources and interests
- Current DOJ Priorities – national security, cyber threats, public safety, vulnerable people, public corruption, and fraud

TheNationalCouncil.org



54

US District Assistant Attorney Working Her Cases



TheNationalCouncil.org

NATIONAL COUNCIL for Mental Wellbeing

55

“Liability” Through Inaction

- What Liability is there when a provider fails to share patients information and they could have and the patient comes to harm because of unshared information?
- What Liability is there when a provider fails to offer the patient the opportunity to have their information shared and they could have and the patient comes to harm because of unshared information?

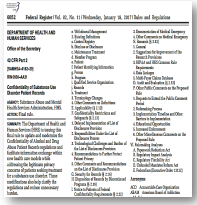
TheNationalCouncil.org

NATIONAL COUNCIL for Mental Wellbeing

56

42 CFR Part 2 Final Rule Revision in 2017

- The final rule was published in the Federal Register on January 18, 2017 (82 FR 6052).
- The effective date was initially scheduled for February 17, 2017.
- Review by the administration resulted in a revised effective date of March 21, 2017.
- <https://www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records>



TheNationalCouncil.org


NATIONAL COUNCIL for Mental Wellbeing

57

Helpful Changes

- Broader Consent allowed
- More Consistent Terminology
- Better “Qualified Service Organization” (BOA) language.
- Clarified applicability to HIEs
- More consistent with HIPAA
- Broader use in research allowed

TheNationalCouncil.org




58

New Rule – 42 CFR Part 2: Main points

- New option for general designation in Consent “to whom” section of consent form
- Limited to those who have “treating provider relationship” with patient
- Can include past, present, and/or future treating providers
 - Example: Consent to HIE & “all my treating providers” (who are members of the HIE)

TheNationalCouncil.org




59

Improved 42 CFR Part 2 Regulation Consent Requirements

- Must specify to “whom” - but it can be general
 - “To all my past, present, and future treatment providers”
- Must be time limited – but can be very long
 - such as an expiration date of “upon my death.”
- Must specify information – but it can be broad
 - “all my substance use disorder information”
 - as long as more granular options are also included.

TheNationalCouncil.org




60

Additional Improvements Effective February 2018

- Allows an abbreviated notice of the re-disclosure prohibition when disclosing Part 2 information;
- Allows disclosure of Part 2 information to contractors, subcontractors and legal representatives (“contractors”) for payment and health care operations activities without additional patient consent, if certain conditions are met;
- Allows disclosure of Part 2 information for Medicaid, Medicare or Children’s Health Insurance Program (“CHIP”) audit or evaluation activities if certain conditions are met.

TheNationalCouncil.org




61

Additional Improvements Effective February 2020

- Treatment records created by non-Part 2 providers based on their own patient encounter(s) are explicitly not covered by Part 2, unless any SUD records previously received from a Part 2 program are incorporated into such records.
- An SUD patient may consent to disclosure of the patient’s Part 2 treatment records to an entity (e.g., the Social Security Administration), without naming a specific person as the recipient for the disclosure.
- OTPs are permitted to enroll in a state prescription drug monitoring program (PDMP), and permitted to report data into the PDMP
- Non-OTP (opioid treatment program) and non-central registry treating providers are now eligible to query a central registry
- Declared emergencies resulting from natural disasters (e.g., hurricanes) that disrupt treatment facilities and services are considered a “bona fide medical emergency,”

TheNationalCouncil.org




62

Remaining Problems

- Prohibition on re-disclosure remains.
- New patient right: Can request & receive list of individuals/entities to whom their info has been disclosed pursuant to a general designation consent.
- The entity that serves as an intermediary, NOT the Part 2 program, is responsible for complying with the List of Disclosures requirement.
- Still many differences from HIPAA – confusing and burdensome

TheNationalCouncil.org




63

The Problem with Prohibition on Re-Disclosures

- If a mixed use clinic adds covered information to their general assessment and notes then those records are all covered information too.
- The record can't be shared without either:
 - 42 CFR part 2 required consents with reporting to the patient on request
 - Redacting the 42 CFR part 2 covered information
- If you accept covered information but don't include it in your notes and there's a bad outcome you have increased liability risk

TheNationalCouncil.org



64

Some Healthcare Organizations decide not to provide SUD treatment because of 42 CFR part two



"I say it's government-mandated broccoli, and I say the hell with it."

TheNationalCouncil.org



65



The New Proposed 42 CFR Part 2 Regulations


January 2023

66

Permits Better Coordination of Care

- Permit Part 2 programs to use and disclose Part 2 records based on a single prior consent signed by the patient for all future uses and disclosures for treatment, payment, and health care operations.
- Permit the redisclosure of Part 2 records as permitted by the HIPAA Privacy Rule by recipients that are Part 2 programs, HIPAA covered entities, and business associates, with certain exceptions.
- Allows patients to restrict specific Part 2 information from disclosure for purposes of treatment payment and operations
- Allows patients to restrict Part 2 information that was entirely paid for out of pocket from being released to payers

TheNationalCouncil.org




67

Better Patient Protections

- Expand prohibitions on the use and disclosure of Part 2 records in civil, criminal, administrative, or legislative proceedings conducted by a federal, state, or local authority against a patient, absent a court order or the consent of the patient.
- Modify the HIPAA Notice of Privacy Practices requirements for covered entities who receive or maintain Part 2 records to include a provision limiting redisclosure of Part 2 records for legal proceedings according to the Part 2 standards.

TheNationalCouncil.org




68

Alignment With Other Regulations

- Create two patient rights under Part 2 that align with individual rights under the HIPAA Privacy Rule:
 - Right to an accounting of disclosures
 - Right to request restrictions on disclosures for treatment, payment, and health care operations.
- Apply HIPAA and HITECH Act civil and criminal penalties to Part 2 violations.
- Prohibit Part 2 programs from requiring patients to waive the right to file a complaint as a condition of providing treatment, enrollment, payment, or eligibility for services.
- Apply the standards in the HITECH Act and the HIPAA Breach Notification Rule to breaches of Part 2 records by Part 2 programs.
- Modify the Part 2 confidentiality notice requirements ("Patient Notice") to align with the HIPAA Notice of Privacy Practices.

TheNationalCouncil.org




69

Program Requirements

- Require Part 2 programs to establish a process to receive complaints of Part 2 violations.
- Prohibit Part 2 programs from taking adverse action against patients who file complaints.
- Prohibit Part 2 programs from requiring patients to waive the right to file a complaint as a condition of providing treatment, enrollment, payment, or eligibility for services.
- Require Part 2 programs provide a listing of all disclosures upon patient request

TheNationalCouncil.org




70

Enforcement Authorities

- Require disclosures to the Secretary for enforcement.
- Permit investigative agencies to apply for a court order to use or disclose Part 2 records after they unknowingly receive Part 2 records in the course of investigating or prosecuting a Part 2 program, when certain preconditions are met.

TheNationalCouncil.org




71

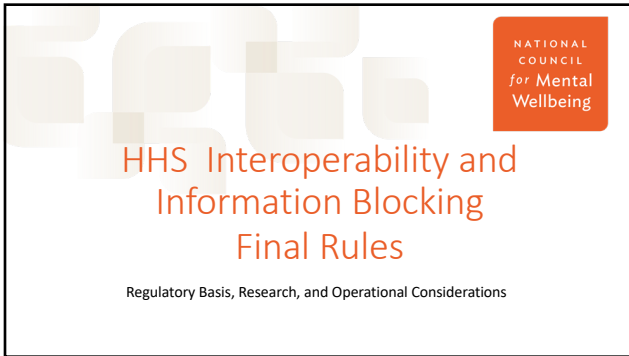
When Does It Take Effect?

- Proposed rule public comment period has closed.
- Sometime after the comment period closes the final rule will be published
- The rule becomes effective 60 days after the final rule was published
- The compliance date this 22 months after the effective date
- So overall organizations will have 24 months to revise their policies procedures patient education material and retrain staff after the rule is finalized.

TheNationalCouncil.org



72

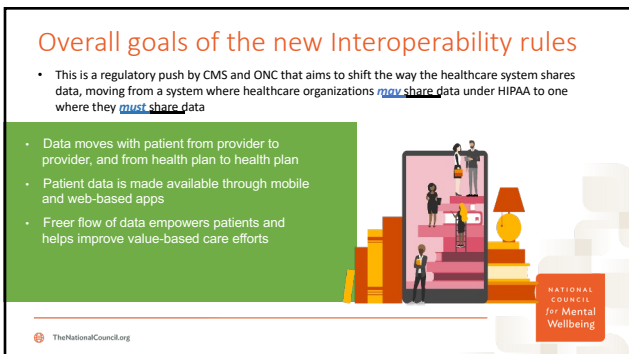


NATIONAL COUNCIL for Mental Wellbeing

HHS Interoperability and Information Blocking Final Rules

Regulatory Basis, Research, and Operational Considerations

80

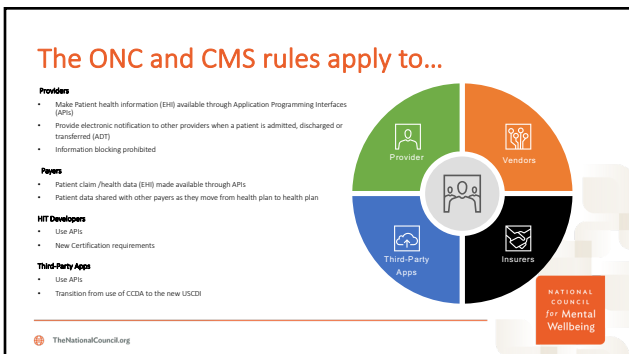


Overall goals of the new Interoperability rules

- This is a regulatory push by CMS and ONC that aims to shift the way the healthcare system shares data, moving from a system where healthcare organizations may share data under HIPAA to one where they must share data
- Data moves with patient from provider to provider, and from health plan to health plan
- Patient data is made available through mobile and web-based apps
- Freer flow of data empowers patients and helps improve value-based care efforts

TheNationalCouncil.org

81



The ONC and CMS rules apply to...

- Providers**
 - Make Patient health information (PHI) available through Application Programming Interfaces (APIs)
 - Provide electronic notification to other providers when a patient is admitted, discharged or transferred (ADT)
 - Information blocking prohibited
- Payers**
 - Patient claim/health data (PHI) made available through APIs
 - Patient data shared with other payers as they move from health plan to health plan
- HIT Developers**
 - Use APIs
 - New Certification requirements
- Third-Party Apps**
 - Use APIs
 - Transition from use of CCD to the new USCDI


TheNationalCouncil.org

82

Impact of 21st Century Cures Act

- Medicare COP drive Encounter Notification effective May 1, 2021
 - Acute Care, Psychiatric Hospitals, and Critical Access Hospitals
 - Real-time encounter notifications (ADT)
 - Electronic Medical Record
 - **"Other Electronic Administrative Systems"** which conform to content exchange standards found at 45 CFR 170.205(d)(2)
- Mandatory API Standards automate Patient Access
 - Medicare Advantage Program
 - State Medicaid
 - Managed Care (MCOs, PHPs, PAHPs)
 - CHIP
 - QIP on a Federally-facilitated exchange
- Information blocking is now **prohibited**
 - Health Care Providers, Interconnectors & Developers of Certified Health IT
 - EHI phased in
 - "Appropriate Disincentives" and Penalties

TheNationalCouncil.org



83

The ONC Rule:
21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule


The CMS Rule:
The Interoperability and Patient Access final rule (CMS-9115-F)

84

Important Dates

- April 5, 2021 - **Information blocking prohibited**
 - Electronic health information (EHI) definition is limited to only information defined in United States Core Data for Interoperability (USCDI) standards
 - USCDI standards expanded to include progress notes
 - Only data in USCDI standards must meet interoperability requirements on HIEs
- May 1, 2021 - **ADT Notifications Required**
- October 6, 2022
 - EHI definition is expanded beyond defined elements in USCDI to include **any information that an organization has that is:**
 - (i) Transmitted by electronic media;
 - (ii) Maintained in electronic media; or
 - The above definition includes information and other provider impaired data systems beyond the EMR alone
- December 31, 2023
 - Providers and payers required to have full export capability for all their EHI

TheNationalCouncil.org



85

Scope of ONC Rule

ONC Rule covers two main areas: **Information Blocking** and **HIT Certification Criteria**

Information Blocking	Information Blocking Exceptions
<ul style="list-style-type: none"> Information Blocking <p>A practice by a healthcare provider, HIT developer, or HIS/HIM that, unless as required by law or specified by the Secretary as a reasonable and necessary activity, is likely to interfere with, prevent, or materially discourage access, exchange or use of EHI</p>	<ul style="list-style-type: none"> Preventing Harm Privacy Exception Security Exception Infeasibility Exception HIT Performance Exception Content and Manner Exception Fees Exception Licensing Exception

TheNationalCouncil.org | NATIONAL COUNCIL for Mental Wellbeing | March 2020

86

What data needs to be shared?

Within the first 24 months – expands to HIPAA data set after 24 months

- Allergies and intolerances
- Assessment and Plan of Treatment
- Care Team Members
- Goals
- Health Concerns
- Immunizations
- Laboratory
- Medications
- Patient Demographics
- Problems
- Procedures
- Provenance
- Smoking Status
- Unique Device Identifier(s)
- Vital Signs
- Clinical Notes*
 - Consult Note
 - Discharge Summary
 - H&P
 - Imaging Narrative
 - Pathology Narrative
 - Procedure
- Progress Note

Standards:
<https://www.hhs.gov/irs/united-states-core-data-interoperability/>
<https://www.fda.gov/oc/2017/08/01/2017-08-01-ucd-standards/>
 * Currently not part of NetSmart CCD Standard

TheNationalCouncil.org | NATIONAL COUNCIL for Mental Wellbeing

87

Privacy Exception

- Exception #2 Privacy Exception— When will an actor's practice of not fulfilling a request to access, exchange, or use EHI in order to protect an individual's privacy not be considered information blocking?
- Whereas the HIPAA Privacy Rule permits, but does not require, covered entities to disclose ePHI in most circumstances, **the information blocking rule requires the actor to provide access, exchange, or use of EHI unless prohibited by law or covered by one of the exceptions.**
- Sub-exception 4: "Respecting an individual's request not to share information" applies if the following requirements are met:
 - The individual makes the request orally or in writing without any improper encouragement or inducement by the actor.
 - The actor documents the request within a reasonable period of time. The final rule does not require a specific form of documentation and indicates a note in the certified EHR or similar notation is sufficient.

TheNationalCouncil.org | NATIONAL COUNCIL for Mental Wellbeing

88

More on Exceptions

- EHRs with the capability to give patients direct and immediate access will generally need to provide instant access. If you keep EHI but do not have an EHR that allows for direct and immediate patient access will likely come under the infeasibility exception to the instant access requirement.
- May exclude notes of any type that may cause harm to the patient or others should the patient have access. However, **the rule specifically states that psychological distress does not meet the definition of harm** (Torous, 2020). "Substantial Harm" meaning life threatening or physical harm.
- To exercise the privacy exemption the patients request to not share EHI must be documented in the record

TheNationalCouncil.org



89

Psychotherapy Note Exception

- Psychotherapy notes are exempt from the information blocking prohibition
- Psychotherapy Notes Are Not
 - Any documentation information required for billing
 - History, symptoms, mental status exam, therapist interventions
- Psychotherapy Notes Are
 - Documentation about the therapist's emotional reactions, fantasies, and internal associations that occur in relation to the patient
 - I.e. Traditional psychoanalytic process notes
- To be exempt from information blocking psychotherapy notes must be kept entirely separate from the rest of the patient record
- Uncertified EHRs such as PsyBooks are not required to follow the Open Notes Rule

TheNationalCouncil.org



90

Psychotherapy with content that is considered medical record notes cannot be blocked.

- | | |
|---------------------|---|
| • Diagnosis | • Session start and stop times |
| • Symptoms | • Test results |
| • Functional status | • The modalities and frequencies of treatment furnished |
| • Treatment plans | • Medication prescription and monitoring |
| • Prognosis | |
| • Progress to date | |

TheNationalCouncil.org




91

Information Blocking Penalties

- Impacts everyone
- Every healthcare provider is subject to Information Blocking penalties
- It doesn't matter if they're participating in an incentive program
- It doesn't matter if their EHR is not certified
- If they are one of these providers...they are subject to penalties
 - Hospital
 - Laboratory
 - Rural health clinic
 - Ambulatory surgical center
 - Therapist
 - Federally qualified health center
 - Provider operated by or under contract with, the Indian health service or by an Indian tribe, tribal organization, or urban Indian organization
 - Pharmacy
 - Nursing facility
 - Practitioner
 - Community mental health center
 - Blood center
 - Group practice
 - Home health entity or other long-term care facility
 - Skilled nursing facility
 - Physician
 - Health care clinic
 - Renal dialysis facility
 - Pharmacist
 - Emergency medical services provider
 - Covered entity under section 256b of title 42

Final penalties have not been defined – but rule allows for up to \$1M per violation




92

Admission, Discharge, Transfer (ADT) Notifications

- Required from: Hospitals, Psychiatric Hospitals, Critical Access Hospitals
- Required when: Inpatient, ER, Observation, Discharge
- Required for: Treatment, Care Coordination, Quality Improvement
- Required to: PCP, ACOs, FQHCs, Specialty Practices, NH, Hospice, Home Health

TheNationalCouncil.org




93

IT Considerations

- EMR Vendors are required to have their EMR capable of meeting the ONC requirements in order to be ONC/CMS certified which is a requirement for submitting billing to CMS
 - The EMR internal capability to extract and export patient information is likely to be implemented as part of a regular EMR update without additional cost
 - The ability to provide access to the exported data via a patient portal or connection to an HIE is usually a functional module that must be purchase/subscribe to separately from the basic EMR package
- The information blocking exception for privacy requires specific documentation that the patient has requested that their information not be shared. Uniformly encouraging patients to exercise this is considered information blocking.
- There are currently no penalties for providers not complying with the interoperability requirements. CMS has stated that disincentives for noncompliance will be implemented in the future

TheNationalCouncil.org




94

Implementation to Do List

- Contact your EMR vendor find out the details of how they will be implementing the interoperability requirements
- Review and Revise Policies forms and procedures for:
 - Providing information to patients and other healthcare providers
 - Requesting information from other healthcare providers including ADT from hospitals
 - Documenting privacy exemption to information blocking
- Review and Revise Patient education materials
- Staff training program
 - Policies and procedures listed above
 - Open notes and/or collaborative documentation

TheNationalCouncil.org




95

OpenNotes (aka Concurrent Documentation) Research

- In 2010, Beth Israel Deaconess, Geisinger Health System, and Seattle's Harborview Medical Center did a study involving 105 primary care doctors with 20,000 of their patients able to read their clinical notes via secure online patient portals.
 - Doctors reported little change in workload and clinician fears were unfounded.
 - Patients overwhelmingly approved of note sharing; few were worried or confused by their notes.
 - patients reported that reading notes helped them feel more in control of their health and health care.
 - 25% reported finding errors- most commonly diagnosis, history and medication
- OpenNotes in Mental Health
 - VA study - patient experiences are more positive than negative when reading mental health notes
 - Beth Israel Deaconess Medical Center study
 - 94% agreed that having open therapy notes is a good idea and 87% wanted it to continue.
 - More than half reported therapy notes were 'very important'... for feeling in control of their care, trusting their providers and taking care of themselves.
 - Two felt offended, and 7 (11%) felt judged by something they read in a note.

TheNationalCouncil.org




96

Collaborative Documentation

- Collaborative documentation is a practice where clinician and patient document together, during the session.
- Collaborative documentation = (Concurrent Documentation + Shared Decision-Making)
X Patient centered
- Advantages
 - Reduces errors and misunderstandings
 - Enhances patient engagement and empowerment
 - Documentation is always completed on time by the end of the session
 - Patients are never surprised when they read the note

Training available Through MTM and the National Council

TheNationalCouncil.org



97

Resources

- For more information about the ONC Rule and CMS Rule, please see below sites:

ONC Rule

- For more information on the ONC final rule, please visit: <https://healthit.gov/2020/rule/>
- To view the ONC final rule, please visit: <https://www.federalregister.gov/documents/2020/07/20/2013-00001>

CMS Rule

- For more information on the CMS final rule, please visit: <https://www.cms.gov/medicare/medicare-eligibility/medicare-eligibility-2020/medicare-eligibility-2020-fact-sheet>
- To view the CMS final rule, please visit: <https://www.cms.gov/1-800-MY-GOV/medicare-eligibility/medicare-eligibility-2020>

TheNationalCouncil.org

