

21ST CENTURY CURES ACT

OVERVIEW AND IMPLICATIONS FOR PROVIDERS, PATIENTS AND RISK MANAGERS

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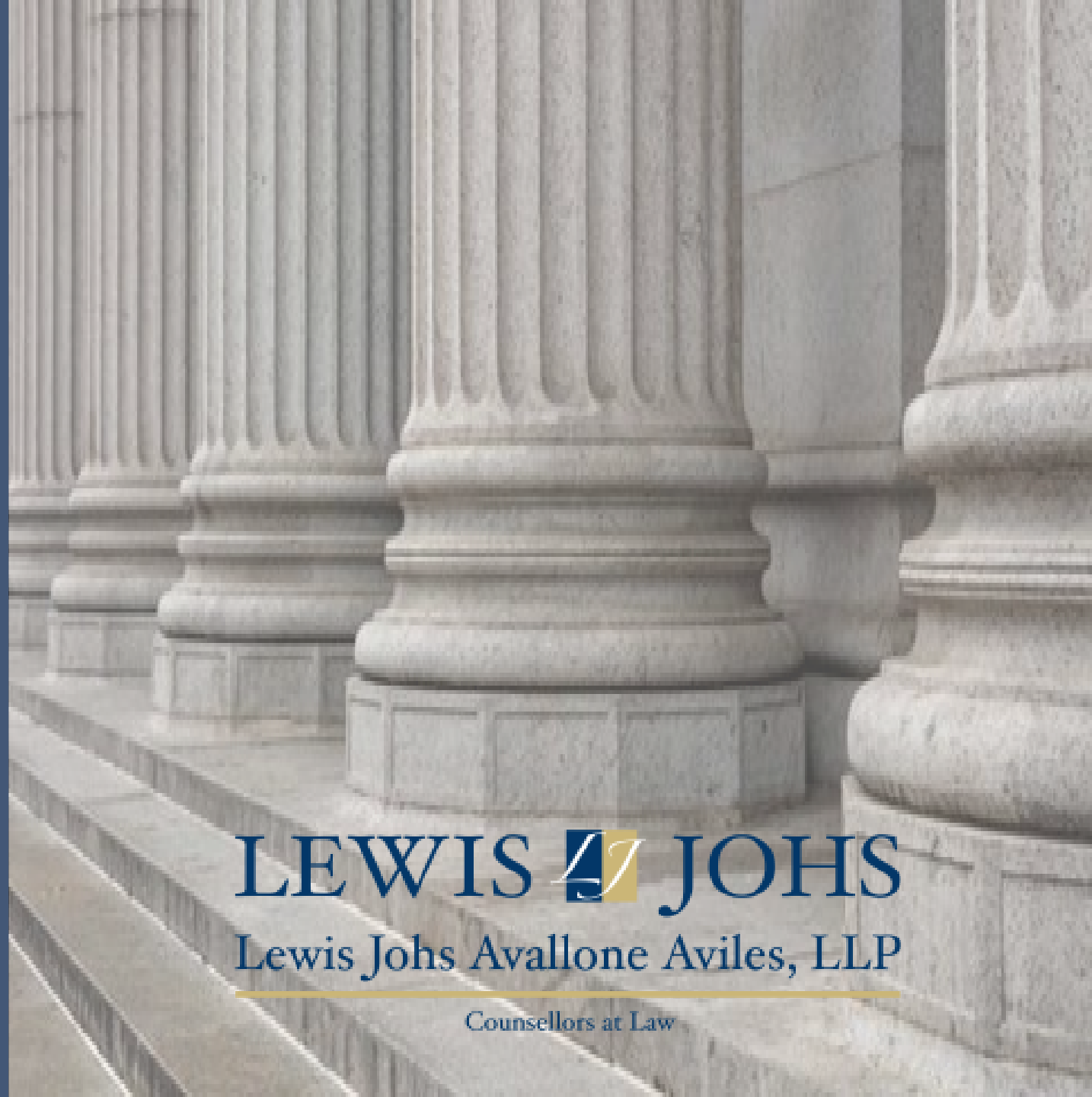
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THE CURES ACT:

THE LEGAL FRAMEWORK

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TIMELINE

2015	-	ONC Reports to Congress about Information Block
12/2016	-	21st Century Cures Act signed into law "To accelerate the discovery, development and delivery of 21st century cures and for other purposes"
5/1/2020	-	Final Rule Issued by Human and Health Services Department
11/4/2020	-	Interim Final Rule Issued to Address Covid
4/5/2021	-	Information Blocking Compliance Date

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INFORMATION BLOCKING IN THE 21ST CENTURY CURES ACT

21ST CENTURY CURES ACT, SECTION 4004:

- Defines "information blocking"
- Authorizes the Secretary to identify, through rulemaking, reasonable and necessary activities that do not constitute information blocking
- Identifies the HHS Office of Inspector General (OIG) as the HHA Office for Civil Rights (OCR)
- Prescribes penalties for information blocking
- Charges ONC with implementing a complaint process for reporting information, and provides confidentiality protections for complaints

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WHAT MAKES AN INDIVIDUAL OR ENTITY AN INFORMATION BLOCKER?

ELEMENTS OF INFORMATION BLOCKING

- Actor regulated by the information blocking provision
- Involves electronic health information (EHI)
- Practice is likely to interfere with, access, exchange, or use of EHI
- Requisite knowledge by the actor
- Not required by law
- Not covered by an exception

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CONSEQUENCE OF BEING AN INFORMATION BLOCKER

- **Cures Act prescribes penalties for information blocking**
  - Health IT developers of certified health IT, health information networks, and health information exchanges → Civil monetary penalties (CMPs) up to $1 million per violation
  - Health care providers → Appropriate disincentives
- **Certification ban (§ 170.581) for health IT developers in violation of the Conditions of Certification**
  - Information blocking Condition of Certification (§ 170.401)
  - Public listing of certification bans and termination

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INFORMATION BLOCKING DEFINITION IN THE FINAL RULE



(a) Information blocking means a practice that-

(1) Except as required by law or covered by an exception, is likely to interfere with access, exchange, or use of electronic health information; and

(2) **If conducted by a health information technology developer, health information network or health information exchange,** such developer, network or exchange knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI; or

(3) **If conducted by a health care provider**, such provider knows that such practice is unreasonable and is likely to interfere with the access, exchange, or use of EHI.

(b) Until 24 months after the publication date of the final rule, EHI for purposes of paragraph (a) of this section is limited to the EHI identified by the data elements represented in the USCDI standard adopted in §170.213.



"ACTORS" REGULATED IN THE FINAL RULE

- Health Care Providers
- Health IT Developers of Certified Health IT
- Health Information Networks (HIN)/ Health Information Exchanges (HIE)

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HEALTH CARE PROVIDERS WHO ARE THEY?

- hospital
- skilled nursing facility
- nursing facility
- home health entity or other long term care facility
- health care clinic
- community mental health center
- renal dialysis facility
- blood center
- ambulatory surgical
- emergency medical services provider
- federally qualified health center
- group practice
- pharmacist
- pharmacy
- laboratory
- physician
- rural health clinic
- ambulatory surgical center
- provider operated by, or under contract with, the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization
- "covered entity" under certain statutory provisions
- therapist
- any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary

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ELECTRONIC HEALTH INFORMATION WHAT DOES IT MEAN?

Electronic protected health information (ePHI) as the term is defined for HIPAA in 45 CFR 160.103 **to the extent that the ePHI would be included in a designated record set (DRS)** as defined in 45 CFR 164.501 (other than psychotherapy notes as defined in 45 CFR 164.501 or information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding), regardless of whether the actor is a covered entity as defined in 45 CFR 160.103.

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"INTERFERE WITH" OR "INTERFERENCE" WHAT IS IT?

Interfere with or interference means to prevent, materially discourage, or otherwise inhibit.

- **Publication of "FHIR service base URLs" (sometimes also referred as "FHIR endpoints") –** A FHIR service base URL cannot be withheld by an actor as it (just like many other technical interfaces) is necessary to enable the access, exchange, and use of the EHI.
- **Delays –** An actor's practice of slowing of delaying access, exchange, or use of EHI could constitute an interference and implicate the information blocking provision.
- **Cost for Electronic Access by Patients/Individuals -** An actor's practice of charging an individual, their personal representative, or another person or entity designated by the individual for electronic access to the individual's EHI would be inherently suspect under an information blocking review.

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"INTERFERE WITH" OR "INTERFERENCE" WHAT IS IT NOT?

Interfere with or interference means to prevent, materially discourage, or otherwise inhibit.

- **Business Associate Agreements (BAAs)** – Actors are **not** required to violate BAAs or associated service level agreements. *However*, a BAA or its associates service level agreements must not be used in a discriminatory manner by an actor to forbid or limit disclosures that otherwise would be permitted by the Privacy Rule.
- **Educate Patients about Privacy and Security Risks or Apps and 3rd Parties** – Actors may provide patients with information that:
  - Focuses on any current privacy and/or security risks posed by the technology or the third-party developer of the technology;
  - Is factually accurate, unbiased, objective, and not unfair or deceptive; and
  - Is provided in a non-discriminatory manner.

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KNOWLEDGE STANDARD





Health Care Providers

"**...knows** that such practice is **unreasonable** and is likely to interfere with, prevent, or materially discourage the access, exchange or use of electronic health information..."

Health IT Developers of Certified Health IT and HINs/HIEs

"**...knows, or should know**, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange or use of electronic health information..."

REQUIRED BY LAW
WHAT DOES IT MEAN?

- Refers specifically to interferences with access, exchange, or use of EHI that are explicitly required by state or federal law.
- Distinguishes between interferences that are “required by law” and those engaged in pursuant to a privacy law, but which are not “required by law”.

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EXCEPTIONS

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OVERVIEW OF THE EXCEPTIONS

- On behalf of HHS, ONC has defined **eight** exceptions that offer actors **certainty** that, when their practices with respect to accessing, exchanging, or using EHI meet the conditions of one or more exceptions, such practices will **not** be considered information blocking.
- An actor's practice that does **not** meet the conditions of an exception will **not** automatically constitute information blocking.
- Instead, such practices will be evaluated on a **case-by-case** basis to determine whether information blocking has occurred.





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OVERVIEW OF THE EXCEPTIONS

The **eight** exceptions are divided into **two categories**:

Exceptions for not fulfilling requests to access, exchange, or use EHI

1. Preventing Harm
2. Privacy
3. Security
4. Infeasibility
5. Health IT Performance

Exceptions for procedures for fulfilling requests to access, exchange, or use EHI

6. Content and Manner
7. Fees
8. Licensing

PREVENTING HARM EXCEPTION

Overview

It will not be information blocking for an actor to engage in practices that are reasonable and necessary to prevent harm to a patient or another person, provided certain contains are met.

Objective

This exception recognizes that the public interest in protecting patients and other persons against unreasonable risks of harm can justify practices that are likely to interfere with access, exchange, or use of EHI.

To satisfy this exception:

The actor must hold a reasonable belief that the practice will substantially reduce a risk of harm and the practice must be no broader than necessary

+

The practice must satisfy at least one condition from each category: type of risk, type of harm and implementation basis

+

The practice must satisfy the condition concerning a patient right to request review of an individualized determination of risk of harm

PRIVACY EXCEPTION

Overview

It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI in order to protect an individual's privacy, provided certain conditions are met.

Objective

This exception recognizes that if an actor is permitted to provide access, exchange, or use of EHI under a privacy law, then the actor should provide that access, exchange, or use. However, an actor should not be required to use or disclose EHI in a way that is prohibited under state or federal privacy laws.

To satisfy this exception, an actor's privacy-protective practice must:

SATISFY AT LEAST ONE SUB-EXCEPTION

+

MEET ALL CONDITIONS APPLICABLE TO A SUB-EXCEPTION BEING RELIED UPON

PREVENTING HARM EXCEPTION

Overview

It will not be information blocking for an actor to engage in practices that are reasonable and necessary to prevent harm to a patient or another person, provided certain contains are met.

Objective

This exception is intended to cover all legitimate security practices by actors but does not prescribe a maximum level of security or dictate a one-size-fits-all approach.

To satisfy this exception, an actor's security-related practice must:

SATISFY THRESHOLD CONDITIONS

+

Implement a Qualifying Organizational Security Policy

OR

Implement a Qualifying Security Determination

INFEASIBILITY EXCEPTION

Overview

It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI due to the infeasibility of the request, provided certain conditions are met.

Objective

This exception recognized that legitimate practical challenges may limit an actor's ability to comply with requests for access, exchange, or use of EHI. An actor may not have – and may be unable to obtain – the requisite technological capabilities, legal rights, or other means necessary to enable access, exchange, or use.

To satisfy this exception, an actor must:

Demonstrate that the practice meets <u>one</u> of the conditions for uncontrollable events, segmentation, or infeasibility under the circumstances

+

Provide written response, within 10 business days of receipt of the request, with the reason(s) why the request is infeasible

HEALTH IT PERFORMANCE EXCEPTION

Overview
It will not be information blocking if an actor to take reasonable and necessary measures to make health IT temporarily unavailable or to degrade the health IT's performance for the benefit of the overall performance of the health IT, provided certain conditions are met.

Objective
This exception recognizes that for health IT to perform properly and efficiently, it must be maintained, and in some instances improved, which may require that health IT be taken offline temporarily. Actors should not be deterred from taking reasonable and necessary measures to make health IT temporarily unavailable or to degrade the health IT's performance for the benefit of the overall performance of health IT.

To satisfy this exception, the practice must meet one of the following conditions:

MAINTENANCE AND IMPROVEMENTS

OR

ASSURED LEVEL OF PERFORMANCE

OR

PRACTICES THAT PREVENT HARM / SECURITY-RELATED PRACTICES

CONTENT AND MANNER EXCEPTION

Overview
It will not be information blocking for an actor to limit the content of its response to a request to access, exchange, or use EHI or the manner in which it fulfills a request, provided certain conditions are met.

Objective
This exception provides clarity and flexibility to actors concerning the required content of an actor's response to a request to access, exchange, or use EHI and the manner in which the actor may fulfill the request. It supports innovation and competition by allowing actors to first attempt to reach and maintain market negotiated terms for the access, exchange, and use of EHI.

To satisfy this exception, an actor must meet <u>both</u> of these conditions:

CONTENT CONDITION

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MANNER CONDITION

CONTENT AND MANNER EXCEPTION

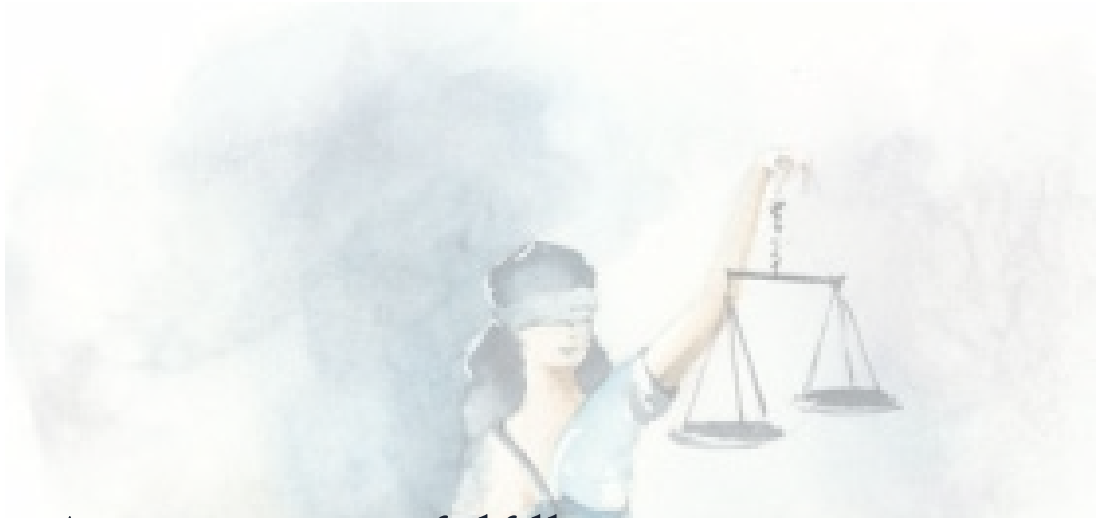
CONTENT CONDITION



1. **Up to 24 months** after the publication date of the final rule, an actor must respond to a request to a request to access, exchange, or use EHI with, at a minimum, the EHI identified by the **data elements represented in the USCDI** standard.
2. **On and after 24 months** after the publication date of the final rule, an actor must respond to a request to access, exchange, or use EHI with **EHI as defined in §171.102**.

CONTENT AND MANNER EXCEPTION

MANNER CONTENT – ANY MANNER REQUESTED



- An actor must fulfill a request **in any manner** requested unless the actor is:

1. Technically unable to fulfill the request in a manner requested; **or**
2. Cannot reach agreeable terms with the requestor to fulfill the request.

- If an actor fulfills a request in **any manner requested**, the actor is **not** required to comply with the Fees or Licensing Exception.

CONTENT AND MANNER EXCEPTION

MANNER CONDITION – ALTERNATIVE MANNER

- If an actor responds in an **alternative manner**, the actor must fulfill the request **without unnecessary delay** in the **following order of priority**, only proceeding to the next consecutive paragraph if **technically unable** to fulfill the request in that manner:

1. Using technology certified to standard(s) adopted in Part 170 that is specified by the requestor.
2. Using content and transport standards specified by the requestor and published by:
    a. Federal Government; or
    b. Standards developing organization accredited by the American National Standard Institute.
3. Using an alternative machine-readable format, including the means to interpret the EHI, agreed upon with the requestor.

FEES EXCEPTION

Overview

It will not be information blocking for an actor to charge fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using EHI, provided certain conditions are met:

Objective

This exception enables actors to charge fees related to the development of technologies and provisions of services that enhance interoperability, while not protecting rent-seeking, opportunistic fees, and exclusionary practices that interfere with access, exchange, or use of EHI

To satisfy this exception, the practice must:

MEET BASIS FOR FEES CONDITION

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NOT BE SPECIFICALLY EXCLUDED

+

COMPLY WITH ASSURANCES AND/OR API CONDITIONS OF CERTIFICATION, AS APPLICABLE

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LICENSING EXCEPTION

Overview

It will not be information blocking for an actor to license interoperability elements for EHI to be accessed, exchanged, or used, provided certain conditions are met.

Objective

This exception allows actors to protect the value of their innovations and charge reasonable royalties in order to earn returns on the investments they have made to develop, maintain, and update those innovations.

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To satisfy this exception, the practice must:

MEET THE NEGOTIATING A LICENSE CONDITIONS

+

MEET THE LICENSING CONDITIONS

+

MEET THE ADDITIONAL CONDITIONS RELATING TO THE PROVISIONS OF INTEROPERABILITY ELEMENTS

THE CURES ACT:

A PRACTICIONER'S PERSPECTIVE



VICTOR R. KLEIN,
MD,MBA,CPHRM

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CURES ACT OVERVIEW



- April 5, 2021- the information blocking rule (aka-Open notes) of 21st Century Cures Act mandates that 8 categories of clinical notes in EHR must be immediately available to patients through a secure portal.
- Cannot block or delay access to results
- 1996-HIPPA rights to records
- 2016-Cures Act-easier –smart phones and computer by vendors of EHR

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8 MANDATORY CATEGORIES OF CLINICAL NOTES

- Consultation Notes
- Discharge Summary Notes
- History & Physical
- Imaging Reports
- Lab Reports
- Pathology Reports
- Progress Notes

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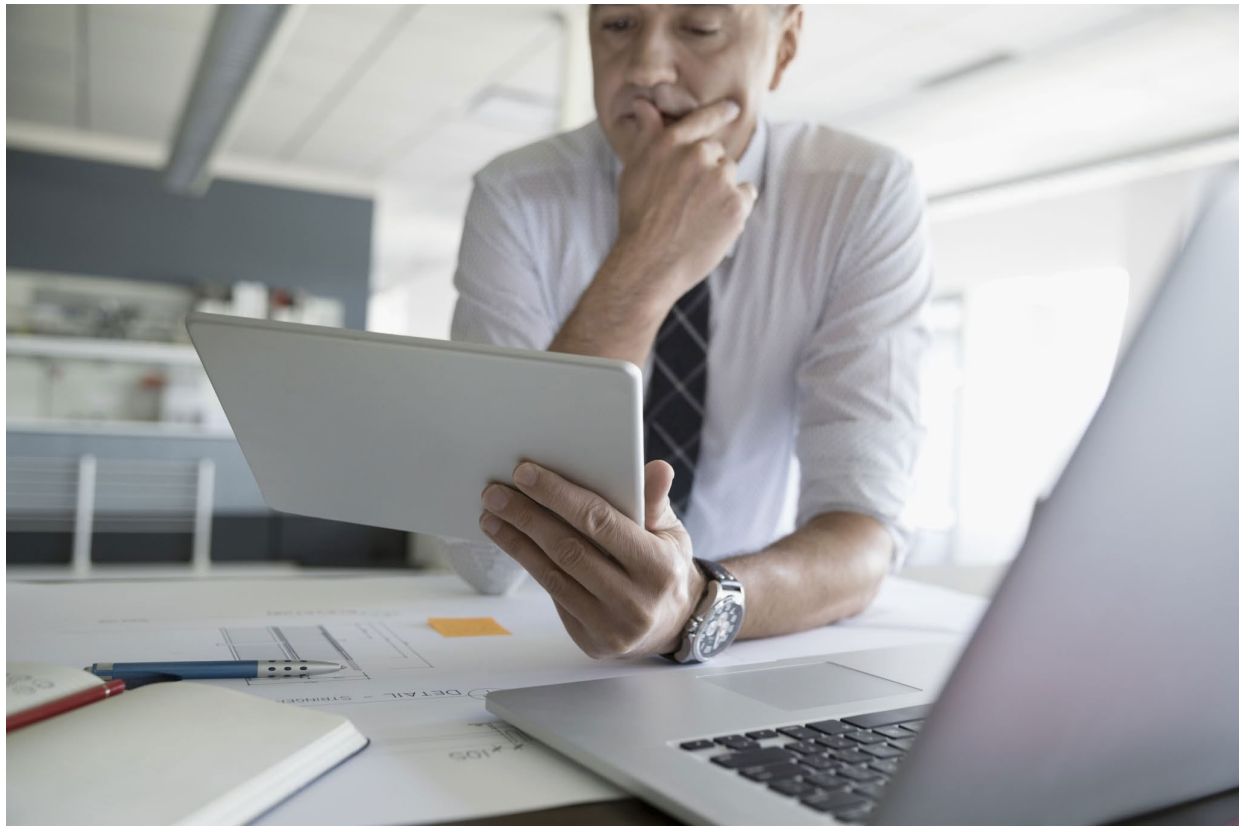
EXEMPT CLINICAL NOTES



- Notes compiled in anticipation of civil or administrative action, malpractice
- Psychotherapy notes-diagnosis , medications and appointments NOT blocked

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OPEN NOTE ISSUES

- Patients may see labs before the provider
- Some results no clinical significance
- Dr. Google
- Patients may disagree with findings
- Interpretation of complex tests/ imaging

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OPEN NOTES SUGGESTIONS



- Continue using proper billing/coding language
- Avoid copy/paste not current
- Don't import social history if you didn't review
- Avoid abbreviations
- Define medical terms
- Plain language
- Preferred pronoun
- Avoid language that seems judgmental

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OPEN NOTES SUGGESTIONS



- Document BMI-not morbid obesity
- Document disease as condition-i.e. diabetic
- Noncompliance-describe
- IVDA, Alcoholic -SUD

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RISK MANAGEMENT ISSUES



- CRICO-2015-inadequate communication-55% malpractice cases
- Potential miscommunication issues-don't understand, don't agree-potential to educate if patient did not understand initially
- Goal is for patients to be able to read and comprehend-plans, tests , appointments
- Accurate , complete ,contemporaneous medical charting is more critical than ever

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THE CURES ACT:

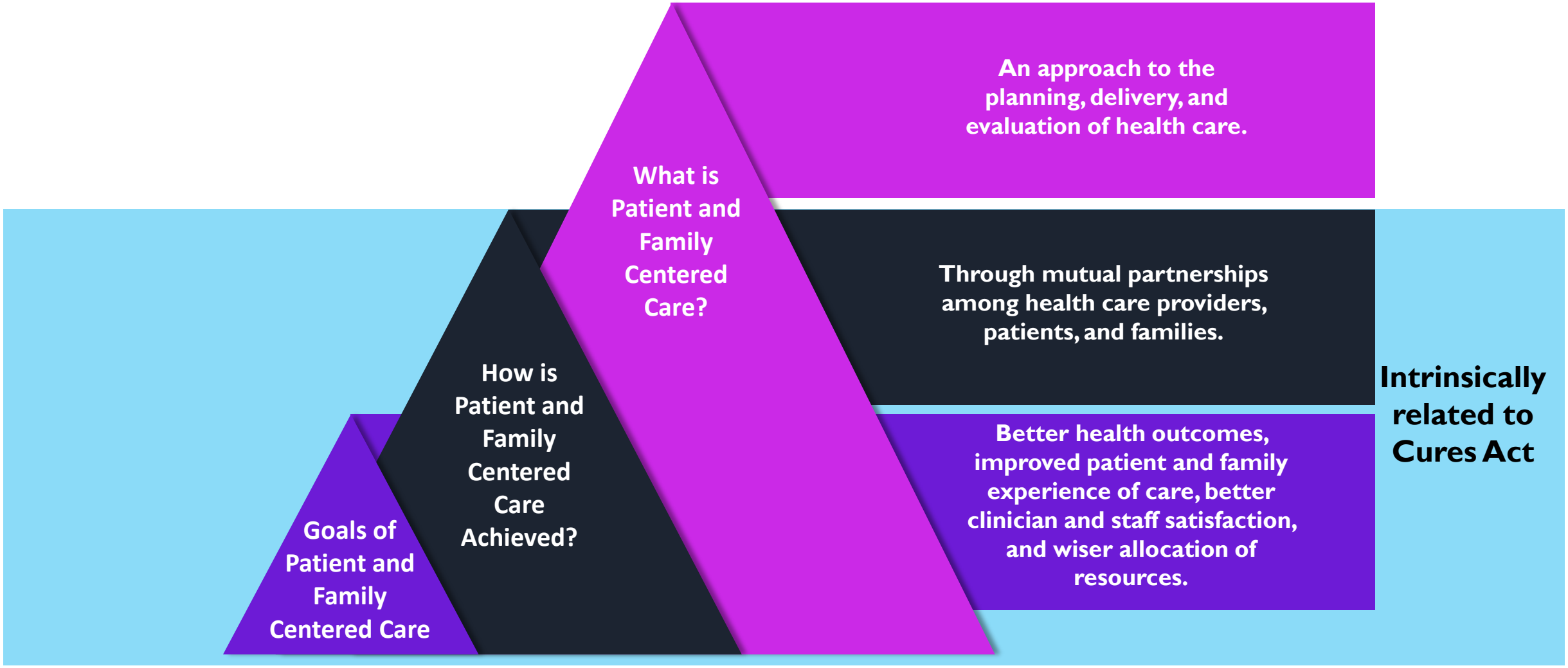
PATIENT – AND FAMILY – CENTERED CARE

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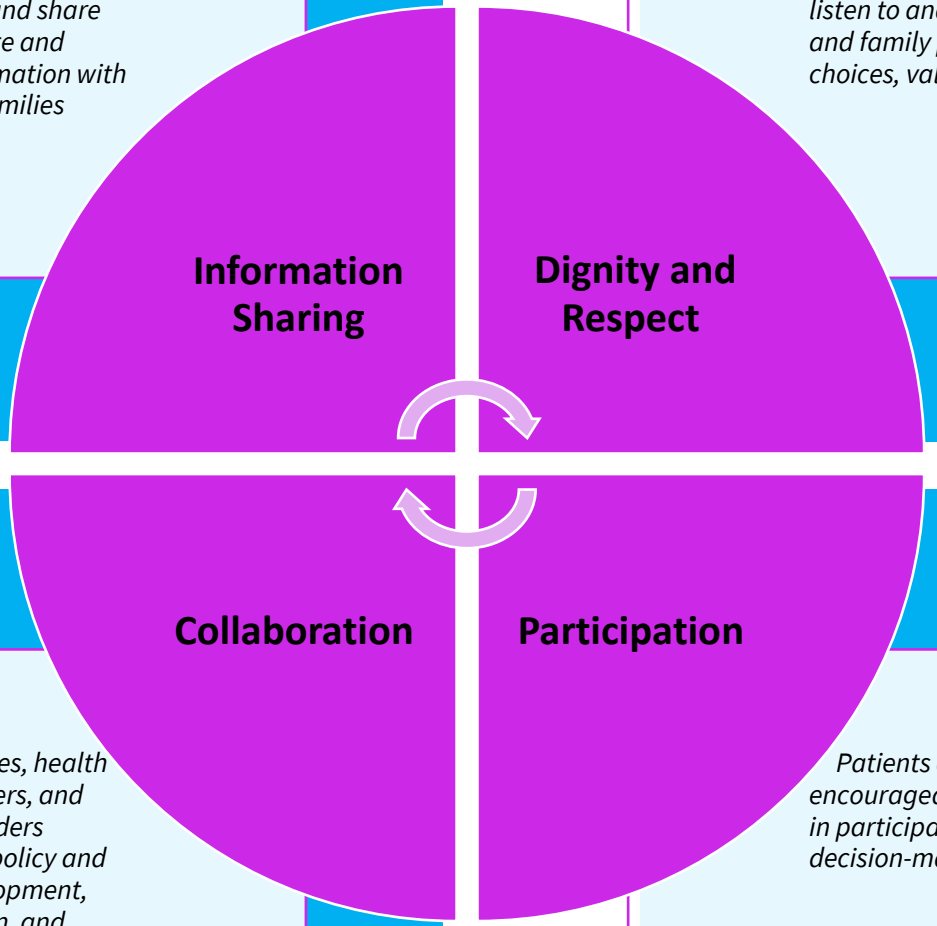
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PATIENT- AND FAMILY-CENTERED CARE



CORE CONCEPTS OF PATIENT- AND FAMILY-CENTERED CARE

ALIGNING TO THE CURES ACT



- **Information is power**
- **Proactively provides information to anticipate needs**
- **Provides electronic written access to documentation, plan of care and instructions**
- **Fosters timely provider communication to patients and families**

- *Health care practitioners communicate and share timely, complete and unbiased information with patients and families*

- *Health care practitioners listen to and honor patient and family perspectives, choices, values and beliefs*

- **Transparency and enhanced communication builds trust between care team, patients and families**

- **Fosters partnership with care team**
- **Promotes dialogue with providers**

- *Patients, families, health care practitioners, and health care leaders collaborate in policy and program development, implementation, and evaluation*

Patients and families are encouraged and supported in participating in care and decision-making

- **Promotes patient ability to be an informed consumer**
- **Affords a sense of participation in one's own care**
- **Prompts specific questions to care team**
- **Infuses voice of patient and family in decision making**



WITH THE PANEL

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