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DOCTORS Rx

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OPEN NOTES:

ARE YOU AND YOUR PATIENT ON THE SAME PAGE?

find out...

- What the Open Notes Rule is and how it applies to you
- What information blocking is and its exceptions
- Key recommendations to implement in your practice

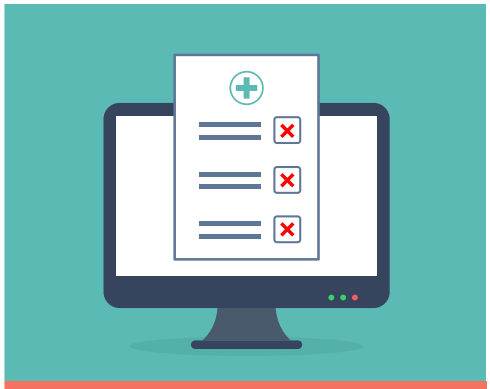
A LETTER FROM THE CHAIR OF THE BOARD

Dear Colleague:

The 21st Century Cures Act was designed to support seamless and secure access, exchange, and use of electronic health information. This edition of the *Doctors RX* newsletter will take a look at the Cures Act and its companion "Open Notes" regulation and how they affect you and your patients moving forward.

George S. Malouf, Jr., M.D., FACS
Chair of the Board
MEDICAL MUTUAL Liability Insurance Society of Maryland
Professionals Advocate Insurance Company

ISSUE HIGHLIGHTS



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OPEN NOTES: ARE YOU AND YOUR PATIENT ON THE SAME PAGE?

Consider this: *One of your patients, a pack-a-day smoker for the past 20 years, calls your office. He has seen his electronic medical record (EMR) and is demanding you change it to reflect that he only "occasionally" smokes cigarettes. He threatens to file a complaint if you do not comply. You think: my record is accurate, and I know his smoking history, how can he demand his record be changed? Did I release too much patient information? What information needs to be disclosed to a patient, and should I keep certain electronic health information (EHI) from my patients? Can I keep my records intact, or do I need to adopt the request?*

On April 5, 2021, provisions of the 21st Century Cures Act went into effect, mandating that certain EHI be made available to patients. In this issue of *Doctors Rx* we will provide answers to these questions by discussing the 21st Century Cures Act and its companion regulation, the Open Notes Rule.[1] You will be able to determine who is subject to the requirements of the Open Notes Rule, identify what types of notes must be made available to patients, define information blocking and its exceptions, and provide general recommendations and tips for handling patient challenges to EHI that may arise under the Open Notes Rule.

I. WHAT IS THE OPEN NOTES RULE?

By way of background, on December 13, 2016, House Rule 34, also known as the 21st Century Cures Act, was signed into law.[2] The Act promotes and funds several health research and development initiatives including providing greater access to EHI. Specifically, with respect to EHI, the stated purpose of the law was to "encourage the exchange of health information," and "encourage partnerships between health information exchanges and others to offer patients access to their electronic health information."[3]

To further EHI access, Federal Rules, known as the Open Notes Rule, went into effect on April 5, 2021. The Open Notes Rule specifies eight types of clinical notes that are considered EHI that must not be blocked and that must be made available free of charge to patients, with limited exceptions.[4] Failing to make this information available without an applicable "exception" may be deemed "information blocking," and may be subject to a penalty.[5]

II. DOES THE OPEN NOTES RULE APPLY TO YOU?

The Open Notes Rule governs the access and availability of a patient's EHI.[6] The specific definition of electronic health information is involved, but generally speaking, the Open Notes Rule likely applies to you if you are a health care provider and you use an EMR.[7] Health care providers include but are not limited to: Physicians, practitioners, clinicians, hospitals, skilled nursing facilities, nursing facilities, home health entities, and health care clinics.[8]

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Note

Physicians who practice in an office setting should contact their office manager or EMR vendor to ensure that they and their offices are following the Open Notes Rule and all future amendments to it.

The Open Notes Rule does not solely apply to and govern health care providers. Other "actors" including health information networks or health information exchanges and health information technology developers are subject to the Open Notes Rule.[9]

Physicians who practice in an office setting should contact their office manager or EMR vendor to ensure that they and their offices are following the Open Notes Rule and all future amendments of the Open Notes Rule.[10]

Hospitals, nursing facilities, surgical centers, and similar entities already should be ensuring compliance and that the required data elements outlined in Section III are available to patients. Physicians should determine whether they are subject to any entity-specific policies and procedures to ensure compliance with those policies and procedures and the Open Notes Rule.[11]

III. WHAT DOES IT MEAN TO YOUR PRACTICE?

A. What do you need to make available?

Pursuant to the Open Notes Rule, at a minimum, there are several EHI items that must be made available to the patient. For example, clinical notes, medications, smoking status, vital signs and other items. For a more detailed description, consult the chart on this page.

Additionally, the Open Notes Rule, identifies eight types of clinical notes that generally must be made available as follows:[14]

1. *Consultation Note* – "contains the response to request from a clinician for an opinion or advance from another clinician"
2. *Discharge Summary Note* – "a synopsis of a patient's admission and course in a hospital or post-acute care setting"
3. *History and Physical* – "documents the current and past conditions and observations of the patient"
4. *Imaging Narrative* – "contains a consulting specialist's interpretation of diagnostic imaging data"
5. *Laboratory Report Narrative* – "contains a consulting specialist's interpretation of the laboratory report"
6. *Pathology Report Narrative* – "contains a consulting specialist's interpretation of the pathology report"
7. *Procedure Note* – "encompasses non-operative procedures including interventional cardiology, gastrointestinal endoscopy, osteopathic manipulation, and other specialty's procedures" (Please note, operative notes are to be made available – this category is intended to encompass non-operative procedures.)
8. *Progress Note* – "represents a patient's interval status during a hospitalization, outpatient visit, treatment with a post-acute care provider, or other health care encounter"

Pursuant to the Open Notes Rule, at a minimum and subject to some exceptions, the following EHI items are to be made available to a patient:[12]

- *Allergies and intolerances*
- *Assessment and plan of treatment*
- *Care team member(s)*
- *Clinical notes*
- *Goals*
- *Health concerns*
- *Immunizations*
- *Laboratory tests/values/results*
- *Medications*
- *Patient demographics*
- *Problems*
- *Procedures*
- *Provenance*
- *Smoking status*
- *Unique device identifier for a patient's implantable device*
- *Vital signs*

Physicians are reminded that psychotherapy notes and "information complied in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding, [are] not EHI, and not to be made available to the patient."[13]

In the future, Physicians should be on the lookout for changes to regulations expanding the types of information that must be shared with patients.[15]

25%
OF DOCTORS
HAVE FOUND THAT PATIENTS HAVE IDENTIFIED ERRORS THAT THEY, THE DOCTORS, FELT WERE SERIOUS.

SOURCE: https://www.opennotes.org/opennotes-for-health-professionals/

B. Avoid information blocking

Information blocking is formally defined as "a practice that is likely…to interfere with access, exchange, or use of electronic health information."[16] The determination of whether information blocking has occurred depends upon the "actor" alleged to have committed the information blocking.[17] Physicians will have committed information blocking if "such provider knows that such practice is unreasonable and is likely to interfere with access, exchange, or use of electronic health information."[18]

1. Information blocking exceptions

Not all alleged interference with access, exchange, or use of EHI is considered information blocking.[19] There are eight established "exceptions."[20] In other words, if the conditions of any *one* of the eight "exceptions"apply, the health care provider is deemed to *not* have committed information blocking.[21] These exceptions typically are split into two categories – "exceptions that involve not fulfilling requests to access, exchange, or use electronic health information" and "exceptions that involve procedures for fulfilling requests to access, exchange, or use electronic health information."[22]

There are five exceptions that involve not fulfilling requests to access, exchange, or use EHI:

1. Preventing harm exception;
2. Privacy exception;
3. Security exception;
4. Infeasibility exception; and
5. Health information technology performance exception.[23]

There are three exceptions that involve procedures for fulfilling requests to access, exchange, or use EHI:

6. Content and manner exception;
7. Fees exception; and
8. Licensing exception.[24]

Health care providers should be aware of these exceptions and their conditions to avoid information blocking and to know when an exception can or should be employed.

One exception that likely will be most applicable for Physicians of all specialties is the preventing harm exception. Under this exception, it will *not* be information blocking if a health care provider *"engage[s] in practices that are reasonable and necessary to prevent harm to a patient or another person provided certain conditions are met."*[25] In summary, organizations and practices can deny EHI requests to protect patients from harm. However, the potential risk and harm that would trigger this exception must be appropriately documented.[26] A Physician's practice that does not meet the conditions of an exception will *not* automatically constitute information blocking; however, as we will see below, information blocking will be assessed on a case-by-case basis.[27]

2. Information blocking is assessed on a "case-by-case" basis

Instances of information blocking are assessed on a "case-by-case" basis and require an assessment of whether:

1. The individual or entity engaging in the practice is an "actor" as defined in 45 C.F.R. §171.102;
2. The claim involves [electronic health information] as defined in 45 C.F.R. §171.102;
3. The practice was required by law;
4. The actor's practice met the conditions of an exception under 45 C.F.R. §171;
5. The practice rose to the level of an

Did you know?

One exception that likely will be most applicable for Physicians of all specialties is the preventing harm exception.

Documentation

Documentation is an essential part of clinical care. Its importance does not change because of the Open Notes Rule. But Physicians may want to consider how they document since notes will be made available to patients.

interference under 45 C.F.R. §171; and

6. The actor met the requisite knowledge standard.[28]

Future rulemaking will "establish appropriate disincentives" for health care providers engaging in information blocking.[29]

3. Examples of interference

Because instances of information blocking are assessed on a case-by-case basis, examples of what would likely be deemed to be interference and what would likely *not* be interference may be instructive. Here are a few examples:

Unlikely to be an interference – If the release of EHI is delayed to ensure that the release complies with state law. However, any delay "should not be any longer than necessary." Longer delays might be possible if the release involves manual retrieval of EHI.

Likely to be interference – If a health care provider established an organizational policy that imposed the delay of the release of any lab results to review them before they are made available to the patient.

These examples are instructive for identifying and formulating policies and best practices. For additional information, please consult **healthit.gov/curesrule/resources/information-blocking-faqs** that accompanies this newsletter for more "Information Blocking FAQs."

C. Practice "pointers"

The Open Notes Rule contemplates and introduces numerous practice "pointers." Several medical boards, associations, and journals provide their own recommendations, guidance, and input.[30] Specific practice points will vary based upon the type of medicine that a Physician practices and the setting in which they practice. Physicians should consider reviewing any recommendations, practice guidelines, or guidelines issued for their respective fields of practice.

This section considers and expounds upon two practice points that are applicable to many Physicians across specialties and settings.

1. Documentation, documentation, documentation

The first practice point involves considerations regarding documentation in light of the Open Notes Rule.

77–87%

of patients in one study said that accessing their notes made them feel more in control of their health care

SOURCE: https://www.opennotes.org/opennotes-for-health-professionals/

Documentation is an essential part of clinical care. Its importance does not change because of the Open Notes Rule. But Physicians may want to consider *how* they document since notes will be made available to patients.[31] As an example, the following "tips" have been suggested from the *FPM Journal:*[32]

a) **Be transparent.** Your communication with the patient in the office should reflect what you put in the note. There should be no surprises.

b) **Minimize jargon and abbreviations.** If there are medical terms that patients might easily misinterpret, briefly define or simplify them, such as "short of breath," rather than SOB or dyspneic.

c) **Highlight the patient's strengths and achievements in addition to the patient's problems.** This can be particularly helpful for patients with mental health issues because it gives them a more balanced perspective of their illness as they tackle difficult behavioral changes.

d) **Describe behaviors rather than labeling the patient or making judgments.** For example, consider these alternatives:
   - "Patient could not recall" instead of "Poor historian"
   - "Patient is not doing X" instead of "Non-compliant"

- "Patient prefers not to" or "Patient declines" instead of "Patient refuses"

Keep in mind that ensuring accuracy and completeness of notes is imperative, regardless of the Open Notes Rule. Referring to the scenario above, while the Open Notes Rule requires certain EHI to be made available to patients, it does *not* give them the right to bully or threaten the Physician into changing their records. Under the Health Insurance Portability and Accountability Act (HIPAA) a patient can request changes to their records and must do so in writing; however, a Physician is not required to make the change in the record if they determine the record is "complete and accurate."[33] Documentation is essential in these situations as you must document the request and the reasoning behind not adopting the requested change.

2. Results made available before Physician interpretation

The second practice point examines implications of and considerations regarding patients having access to their results (imaging studies, pathology studies, lab work, etc.), before a Physician reviews or even interprets these results.

As mentioned previously, "an organizational policy that, for example, imposed delays on the release of lab results for *any* period of time in order to allow an ordering clinician to review the results or in order to personally inform the patient of the results before a patient can electronically access such results" would likely be an interference and therefore may be information blocking if all other criteria are met.[34] Physicians may want to consider implementing policies or procedures to identify whether such access in a specific case may, for example, meet any information blocking exceptions before making the EHI available.

Physicians also may consider engaging in dialogue with patients regarding imaging studies, pathology studies, or lab work *before* they are performed or incorporating standard language to accompany results before Physician interpretation to notify patients that Physician interpretation and input is forthcoming.[35]

The American Neurology Association, for example, recommends as follows:[36]

[C]onsider working with [the] healthcare administrative leadership and Physician colleagues for standardized language to be included as part of clinical notes and patient portal disclaimers and for policies to handle rare exemptions. Discuss with patients upfront prior to ordering a test (imaging or lab) about what you are looking for and what the next steps are if the test is either 'positive' or 'negative.'

IV. RECOMMENDATIONS

What follows is a list of general guidance and recommendations for health care providers in light of the Open Notes Rule:[37]

1. Know whether the Open Notes Rule

Consider

Physicians also may consider engaging in dialogue with patients regarding imaging studies, pathology studies, or lab work before they are performed or incorporating standard language to accompany results before Physician interpretation to notify patients that Physician interpretation and input is forthcoming.

Remember

Be mindful that while the record is yours, you are not the sole audience and patients can access it in real-time.

applies to you.

2. If it applies to you, contact your office manager or EMR provider to ensure that you are making the required EHI available to your patients and otherwise complying with the Open Notes Rule.
3. If you work at a hospital, nursing facility, etc., determine whether specific policies or procedures exist based upon the Open Notes Rule and ensure your compliance with those policies and procedures.
4. Know the exceptions criteria to the information blocking rule and consider implementing policies, guidelines, and procedures if not already in place to identify and address potential exceptions on a case-by-case basis.
5. Be mindful that while the record is yours, you are not the sole audience and patients can access it in real-time. Use your notes as an opportunity to detail the visit, clearly document the history of present illness, review of systems, physical examination, and explain your thought process in a way that will be helpful to other providers and your patients alike.
6. Document requests from patients to change the record. If the record is complete and accurate, remember that you do not have to make the change. Always document why you did or did not make the change requested by the patient.

references

[1] See generally ONC Interim Final Rule. www.healthit.gov/cures/sites/default/files/cures/2020-10/IFC_FactSheet_Information_Blocking.pdf

[2] See H.R. 34 – 21st Century Cures Act (2016) available at https://www.congress.gov/bill/114th-congress/house-bill/34

[3] See supra at fn 2.

[4] See generally supra at fn 1.

[5] See id.

[6] See id.

[7] See 85 FR 25642 (VIII)(B)(3)(C)(2)(c)(3)

[8] See Cures Act Final Rule: Information Blocking Actors available at https://www.healthit.gov/cures/sites/default/files/cures/2020-03/InformationBlockingActors.pdf

[9] See id.

[10] See American Medical Association: How do I comply with info blocking and where do I start? Available at https://www.ama-assn.org/system/files/2020-11/info-blocking-compliance.pdf

[11] See id.

[12] See 85 FR 70064 (II)(4)(B)(1) (adopting USCDI v1); see also United States Core Data for Interoperability (USCDI) available at https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#uscdi-v1

[13] 45 CFR 171.102.

[14] See United States Core Data for Interoperability (USCDI) available at https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#uscdi-v1

[15] See New Applicability Dates included in ONC Interim Final Rule available at https://www.healthit.gov/cures/sites/default/files/cures/2020-10/Highlighted_Regulatory_Dates_Information_Blocking.pdf

[16] See 45 CFR 171.103.

[17] See id.

[18] See 45 C.F.R. § 171.103(a)(3).

[19] See Cures Act Final Rule: Information Blocking Exceptions available at https://www.healthit.gov/cures/sites/default/files/cures/2020-03/InformationBlockingExceptions.pdf

[20] See id.

[21] See id.

[22] See id.

[23] See id.

[24] See id.

[25] See id.

[26] Slivochka, S. & Warner, D. (2021, May 11). Understanding the eight exceptions to information blocking. Journal Of AHIMA. Retrieved October 14, 2021, from https://journal.ahima.org/understanding-the-eight-exceptions-to-information-blocking/

[27] See Cures Act Final Rule: Information Blocking Exceptions available at https://www.healthit.gov/cures/sites/default/files/cures/2020-03/InformationBlockingExceptions.pdf

[28] Information Blocking FAQs available at https://www.healthit.gov/curesrule/resources/information-blocking-faqs

[29] See id.

[30] See, e.g. Quick Tips: A Blog from FPM Journal available at https://www.aafp.org/journals/fpm/blogs/inpractice/entry/open_notes.html ; see also American Academy of Neurology: Sharing Information Electronically with Patients available at https://www.aan.com/practice/practice-management/health-information-technology/electronic-health-records/notes-release-toolkit/ ; see also American Optometric Association: New Rules Ahead for Patient Access to Electronic Health Records available at https://www.aoa.org/news/practice-management/perfect-your-practice/new-rules-ahead-for-patient-access-to-electronic-health-records?sso=y ; see also American Medical Association: What is information blocking? available at https://www.ama-assn.org/system/files/2021-01/information-blocking-part-1.pdf ; see also American Medical Association: How do I comply with info blocking and where do I start? Available at https://www.ama-assn.org/system/files/2020-11/info-blocking-compliance.pdf

[31] See, e.g. Quick Tips: A Blog from FPM Journal available at https://www.aafp.org/journals/fpm/blogs/inpractice/entry/open_notes.html

[32] Id.

[33] JainH. (2020, January 30). Patient rights explained: Amendment of records. HIPAAtrek. Retrieved October 21, 2021, from https://hipaatrek.com/amendment-of-records/

[34] Information Blocking FAQs available at https://www.healthit.gov/curesrule/resources/information-blocking-faqs

[35] American Academy of Neurology: Sharing Information Electronically with Patients available at https://www.aan.com/practice/practice-management/health-information-technology/electronic-health-records/notes-release-toolkit/

[36] See id.

[37] See e.g., American Medical Association: How do I comply with info blocking and where do I start? Available at https://www.ama-assn.org/system/files/2020-11/info-blocking-compliance.pdf

CME TEST QUESTIONS

1. *All* alleged interference with access, exchange, or use of EHI is considered information blocking and should be avoided.

   A. True B. False

2. The Open Notes Rule solely applies to health care providers.

   A. True B. False

3. *How* a Physician documents a patient record becomes important due to notes being made available to patients.

   A. True B. False

4. Physicians should *describe* patient behavior rather than labeling or making judgments.

   A. True B. False

5. Physicians may wish to incorporate standard language to accompany lab results, imaging studies, and pathology reports to let patients know Physician interpretation is forthcoming.

   A. True B. False

6. Only highlight patient problems to get their attention.

   A. True B. False

7. Instances of information blocking are assessed on a "case-by-case" basis.

   A. True B. False

8. Physicians should not worry about the "preventing harm" exemption to information blocking since it does not apply to them.

   A. True B. False

9. The Open Notes Rule prevents access to and availability of a patient's EHI.

   A. True B. False

10. Physicians will have committed information blocking if they know the practice is unreasonable and is likely to interfere with access, exchange, or use of EHI.

    A. True B. False

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1. One of our goals is to assess the continuing educational needs of our readers so we may enhance the educational effectiveness of the *Doctors RX*. To achieve this goal, we need your help. You must complete the CME evaluation form to receive credit.
2. Completion Deadline: March 31, 2022
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Doctors RX is a newsletter sent twice each year to the insured Physicians of MEDICAL MUTUAL/Professionals Advocate.® Its mission and educational purpose is to identify current health care-related risk management issues and provide Physicians with educational information that will enable them to reduce their malpractice liability risk.

Readers of the newsletter should be able to obtain the following educational objectives:
1) Gain information on topics of particular importance to them as Physicians
2) Assess the newsletter's value to them as practicing Physicians
3) Assess how this information may influence their own practices

CME Objectives for "Open Notes: Are You and Your Patient on The Same Page"

Educational Objectives: Upon completion of this enduring material, participants will be better able to:
1) Understand the Open Notes Rule and what it means for your practice.
2) Learn what needs to be disclosed in real time and what constitutes "information blocking."
3) Learn "practice pointers" to implement in your practice to help ensure compliance with the Open Notes Rule.

	Strongly Agree				Strongly Disagree
Part 1. Educational Value:	5	4	3	2	1
I learned something new that was important.	❑	❑	❑	❑	❑
I verified some important information.	❑	❑	❑	❑	❑
I plan to seek more information on this topic.	❑	❑	❑	❑	❑
This information is likely to have an impact on my practice.	❑	❑	❑	❑	❑

Part 2. Commitment to Change: What change(s) (if any) do you plan to make in your practice as a result of reading this newsletter?

_____

_____

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Part 3. Statement of Completion: I attest to having completed the CME activity.

Signature:_____ Date:_____

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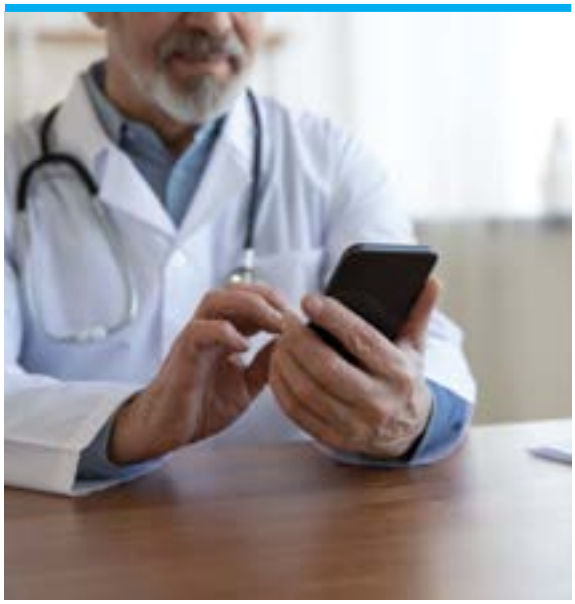

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THE BEST OF BOTH WORLDS: NEW EDUCATION SCHEDULE FORMAT FOR 2022

We have received positive feedback from Insureds and presenters on both the in-person and online learning formats. Therefore, the 2022 Risk Management Education Program will be offered via a hybrid schedule in 2022. Some courses will return to an in-person event while others will be offered via live webinar as in 2021. From the topics covered to the learning formats available, MEDICAL MUTUAL and Professionals Advocate are attuned to the needs of our Physicians. The 2022 education schedule will be announced in February 2022.

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