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How Will the 21st Century Cures Act Affect Genetic Counseling and Testing Services?

A MY GENE COUNSEL REPORT

The Office of the National Coordinator for Health Information Technology

The ONC 21st Century Cures Act Final Rule gives patients immediate digital access to their health data – including their genetic information. This report is based on a webinar[1] hosted by My Gene Counsel that examined what this rule may mean for genetic counseling and testing services.

My Gene Counsel is a digital health company whose mission is to ensure that patients and healthcare providers have access to accurate, scalable genetic counseling information that updates over time. The 21st Century Cures Act was of great interest to us; however, as we started to dig in, we found that it was evolving and murky. We searched for industry leaders who could help us forge a path towards understanding and brought together a virtual panel of experts, moderated by Ellen Matloff, President and CEO of My Gene Counsel, for an open discussion.

Topics covered included:

- An overview of the Cures Act as it applies to genetic and genomics services
- Stakeholders that must consider this legislation, including laboratories, genetic counselors, physicians, health IT developers, and payers
- What to consider in formulating plans for compliance and to avoid information blocking
- How the landscape may evolve over time

This report is a written transcript of the panel presentation that took place on May 19, 2021 and the audience question-and-answer session that followed. It has been edited for length and clarity.

A very special thank you to our speakers for leading the way and helping us anticipate what to expect in this evolving environment with the 21st Century Cures Act.

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TERM	DEFINITION
The Office of the National Coordinator for Health Information Technology (ONC)	The principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information.
Electronic Health Information (EHI)	Medical chart notes, lab reports, test results, imaging, and other protected medical records; does not include psychotherapy notes or information compiled for a civil, criminal, or administrative action or proceeding.
Information Blocking	A practice likely to interfere with access, exchange, or use of EHI.
Application Programming Interface (API)	A software intermediary that allows two applications to talk to each other.
Actor	A healthcare provider, health IT developer, health information network, or health information exchange.
Interoperability	Standardized methods to access EHI, including using health information networks to provide patient records via smartphone apps; allows apps to interface through an API to transmit EHI.
Genetic Exceptionalism	The belief that genetic information is qualitatively different from other health information and requires enhanced privacy and security in the electronic health record.
United States Core Data for Interoperability (USCDI)	A standardized set of health data classes and constituent data elements for nationwide interoperable health information exchange.
Health Level Seven (HL7)	A standards developing org dedicated to providing a comprehensive framework for exchange, integration, sharing, and retrieval of EHI that supports clinical practice and management, delivery, and evaluation of health services.

OVERVIEW

JOHN RICHARDSON: Here are some helpful definitions we thought everyone should be familiar with when we are talking about the Cures Act and what it means for the exchange of electronic health information (EHI).

An "actor" is a term everyone should familiarize themselves with. Healthcare provider is defined in a very broad sense. It means a hospital, laboratory, physician practice, physician, or nurse practitioner. Many different practitioners are listed under the statute. Most people providing healthcare services are considered "actors." Genetic counselors are not actually listed in the statute, but they are not excluded either. For the benefit of these conversations, genetic counselors should assume they are going to be considered "actors."

The 21st Century Cures Act was a very large bill that did a lot of great things. It provided funding to accelerate medical product development, it addressed the opioid crisis, and it improved mental health service delivery. Today, we are talking about empowering patients by improving healthcare IT to allow patients access to their health records in an easy-to-understand, secure, and automatic way.

The Cures Act Final Rule regarding electronic health information focuses on transparency. It puts patients in charge of their health records to ensure transparency into the cost and outcomes of their care, competitive options in getting medical care, and adoption of standardized methods to access these records, including the use of health information networks that can provide patient records via smartphone apps. It is really about transparency and empowering people to access their health information.

INFORMATION BLOCKING

JOHN RICHARDSON: Under the Cures Act Final Rule, you cannot interfere with patients' access, exchange, or use of their personal electronic health information. It is considered an unacceptable practice with penalties for non-compliance unless certain exception provisions are met. There are fines involved. The fines for providers have not been announced yet, but this is serious business, and you need to allow patients to have access to their electronic health information. This went into effect on April 5, 2021 for providers, health IT developers, health information networks, and health information exchanges. The act is now implemented, and people need to be aware of it and take it seriously.

INFORMATION BLOCKING EXCEPTIONS			
PRIVACY	**SECURITY**	**PREVENTING HARM**	**INFEASIBILITY**
Needed to protect an individual's privacy in compliance with state and federal privacy laws.	Needed to reasonably protect the security of EHI in compliance with state and federal security rules.	Practices that are reasonable and necessary to prevent harm to patients or other persons.	Not feasible due to legitimate practical challenges (e.g., internet disruption, natural disasters).
HEALTH IT PERFORMANCE	**FEES**	**CONTENT AND MANNER**	**LICENSING**
Temporarily necessary to upgrade and maintain IT systems (e.g., planned downtime for Epic upgrades).	Limited to charging reasonable fees to develop technologies and services to enhance interoperability.	Limited to EHI content that's beyond the requirements in terms of scope and method of access, exchange, or use.	Related to protecting the value of innovations and charging reasonable royalties to earn ROI on interoperability tools.

There are some exceptions to information blocking[2]: Privacy, Security, Preventing Harm, Infeasibility, Health IT Performance, Fees, Content and Manner, and Licensing. Today, we are going to focus on the preventing harm exception because that is going to affect a lot of you and how you deliver information.

The preventing harm exception is likely to have the most impact on the genetics community. This exception states that 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 conditions are met. The objective of the preventing harm exception recognizes that the public interest in protecting patients and other persons against unreasonable risk of harm can justify practices that are likely to interfere with access, exchange, or use of electronic health information.

There are four requirements needed to demonstrate risk, and the exception cannot be overly broad. It must satisfy at least one of these conditions: (1) be determined by a treating clinician to present an individualized risk of harm to a specific patient; (2) meet the requirements under HIPAA to limit a specific individual's right to access protected health information (PHI); (3) be consistent with an organizational policy that is based on a known or reasonable belief by experts that the practice is needed to prevent significant harm; or (4) be related to data that is known or reasonably suspected to be misidentified, corrupt, or erroneous. If you are going to block information, the patient has the right to request a review to determine what harm would be in place if you were to block this information from that patient.

At the heart of information blocking should be a written organizational policy that permits limitations to the access, exchange, or use of electronic health information on a systematic basis. If you are going to block certain types of information, you have to have this policy. For healthcare providers and other actors, the organizational policy is very important for you to understand. You may have been involved in developing these policies; hopefully, you were. If you are not aware of your organizational policy, definitely talk to your compliance office. If you think it is reasonable, that's great. If you think it is unreasonable, then open up a discussion because this is going to evolve.

In real-world practice, people will have a greater understanding of what is working and what is not for both patients and practitioners. There may be changes down the road that will ensure patients are receiving timely information that they can understand and that reduces the risk of harm. When there is an increased risk of harm, there is a way to put some brakes on the process so that patients are not receiving information in real-time. This theory of patient harm is really the key to your organizational policy that may allow some of this information to be blocked.

IMPACT ON GENETIC TESTING LABORATORIES

KIM LINTHICUM: With regard to what is an "actor" and how laboratories fit into this, some forget that we are providers in the space, even though we are providing a service that is ordered by another clinician. Laboratories are "actors" under the final rule, and we need to comply with patient requests.

A common question is: Are we required to push results out proactively when they're completed? The answer is, no. Results are not required to be proactively provided to patients. We do believe patients will increasingly be able to access their results at the same time as the ordering clinician. It is an important timing factor to understand.

Patient portals are not required but will likely be established because the overall goal of this act is to increase interoperability. This information can provide a lot of empowerment to patients, so I think patient portals will be more likely in the future.

The preventing harm exception will be directed by the ordering clinician and judged on a case-by-case basis. The idea that a particular type of lab result will, across the board, be something that could cause harm, is not likely to meet that exception. As laboratorians, we will be looking to the clinician who has requested the result and is using it in the treatment and care of a patient in order to make that case-by-case decision.

The final rule does not supersede state laws, although the HIPAA Privacy Rule[3] remains. We are all familiar with a request for records and a designated record set under HIPAA, and that stays in place, but think of that as the far bookend. If a state law were to be in contrast with HIPAA, then HIPAA would take the place of it.

As "actors" who may be operating in multiple states, we are permitted to adopt uniform policies to implement consistently across the organization. The laboratory could choose to comply with the laws of each state they work in or with the most restrictive laws. What is important is that it be in the standard operating procedure of the laboratory and be implemented consistently. If you had a particular state that said you could not provide results in a certain time period, you could take that and apply it across the board. A laboratory could choose to look at test results on a state-by-state basis and apply those individual state laws as they come.

BRIDGING LABORATORIES AND CLINICIANS

KIM LINTHICUM: Let's touch on how to bridge the gap between laboratories and those involved in ordering and/or discussing genetic test results with patients. Delaying results to patients until after a clinician reviews them constitutes as interference and non-compliance under the final rule, unless there are state laws you are looking to adhere to. Laboratories may be caught between the ordering clinician and the patient. Education is the key to reducing this friction and ensuring everybody has a good experience.

From a Myriad Genetics' perspective, we have added notifications to our websites and ordering portals about the Cures Act. Our test results are still sent to the ordering clinician first. We have no change to how ordering clinicians receive test results under the final rule.

Our experience is that patients typically request a copy of their test results after first speaking to their provider. Patients who are unable to get in touch with their provider and are anxious about their results may request them directly from the laboratory. If the provider is on vacation or just busy and has not gotten back to them yet, that is where labs get a lot of direct requests. We have not seen a huge increase in patient requests as a result of the final rule, but we have seen a small increase over time.

IMPACT ON GENETIC COUNSELORS

CORI FEIST: I want to speak about some of the potential impacts of the final rule on clinical practitioners, particularly genetic counselors. It is important to understand that there is evidence that enabling patients to have open access to their records actually improves the provider-patient relationship and patient engagement, as well as their treatment and medication adherence. It can remove some of the barriers to equitable treatment because it allows patients to better understand their medical records, and this appears to be especially true for patients with lower education or health literacy.

Genetic counselors have a unique skill set that allows them to be especially successful in regard to the final rule. The priority of genetics providers has always been on communication with patients and patient advocacy, so the training of a genetic counselor allows us to uniquely meet the goals of the Cures Act.

Personally, my concern was that I was not going to be able to get my patients' results back in a timely manner and that they might see their test results before I did. Patients might misunderstand these results, but that is really not anything new to us in the genetics field. The final rule highlights the importance of well-trained genetic counselors, who can help seamlessly transition and advocate for their patients. I encourage you not to fear the final rule but to remember that its ultimate goal is to give patients the right to their own medical information and to improve their experience.

There are two major ways this rule is going to impact genetic counselors. First, how will it impact our clinical practice? And second, how will it impact us from a legal compliance perspective? In order to successfully navigate the Cures Act, genetic counselors need to prepare patients in advance that they may see appointment notes or letters as soon as they leave clinic. They may see lab results, including genetic and genomic test results, pathology results, or imaging results before their ordering provider or genetic counselor.

I realize that not all genomic and genetic testing is equal. For example, a carrier screening test is not the same as a predictive test result for Huntington's disease. The responsibility of genetic counselors will be to work with their organization to create policies that respect the differences between certain results or categories of results. We have a different perspective and skill set than individuals in the legal and compliance departments, and they may appreciate our input in creating these policies.

It is important for those working in a clinical setting to reach out to your employer, whether that is a hospital, medical facility, or private clinic, to find out how they are interpreting the final rule. It seems to be interpreted differently depending on the institution or provider. Reach out to your legal or compliance departments or privacy office. What do they know about the final rule? What policies do they have in place? You may need to speak with the director of your laboratory or pathology department or your EMR heads to get more information to ensure you are compliant with your organization's policy.

In regard to the final rule's impact on clinical practice, I recommend that you read the American College of Medical Genetics and Genomics 2020 Points to Consider Statement[4]. This is an excellent paper that supports patient access to their healthcare information but advocates that the information be clear and useful to the patient. For example, they state that results should be in a form that is reasonable and that a patient can understand and utilize. Test reports should be electronically linked to a clinician note to aid in the interpretation of results and to clarify if a clinical diagnosis has been made. Since the interpretation of test results might evolve over time through reanalysis or reclassification of variants, new interpretations should be time stamped, stating that they supersede any prior reports.

The NSGC Public Policy Committee was asked to write a Final Rule FAQ[5] for our membership. In preparing this document, members of our task force interviewed genetic counselors who work in clinical settings throughout the United States and asked: How is your institution or your employer preparing to comply with the final rule? What policies and procedures do you already have in place? And we realized that everyone is doing something a little bit differently, and when we recontacted them, sometimes those policies had drastically changed. This is an evolving process, and the ONC and Congress know that.

> *"In a free society, individuals have a right to govern their own health care decisions, and as such, should have direct access to view and utilize their own test results, including genetic information."*
>
> **ACMG Statement**

PUTTING THEORY INTO PRACTICE

CORI FEIST: Here are some examples of organizational policies, what they are considering to be exceptions to information blocking, and how they are interpreting the final rule. This is not an endorsement in any way.

There is an institution in the Pacific Northwest that uses an electronic medical record called Epic. Their patients have access to MyChart. All labs, pathology reports, and imaging notes are released to the patient through MyChart immediately upon finalization. So, once the provider or the laboratory releases those reports, the patient can see them. The only way for them not to be released immediately is for the provider to select "manual release" at the time of ordering or at the time of opening the chart note. Manual release means that they have decided that they meet one of the exceptions for information blocking. For clinicians, that is usually the preventing harm exception, which is going to be based on a provider's expertise and their personal clinician-patient relationship. It is going to be on a case-by-case or patient-by-patient basis. For lab testing, it will be on a lab-by-lab basis. You cannot just blanket say that any sort of prenatal genetic test result will be manually released. It has to be case-by-case, lab-by-lab, or patient-by-patient.

There is a facility on the east coast that is releasing most labs and X-rays within 24 hours, with some exceptions. They have a written organizational policy that states that any complex imaging, pathology results, sensitive lab results (e.g., sexually transmitted infection results), pregnancy tests, or drug screens will be released after seven days. They also have a policy currently under review to ensure it complies with the final rule, which is that all genetic tests results are released after a 45-day delay. They have made a specific policy for Huntington's disease results, which will be paper only and won't go into an electronic medical record.

Finally, in California, there is an institution that does things quite differently because their state law requires that abnormal results be given verbally, and they have decided that any prenatal genetic testing results will be "manual release." Pre-symptomatic testing results will be "manual release" as long as the provider feels it meets the preventing harm exception. Any labs that are performed internally will be delayed and will not go into the electronic medical record until 20 days have passed.

FUTURE DIRECTIONS

KIM LINTHICUM: We expect future revisions to the implementation of the Cures Act. The rule to impose civil monetary penalties for non-compliance has not yet been issued. Once that's finalized, that's something for us to be reviewing to understand how it will work. If folks are interested in filing complaints, there are ways to do that on the U.S. Department of Health and Human Services website and can be done anonymously. Again, how those will be adjudicated and whether or not fines are levied is still to come.

In general, we're seeing an increased focus on consumerism and technology in healthcare. The final rule requires interoperability between everyone in the healthcare space. In particular, there are segments of the rule that we have not talked about today that have to do with application programming interfaces (APIs). The goal here is to make sure everyone is talking in a similar language, so that things can be easily transferred from one system to another and so that information about your health, as a patient or provider, can be readily accessible and can be applied in various situations.

Apps will continue to be developed, driven by consumer demand. We're seeing healthcare systems and practices increasingly relying on apps. People want to condense information and make things easier on those patients and providers they might be working with across the entire care continuum. Another thing for us to watch for is what payers might be doing. Payers may end up requiring immediate transmission of lab results for patient apps. Systems like MyChart and Epic are meant to drive people toward a common language, so that the transmission of information can be standardized.

The other thing to be thinking about as we go forward is health disparity. We've seen a lot in telehealth during the pandemic to increase access to healthcare, but there are questions being debated in Congress right now about broadband access. Who has smartphones? Are they getting apps? Are they knowledgeable about those apps? Do they have internet? I think you'll see a lot more pairing of apps and additional information driven to patients as we get more digital and have more telehealth encounters.

Those are some things we wanted to tee up for future conversations and things to watch out for. We've already shared the NSGC Fact Sheet[5]. In addition, there is an entire website that the U.S. government has put together on the 21st Century Cures Act[6]. That is probably your best place to go for a trusted resource.

AUDIENCE QUESTIONS

Will Myriad Genetics establish a patient portal, and if so, will it provide results proactively or only if the patient requests it?

KIM LINTHICUM: For those who work with Myriad, you may get a different experience from us based on whether you are in mental health, women's health, or oncology. We have some channels where we release a result simultaneously to the patient through a patient portal. That tends to be on the women's health side, and the clinician is aware of that. We are definitely looking into patient portals. It is to be determined on when and whether we will have a uniform patient portal. To meet the compliance of this act, we are continuing to respond to patient requests for test results.

Does the result concept apply if the patient wants their raw sequencing data?

KIM LINTHICUM: This should fall under HIPAA. Raw sequencing data would not be part of the United States Core Data for Interoperability (USCDI)[7] standardized set of health data. Those requests could take longer to respond to, and we would manage that in accordance with HIPAA rules. It is outside of the final rule and compliance with electronic health information, as I understand it.

What if results are available but there is information that is incorrect or missing from the report? Are we required to release those results upon patient request?

KIM LINTHICUM: One of the questions that has come up from labs is that there could be an incomplete result. This may have to do with multiple types of lab results ordered at the same time and not all are complete. We're still waiting on a response from ONC with regard to that. If you know a result is wrong, I'm concerned about that being final. We'd have to look at that on a case-by-case basis.

Do you think that since patients may be able to see results immediately, it will lead to updating the wording of genetic test reports to make the language more patient friendly? Or do you think laboratories will team up with digital health companies, like My Gene Counsel, that handle those services for them?

KIM LINTHICUM: That is a great question as we see how the space evolves. I have not been involved directly in result report wording. There are a lot of individuals at the table considering this, and there are varying levels of

information that providers want versus what patients want. There are some who just want to know whether a result is positive or negative. Others want a higher level of information beyond that report. It is a good time to be raising those potential needs.

CORI FEIST: One of the goals of the final rule is to make sure that patient information is shared in an easy-to-understand and easy-to-utilize manner. As the ACMG paper[4] points out, we need to work together as a genetics community, and greater medical community in general, to consider exactly that – changing how we write reports, changing the layout of reports, in a way that a patient could reasonably understand and utilize.

Is there any obligation for language translation under the final rule?

CORI FEIST: That is an access issue that needs to be addressed, and Congress is aware. Not everyone speaks and reads English, and not everyone has access to electronics. I have patients who cannot afford a smartphone or Internet, or they don't use them. This could be because of their age, culture, or access. I have patients who are incarcerated, and they don't have access but still have a right to their medical information. These are things that the Cures Act, as an evolving process, is going to need to address.

JOHN RICHARDSON: When we are talking about foreign languages, I think the future is additional APIs that can be built into these platforms that would provide electronic translation services in real-time.

My clinic works primarily with the Amish population who don't have access to technology. To comply with the act, would we need to mail patient lab reports, clinic notes, etc., or just upon patient request?

JOHN RICHARDSON: If they request it, then you should probably mail the information, but this rule addresses the *electronic* exchange of information. Generally speaking, some entities and providers have had patient portals for years. A lot of it will be pushing information to the consumer through a web portal that they can access. Mailing is outside of the current law. But as we talk about disparities and trying to empower people with more information, which is the goal, maybe that will change.

Results are often not easily accessible to patients because they are scanned in as PDFs and don't automatically flow into the patient portal. Do you have insight on how that might be handled?

CORI FEIST: Health IT developers are working on this right now. My institution uses Epic. Patients can only see the interpretation in their MyChart: normal versus abnormal. They know that the result is in, but they cannot see it. That is not going to be allowed in the future. Health IT and EMR departments are going to have to work on that. It all looks great on paper, but we know things work differently in the real world, and there is going to be some give and take and trial and error.

JOHN RICHARDSON: Interoperability with the Cures Act is really important. We started out with EHR and interoperability years ago, but then that went away. Hopefully, this will all become more efficient because there is more focus on it. APIs that allow different platforms to talk to each other will help immensely, but it definitely is an area where improvement will need to come sooner rather than later.

For patients who decline the use of EHI because they are concerned about privacy, should there be written documentation of this?

JOHN RICHARDSON: Most likely you would want to make sure a patient signs a document saying they have waived their rights to this information.

KIM LINTHICUM: Yes, that is probably handled in a proactive way, as opposed to the information blocking rule, which is responding to a patient request for results. As laboratories build their patient portals, they will need to consider an opt-out function.

CORI FEIST: If a patient signs up for access to their medical records, they are giving their consent to have all of their results put in the portal and viewed. At my institution, when we talk to new patients and ask, "Would you like to sign up for MyChart," we have to explain that. I have had patients who say, "I want my CBC result, but I don't want my BRCA result." Well, then don't click on the tab that says results are available. I can imagine a lot of patients may see something that they don't want to see. The bottom line is, if you consent to MyChart, you are giving your consent to view your records, including opening up your messages, links, or lab results.

How do clinicians comply for partner or proband tests when one result falls under manual release and the other does not?

CORI FEIST: For most, it is either the test category itself falls under "manual release" because of a written organizational policy, or it falls on the provider to select

"manual release." This situation could arise if an ordering provider forgets to select "manual release" for one person and not the other. Providers are going to need to pay attention and understand their organizational policy. I think part of what will be helpful is that you can't just click "manual release." Most EMRs require you to answer questions and prove that the case would be considered an exception to the rule against information blocking.

KIM LINTHICUM: My colleagues have been working on the language within HL7 that would be very specific to the preventing harm exception. One of the interoperability factors of this rule is that information has to get into HL7 FHIR 4.0 format. They're trying to standardize that language, but they're looking at how to build these exceptions into user-friendly electronic language.

What would you advise people do in the meantime as we wait for EMRs to work through these issues? What happens if people are getting direct requests and they don't have an easy way to comply through their EMR?

KIM LINTHICUM: It is not required that information be disseminated through an EMR. Finding another electronic way to share information that the patient has requested is really what is necessary. The USCDI[7] parameters include patient name, sex, etc. that is held by the provider. If the provider does not have the information, they are not required to create or produce it.

Do you know how much education has been given to the public about this act and how often these requests will come in?

JOHN RICHARDSON: I would say that is evolving. Healthcare providers need to be providing education to their patients to make them aware of this and their ability to access their health records. I have not seen public service announcements, so I think it's likely that not a lot of folks are aware of their ability to access their health records unless they are going to a provider who has been ahead of the curve and has had patient portals where they can see results and other information in close to real-time.

CORI FEIST: For genetic counselors, this is just another point to make during pretest counseling and shows how important pretest counseling and informed consent are. You could work with your EMR to develop a smart phrase that reminds patients that they may have access to their results before their ordering provider discloses them. There's a blurb that every patient at our institution gets that explains what the final rule is and what they might see and have access to if they log in to the patient portal.

CONCLUSION

My Gene Counsel was created to address the need for an automated, scalable solution to meet the growing demand for accurate and timely genetic counseling information. This need will likely be exacerbated by the 21st Century Cures Act as patients gain earlier access to genetic test results – potentially before these results are explained by their healthcare providers[8].

With its industry-leading database of proprietary genetics content organized by gene and variant, My Gene Counsel's HIPAA-compliant SaaS solution delivers continuously updating genetic counseling information to patients and providers via Living Lab Reports® in many areas of genomics, including hereditary and somatic cancer testing, hereditary cardiovascular disease, noninvasive prenatal testing, and more.

By partnering with My Gene Counsel, healthcare systems and laboratories can ensure that patients have access to understandable, actionable information via Living Lab Reports as soon as they receive their genetic test results. Patients and their associated healthcare providers will then be notified when critical new information is available (e.g., updated medical management guidelines, variant reclassifications). For more information on how My Gene Counsel keeps patients and providers in-the-know, see our latest white paper, *Precision Medicine in Practice: Keeping Patients Up to Date After Genetic Testing*[9].

If your practice or company would like to learn more about how My Gene Counsel can support you as you work to achieve compliance with the Cures Act, visit our website for more information on our Living Lab Reports[10] or contact info@mygenecounsel.com to schedule a demo.

RESOURCE LINKS

[1] Cures Act Webinar

[2] Information Blocking Exceptions

[3] HIPAA Privacy Rule

[4] ACMG Points to Consider Statement

[5] NSGC Final Rule FAQ

[6] ONC's Cures Act Final Rule Official Website

[7] United States Core Data for Interoperability

[8] HCPs Adjust to Anti-Information Blocking Regulation

[9] Precision Medicine in Practice White Paper

[10] Living Lab Reports