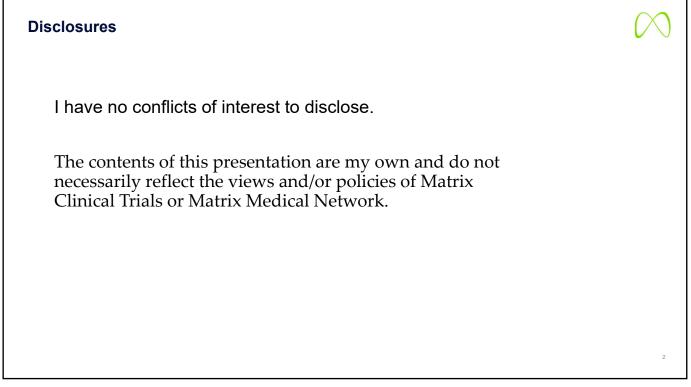


# 21<sup>st</sup> Century Cures Act What is it and How to Operationalize it

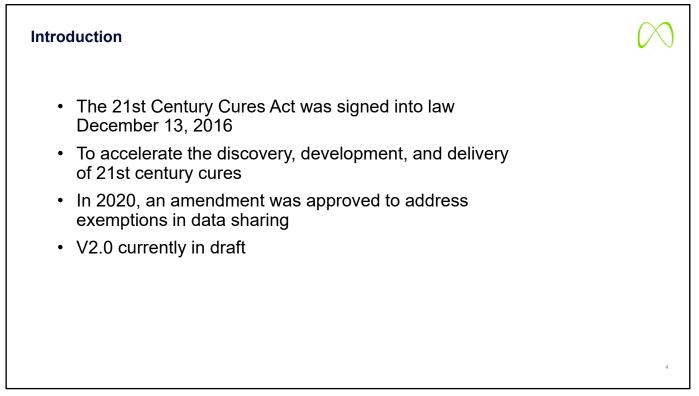
Aurea M. Flores, BS Pharm, PhD, CCRP, PMP, PMI-ACP, CHRC, CHC, CHPC, CCEP, RQAP-GCP, RPh Senior Director, Quality & Compliance, Decentralized Clinical Trials Matrix Clinical Trials Aurea Elores@matrixmedicalnetwork.com

June 10, 2022



# Objectives

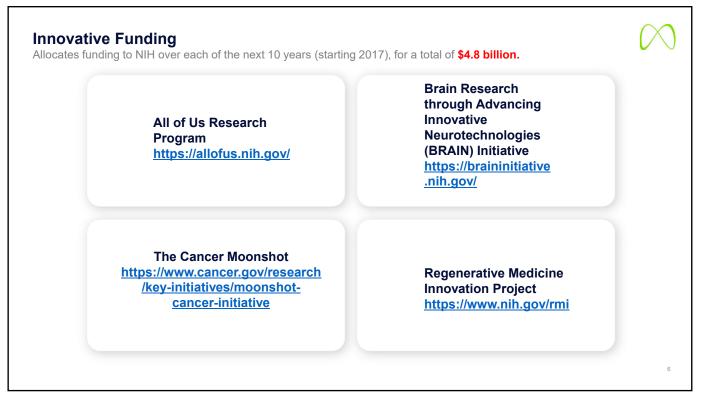
- Describe what is the 21st Century Cures Act
- Describe the 2020 amendment Information Blocking
- Describe how it affects Clinical Research Operations

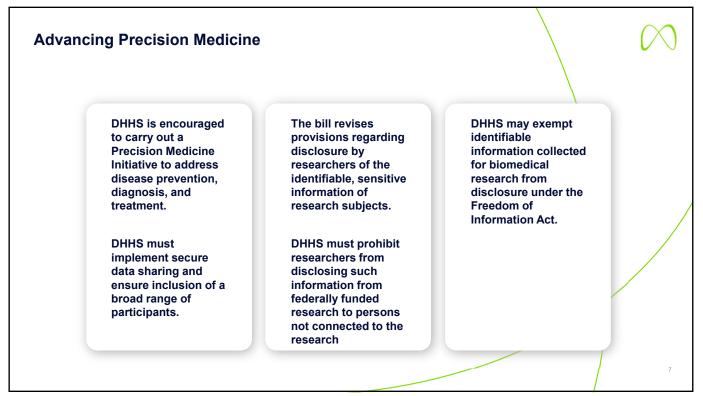


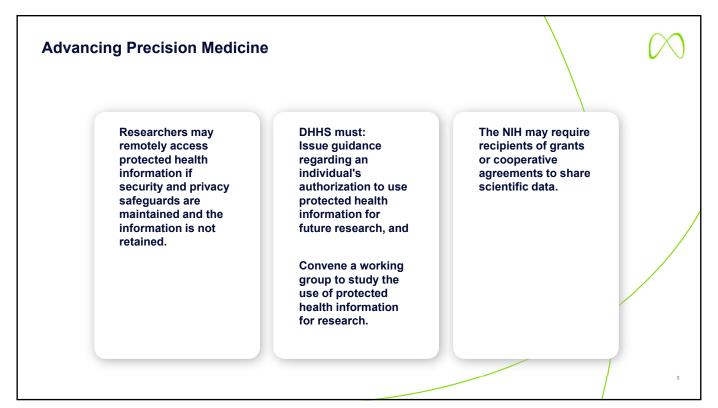
### Accelerating Research

- Originally the 21st Century Cures Act provided NIH with the flexibility and resources needed to accomplish its mission to improve the health of Americans.
- The Cures Act implemented measures to:
  - · alleviate administrative burdens that can prolong the start of clinical trials
  - allow researchers to more easily attend scientific conferences where inperson collaboration can often lead to scientific breakthroughs
  - enhance data sharing among NIH-supported researchers
  - improve privacy protections for research volunteers
  - · encourage inclusion of diverse populations represented in clinical research
  - · open up new NIH funding opportunities for young investigators



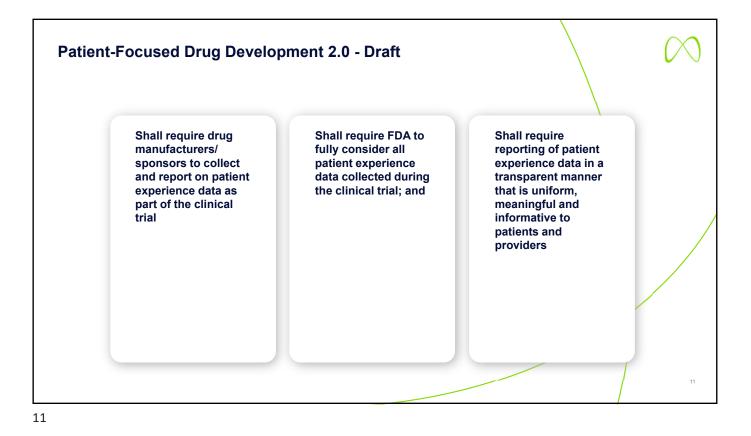




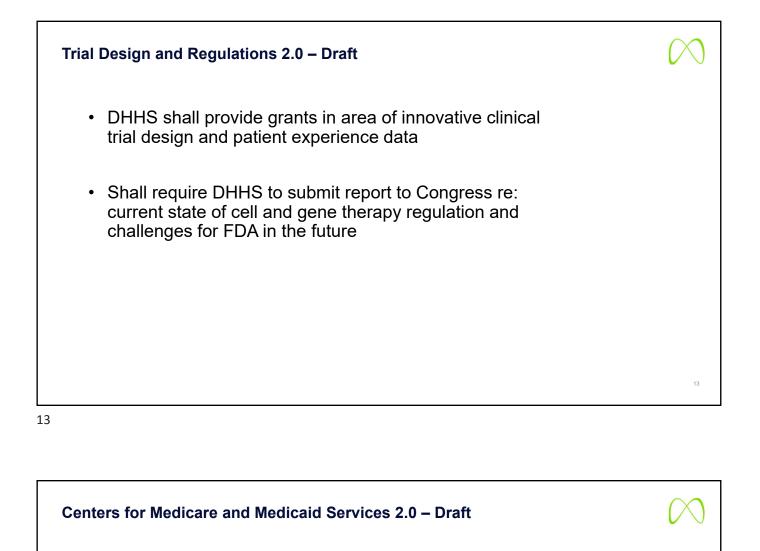




**Patient-Focused Drug Development** Amends the Federal Patient experience The FDA must report Food, Drug, and data is information on its use of patient Cosmetic Act to experience data in about the impact of a require the FDA, medical condition or regulatory decisionafter approving an a related therapy on making. application for a new a patient's life and medication, to the patient's preferences for publish a brief statement on any treatment. patient experience data or related information that was part of the application. 10



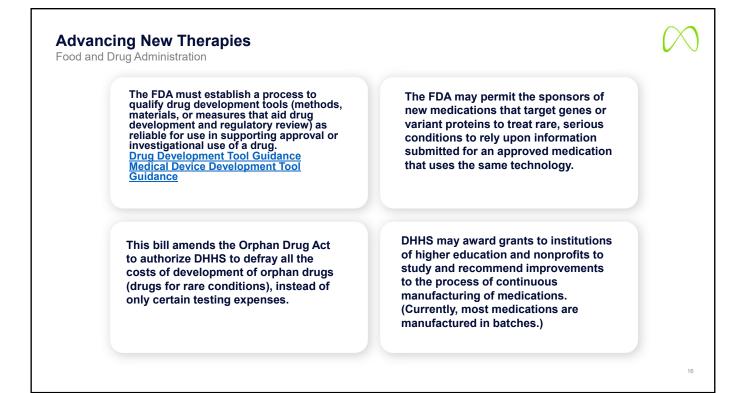
**Diversity in Clinical Trials 2.0 - Draft** Requires an update from FDA on efforts to improve diversity in clinical • trials Requires a GAO study on barriers to clinical research participation • Requires DHHS to conduct a public awareness campaign to increase • awareness and understanding, particularly in minority communities, of clinical trials Establishes a task force on making clinicaltrials.gov more user- and • patient-friendly Enhancing the Diversity of Clinical Trial Populations - Eligibility Criteria, ٠ Enrollment Practices, and Trial Designs Guidance for Industry 12



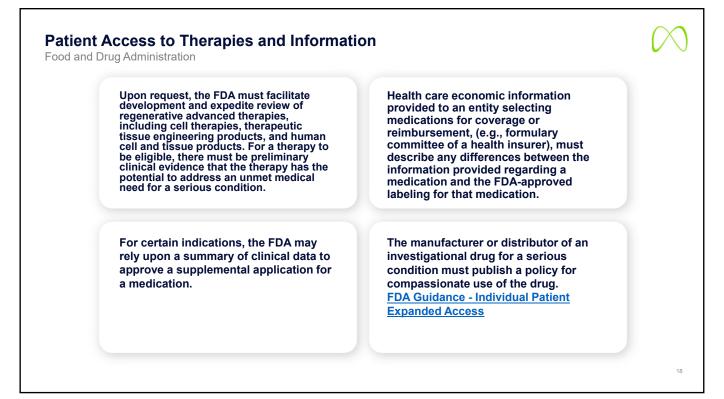
- Shall allow Medicare to cover the costs of their beneficiaries in PCORI-funded studies
- Shall establish an automatic communication requirement between FDA and CMS for breakthrough therapy drugs
- Shall require a GAO report on recommendations to enhance Medicare coverage and reimbursement for innovative health technologies
- Shall provide guidance to states on effectively integrating telehealth services (TIKES and CHIP)
- Codify the current Medicare Coverage of Innovative Technology pathway at CMS
- Shall require DHHS to submit report on current capabilities and deficiencies of CMS's computer systems
- Shall increase access to genetic diagnostics for pediatric patients with rare diseases
- Shall require DHHS to provide pilot grant within CMS to test approaches to delivering personalized-medicine consults

# 21<sup>st</sup> Century Cures Act 2.0 – Draft

- Shall authorize the creation of Advanced Research Projects Agency for Health (ARPA-H)
  - To speed transformational innovation in health research
  - To speed application and implementation of health breakthroughs
- Shall provide \$25 Billion to independent research institutions, public laboratories and universities throughout the country to continue work on thousands of federallybacked projects







## 21<sup>st</sup> Century Cures Act 2.0 – Draft

Food and Drug Administration

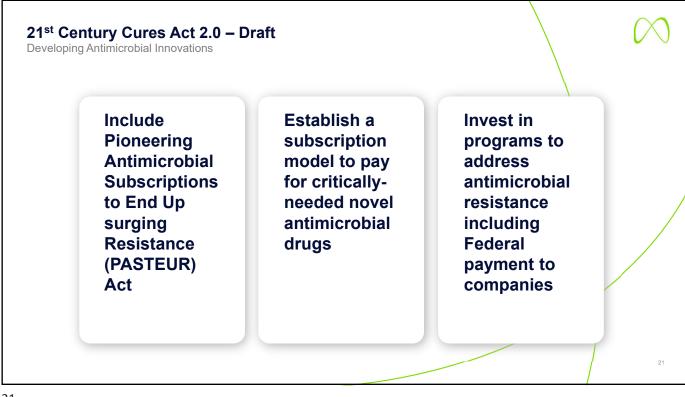
- Shall direct DHHS to establish two (2) additional FDA Centers of Excellence
- Shall not require IND application to initiate accelerated approval
- Shall allow use of other evidence to fulfill post-approval study requirements to confirm predicted clinical benefit
- Shall require FDA to publish guidance on the standards and factors for CMC data development and review



# Antimicrobial Innovation and Stewardship

Food and Drug Administration

- DHHS must:
  - · Annually publish information on antimicrobial resistance and antimicrobial stewardship;
  - · Disseminate guidance and materials regarding antimicrobial stewardship;
  - Continue working with state and local public health departments on antimicrobial resistance programs; and
  - Collect, evaluate, and publish data from the antimicrobial stewardship activities of health care facilities.
- The FDA may, at the request of the drug's sponsor, approve an antibiotic or antifungal drug for use in a limited population if the drug is intended to treat a serious infection in a limited population of patients with unmet medical needs. The FDA's determination of the safety and effectiveness of such a drug must reflect the drug's use in the intended limited population.
- The FDA must identify and publish susceptibility test interpretive criteria for antimicrobial drugs.

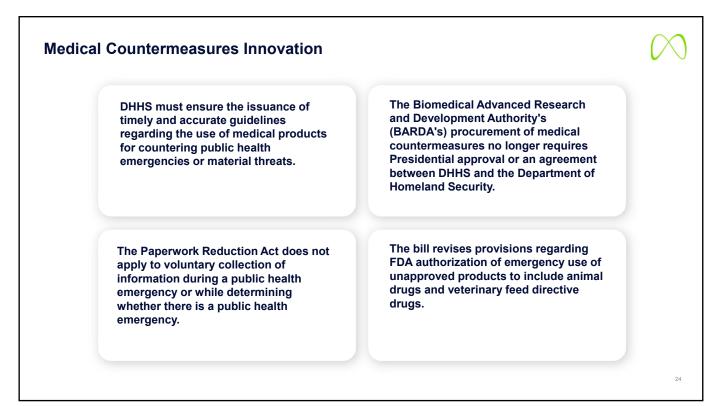


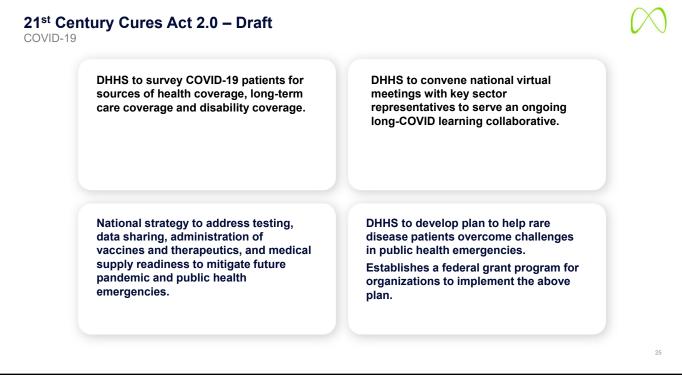
# **Medical Device Innovations** · Upon a sponsor's request, the FDA must determine whether a device meets the criteria for designation as a breakthrough device. • The humanitarian device exemption is expanded to allow the FDA to exempt from effectiveness requirements certain medical devices intended to benefit up to 8,000 individuals (previously up to 4,000 individuals). · Certain software is exempted from requirements for medical devices, including software that provides medical recommendations and the basis for those recommendations to health care professionals. · Software remains subject to regulation as a medical device if: - The software acquires, processes, analyzes, or interprets medical information; or - FDA identifies use of the software as reasonably likely to have serious adverse health consequences. · When assessing a medical device that includes a software function exempted from medical device requirements, the FDA may assess the impact of the software on the functioning of the device. 22

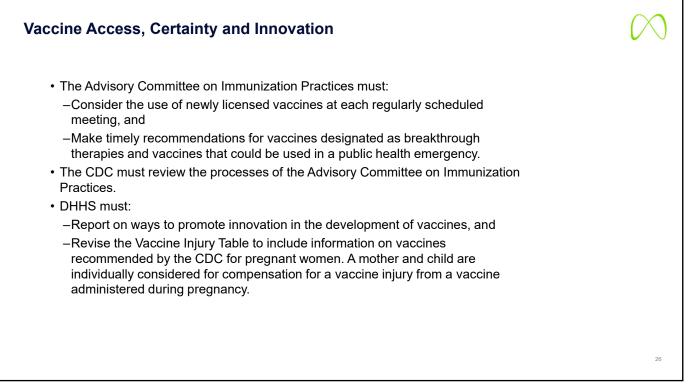
### Improving Scientific Expertise and Outreach

Food and Drug Administration

- Provides new authority to help FDA improve the ability to recruit and retain scientific, technical, and professional experts and it establishes new expedited product development programs, including:
  - -The Regenerative Medicine Advanced Therapy that offers a new expedited option for certain eligible biologics products.
  - -The Breakthrough Devices program, designed to speed the review of certain innovative medical devices.

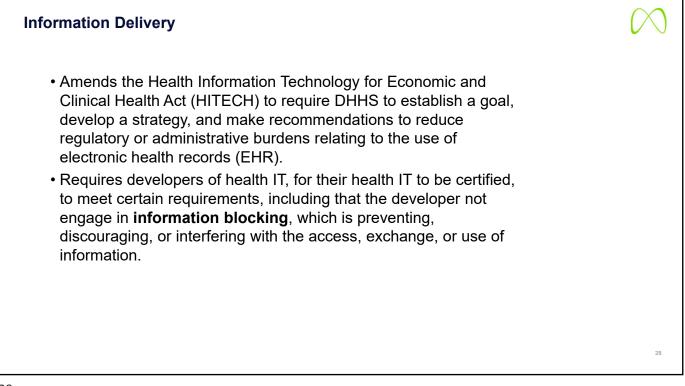


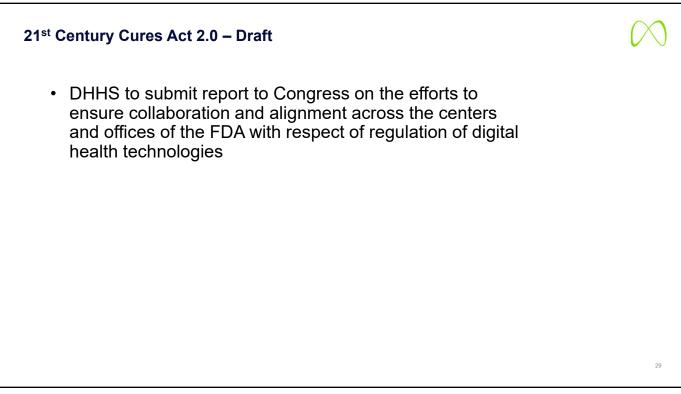




21 <sup>st</sup> Century	Cures	Act 2.0	– Draft
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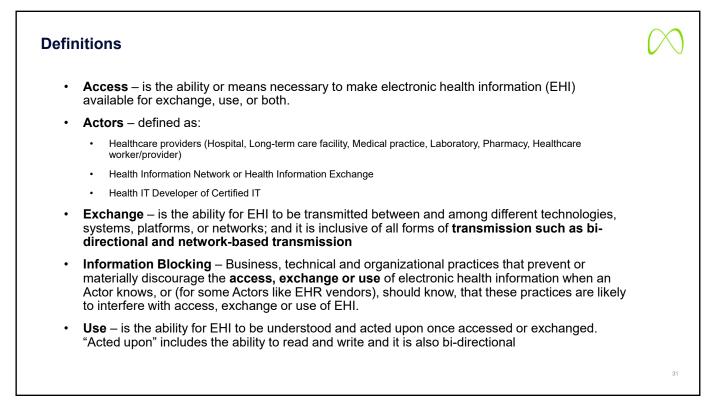
Improve the education of all Americans on the importance of vaccines



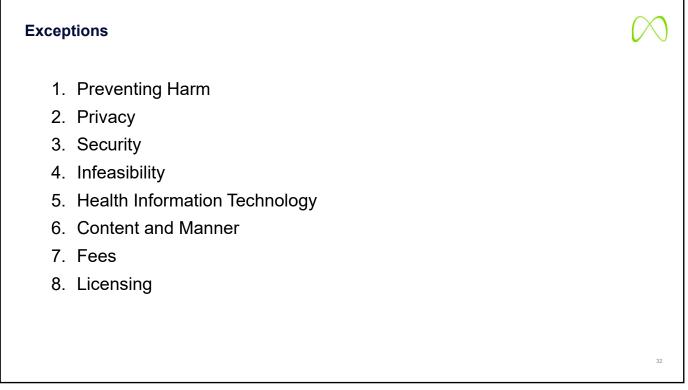


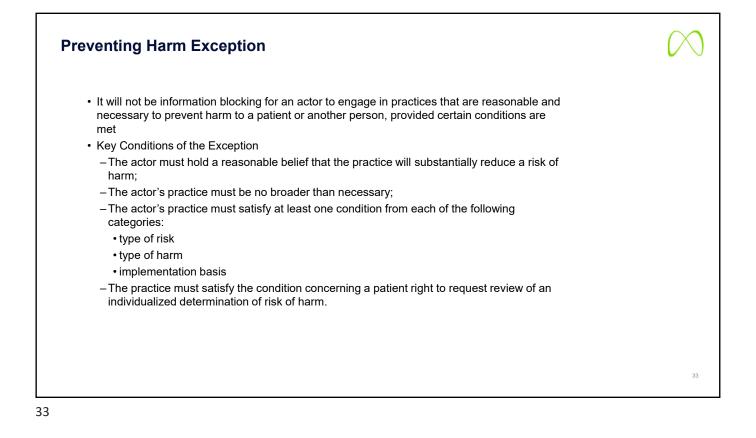








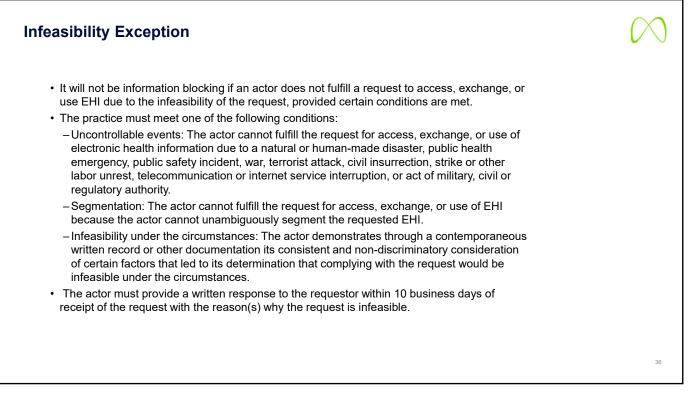




Privacy Exception	$\sim$
<ul> <li>It will not be information blocking if an actor does not fulfill a request to access, exchange, or use EHI in order to protect an individual's privacy, provided certain conditions are met.</li> <li>To satisfy this exception, an actor's privacy-protective practice must meet at least one of the four sub-exceptions: <ul> <li>Precondition not satisfied: If an actor is required by a state or federal law to satisfy a precondition (such as a patient consent or authorization) prior to providing access, exchange, or use of EHI</li> <li>Health IT developer of certified health IT not covered by HIPAA</li> <li>Denial of an individual's request for their EHI consistent with 45 CFR 164.524(a) of the HIPAA Privacy Regulation</li> <li>These include psychotherapy notes and information compiled for use in a civil, criminal or administrative legal proceedings, information obtained by a non-healthcare provider.</li> <li>Respecting an individual's EHI if doing so fulfills the wishes of the individual, provided certain conditions are met.</li> </ul> </li> </ul>	
<ul> <li>45 CFR Part 164.524(a) states:</li> <li>(a) Standard: Access to protected health information <ul> <li>(2) Unreviewable grounds for denial – A covered entity may deny an individual access without providing the individual an opportunity for review <ul> <li>(ii) An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research.</li> </ul> </li> </ul></li></ul>	
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### **Security Exception**

- It will not be information blocking for an actor to interfere with the access, exchange, or use of EHI in order to protect the security of EHI, provided certain conditions are met.
- The practice must be:
  - -Directly related to safeguarding the confidentiality, integrity, and availability of EHI;
  - -Tailored to specific security risks; and
  - -Implemented in a consistent and non-discriminatory manner.
- The practice must either implement a qualifying organizational security policy or implement a qualifying security determination.



# Health IT Performance It will not be information blocking for 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. The practice must: Be implemented for a period of time no longer than necessary to achieve the maintenance or improvements for which the health IT was made unavailable or the health IT's performance degraded; Be implemented in a consistent and non-discriminatory manner; and Meet certain requirements if the unavailability or degradation is initiated by a health IT developer of certified health IT, HIE, or HIN.

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# **Content and Manner Exception**

- 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 to access, exchange, or use EHI, provided certain conditions are met.
- On and after 24 months after the publication date of the Cures Act final rule, an actor must respond to a request to access, exchange, or use EHI with EHI as defined in § 171.102 (definitions).
- An actor may need to fulfill a request in an alternative manner when the actor is:
  - -Technically unable to fulfill the request in any manner requested; or
  - -Cannot reach agreeable terms with the requestor to fulfill the request.

### **Fees Exception**

- 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.
  - -Be based on objective and verifiable criteria that are uniformly applied for all similarly situated classes of persons or entities and requests.
  - -Be reasonably related to the actor's costs of providing the type of access, exchange, or use of EHI.
  - -Not be based on whether the requestor or other person is a competitor, potential competitor, or will be using the EHI in a way that facilitates competition with the actor.

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