HEALTH DATA, TECHNOLOGY, AND INTEROPERABILITY (HTI-1)
UPDATE: DECEMBER 2023
UNDERSTANDING THE IMPACT OF HEALTH IT

Organized by The Healthcare Executive
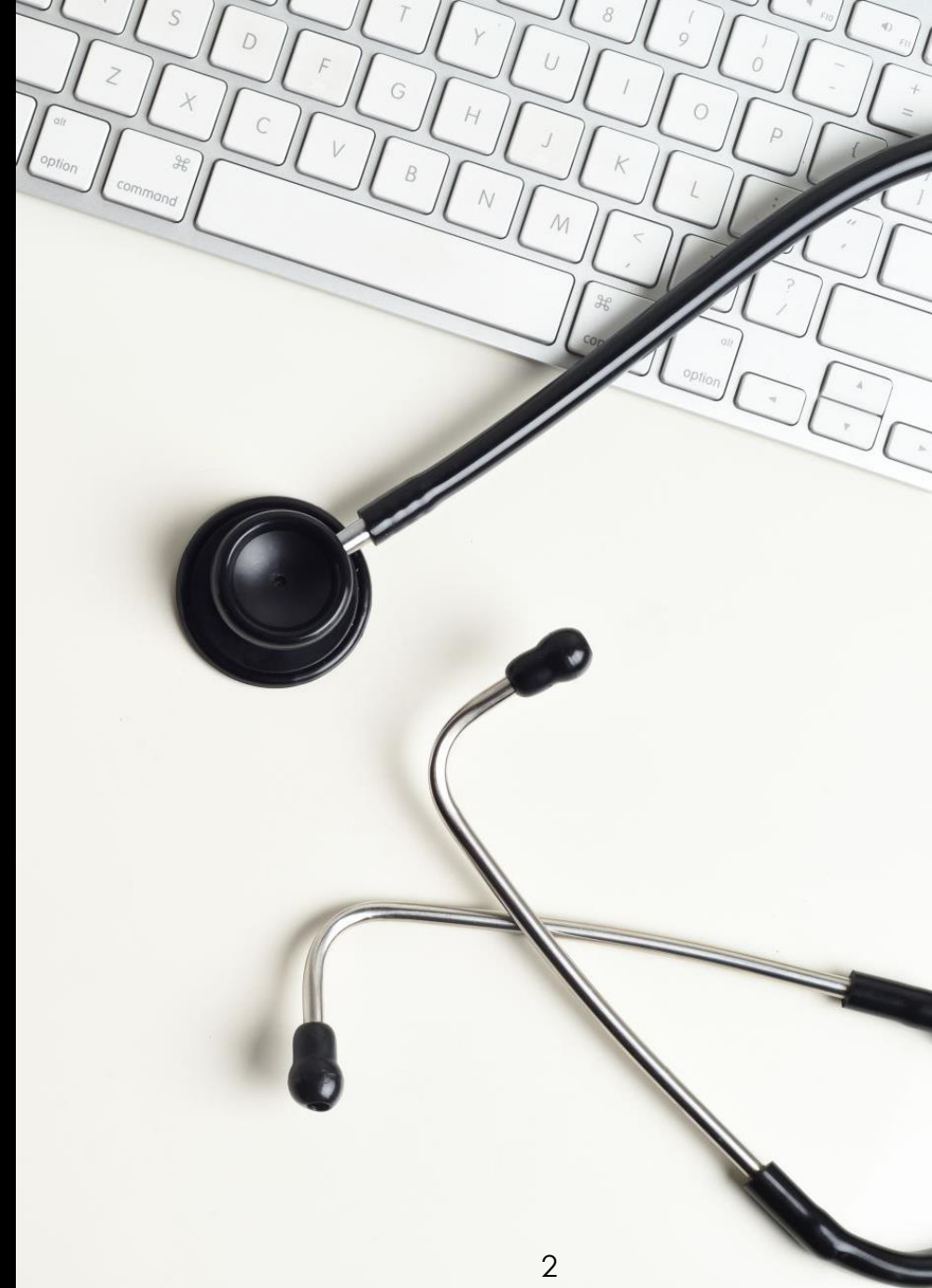
Presenter by Greg Wahlstrom, MBA, HCM

April 2024

INTRODUCTION - UNDERSTANDING THE HTI-1 UPDATE: A KEY MILESTONE IN HEALTH IT

Brief Overview of the 21st Century Cures Act

Enacted in 2016 to accelerate medical product development and bring new innovations in healthcare more efficiently to the public.

Key Focus Areas:
- Enhancing patient access to their own health data.
- Promoting the interoperability of health information systems.
- Supporting the secure exchange and use of electronic health information.
- Encouraging innovation in the healthcare technology sector.

INTRODUCTION – UNDERSTANDING THE HTI-1 UPDATE: A KEY MILESTONE IN HEALTH IT

Importance of HTI-1 Update

- *Impact on Healthcare Delivery:* Explains how the HTI-1 update is set to transform healthcare delivery through improved data sharing and technology utilization.

- *Advancing Patient Care:* Highlights the role of the update in advancing patient care by enhancing access to health data and supporting the effective use of AI and predictive analytics in health IT.

- *Compliance and Adaptation:* Emphasizes the need for healthcare providers, IT developers, and other stakeholders to understand and adapt to these regulatory changes for compliance and optimized healthcare delivery.
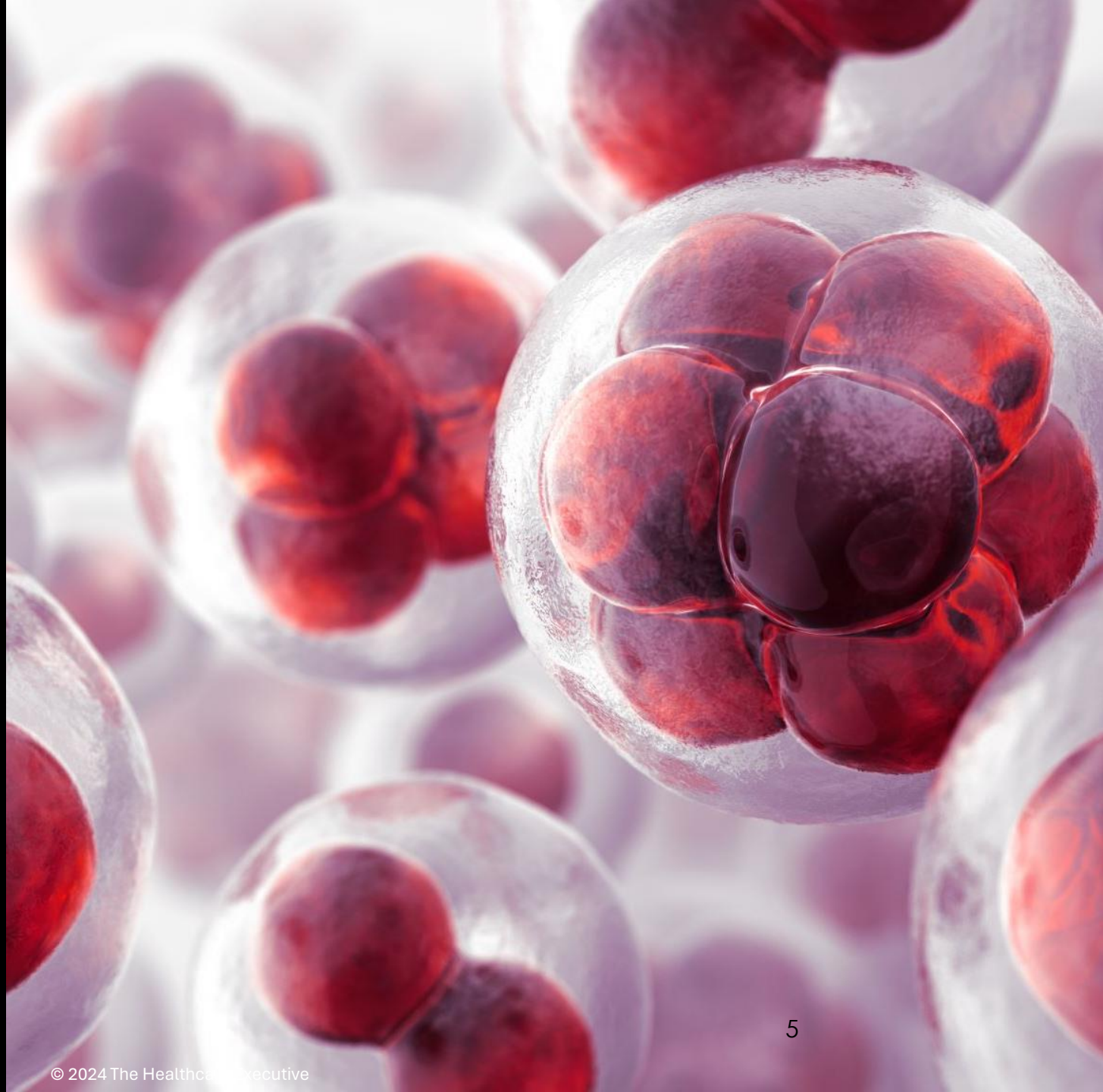
AGENDA – TODAY'S DISCUSSION ROADMAP

1. Background and Overview of the 21st Century Cures Act

2. Introduction to the HTI-1 Rule

3. Algorithm Transparency in Health IT

4. Adoption of USCDI Version 3

5. Revised Information Blocking Requirements

6. Interoperability-Focused Reporting Metrics

7. Provider Disincentives for Information Blocking

8. Implications for Healthcare Providers and Patients

9. Future Directions and Compliance Strategies

10. Q&A Session

11. Conclusion and Key Takeaways

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BACKGROUND AND OVERVIEW OF THE 21ST CENTURY CURES ACT - THE FOUNDATION OF MODERN HEALTHCARE INNOVATION

Historical Context

- *Enactment Year:* 2016

- *Primary Objective:* To accelerate the development of medical products and introduce new innovations in healthcare.

- *Bipartisan Support:* Emphasizes the widespread political support for advancing healthcare technology and research.

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BACKGROUND AND OVERVIEW OF THE 21ST CENTURY CURES ACT - THE FOUNDATION OF MODERN HEALTHCARE INNOVATION

Key Objectives of the Act

1. Enhancing Patient Access to Health Data
2. Promoting Interoperability of Health IT Systems
3. Supporting the Secure Exchange and Use of Electronic Health Information
4. Encouraging Innovation in Health Technology and Digital Health

KEY PROVISIONS AND IMPACTS OF THE 21ST CENTURY CURES ACT - NAVIGATING THE LANDSCAPE OF HEALTHCARE TRANSFORMATION

- Advancement in Medical Product Development
- Funding for Medical Research
- Mental Health and Substance Use Disorder Policy Reforms
- Information Blocking and Health IT Certification

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Impacts on Healthcare

- Enhanced Patient Care and Safety

- Increased Innovation in Healthcare Technology

- Greater Collaboration in Healthcare Research

- Shift Towards Value-Based Care

KEY PROVISIONS AND IMPACTS OF THE 21ST CENTURY CURES ACT - NAVIGATING THE LANDSCAPE OF HEALTHCARE TRANSFORMATION

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INTRODUCTION TO THE HTI-1 RULE - UNVEILING THE HTI-1 RULE: A LEAP FORWARD IN HEALTH IT

Definition and Purpose

- HTI-1: Stands for Health Data, Technology, and Interoperability - 1.

- Primary Objective: To advance patient access, interoperability, and standards within the health IT ecosystem.

Key Components of the HTI-1 Rule

1. Algorithm Transparency
2. Adoption of USCDI Version 3
3. Enhanced Information Blocking Requirements
4. Interoperability-Focused Reporting Metrics

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INTRODUCTION TO THE HTI-1 RULE - UNVEILING THE HTI-1 RULE: A LEAP FORWARD IN HEALTH IT

Role in Health IT

- *Facilitating Better Patient Outcomes:* By improving access and use of health data, leading to more informed healthcare decisions.

- *Driving Healthcare Innovation:* Fosters the development of new technologies and standards in health IT.

- *Ensuring Transparency and Compliance:* Offers a clearer regulatory framework, promoting responsible use of AI in healthcare.

ALGORITHM TRANSPARENCY IN THE HTI-1 RULE - EMBRACING TRANSPARENCY IN HEALTHCARE ALGORITHMS

Importance of Algorithm Transparency

- Trust and Reliability

- Patient Safety

Key Aspects of Algorithm Transparency

1. Transparency Requirements
   - Mandates that developers disclose specific information about the algorithms used in certified health IT.

2. Assessment of Algorithms
   - Encourages clinical users to assess algorithms for fairness, appropriateness, validity, effectiveness, and safety.

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ALGORITHM TRANSPARENCY IN THE HTI-1 RULE - EMBRACING TRANSPARENCY IN HEALTHCARE ALGORITHMS

Challenges and Solutions

- Complexity of AI Systems
- Continuous Monitoring and Updating

Impact on Healthcare Providers and Patients

- Enhanced Decision-Making
- Empowered Patients

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ADOPTION OF USCDI VERSION 3 IN THE HTI-1 RULE – ADVANCING HEALTH DATA STANDARDS: USCDI VERSION 3

Understanding USCDI Version 3

- *USCDI:* Stands for the United States Core Data for Interoperability.

- *Version 3*: The latest iteration, which includes updated standards for health data elements and classifications.

Key Updates in USCDI Version 3

1. *Enhanced Data Elements*
   - Introduction of new data elements for a more comprehensive health record.
   - Includes advancements in capturing patient social determinants of health, clinical notes, and more.

2. *Improved Data Interoperability*
   - Facilitates better data exchange between diverse health IT systems.
   - Aims to streamline data sharing processes across healthcare providers.

ADOPTION OF USCDI VERSION 3 IN THE HTI-1 RULE - ADVANCING HEALTH DATA STANDARDS: USCDI VERSION 3

Importance for Healthcare

- *Promoting Health Equity:* By capturing a broader range of patient data, including social determinants of health.
- *Supporting Public Health:* Enhanced data elements aid in public health surveillance and research.

Implementation Timeline and Implications

- *Effective Date:* January 1, 2026.
- *Transition Period:* Allows health IT developers and providers time to adapt to the new standard.
- *Implications for Healthcare Providers:* Need to update systems and train staff to utilize the enhanced data elements effectively.

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ENHANCED INFORMATION BLOCKING REQUIREMENTS IN THE HTI-1 RULE - NAVIGATING THE NEW LANDSCAPE OF INFORMATION BLOCKING

Understanding Information Blocking

- Definition: Practices that interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information (EHI).

- Objective: To ensure that EHI is accessible and can be readily exchanged across different health IT systems.

Key Updates in Information Blocking Requirements

1. *Revised Definitions and Exceptions*
   - Clarifies what constitutes information blocking under the new rule.
   - Introduces new exceptions and revises existing ones for greater clarity.

2. *Enhanced Compliance and Enforcement*
   - Sets out specific compliance requirements for healthcare providers, IT developers, and exchanges.
   - Details the enforcement mechanisms and potential penalties for information blocking.

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ENHANCED INFORMATION BLOCKING REQUIREMENTS IN THE HTI-1 RULE - NAVIGATING THE NEW LANDSCAPE OF INFORMATION BLOCKING

Challenges and Solutions

- Adapting to New Regulations: Understanding and implementing the revised requirements and exceptions.
- Training and Awareness: Ensuring all stakeholders, including healthcare providers and IT personnel, are aware of and understand these changes.

Impact on Healthcare Providers and Patients

- *Improved Data Sharing:* Facilitates a more seamless and efficient exchange of health information.
- *Empowering Patients:* Enhances patient access to their own health data, contributing to better-informed healthcare decisions.

INTEROPERABILITY-FOCUSED REPORTING METRICS IN THE HTI-1 RULE - EMPHASIZING INTEROPERABILITY: NEW REPORTING METRICS

Overview of Reporting Metrics

- *Purpose:* To provide insights into the usage and effectiveness of certified health IT in supporting care delivery.
- *Requirements:* Developers of certified health IT must report specific metrics as part of their participation in the Certification Program.

Key Metrics for Reporting

1. Usage Metrics
   - Data on how frequently and in what ways certified health IT products are being utilized in healthcare settings.
   - Helps in understanding the practical impact of these technologies.

2. Interoperability Metrics
   - Information on the exchange and integration capabilities of health IT system.
   - Aims to evaluate the effectiveness of data sharing across different platforms.

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INTEROPERABILITY-FOCUSED REPORTING METRICS IN THE HTI-1 RULE - EMPHASIZING INTEROPERABILITY: NEW REPORTING METRICS

Challenges and Solutions

- *Data Collection and Analysis*: Implementing systems to collect, manage, and analyze relevant data.
- *Continuous Improvement:* Using metrics for ongoing evaluation and enhancement of health IT interoperability.

Impact on Healthcare IT Development and Usage

- *Enhanced Product Development:* Informs developers about areas for improvement or innovation in their products.
- *Improved Healthcare Delivery:* Enables providers to understand the benefits and limitations of their health IT tools, leading to better-informed decisions about technology adoption and usage.

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PROVIDER DISINCENTIVES FOR INFORMATION BLOCKING IN THE HTI-1 RULE - ADDRESSING INFORMATION BLOCKING: PROVIDER DISINCENTIVES

Concept of Provider Disincentives

- *Purpose*: To penalize and discourage practices that constitute information blocking.

- Scope: Applies to healthcare providers who engage in actions that hinder the access, exchange, or use of electronic health information (EHI).

Key Elements of Provider Disincentives

1. Nature of Disincentives
    - Financial penalties or corrective action plans for non-compliance.
    - Potential impact on participation in federal healthcare programs.

2. Criteria for Enforcement
    - Based on the severity and impact of the information blocking practices.
    - Determined through investigations and findings by relevant authorities.

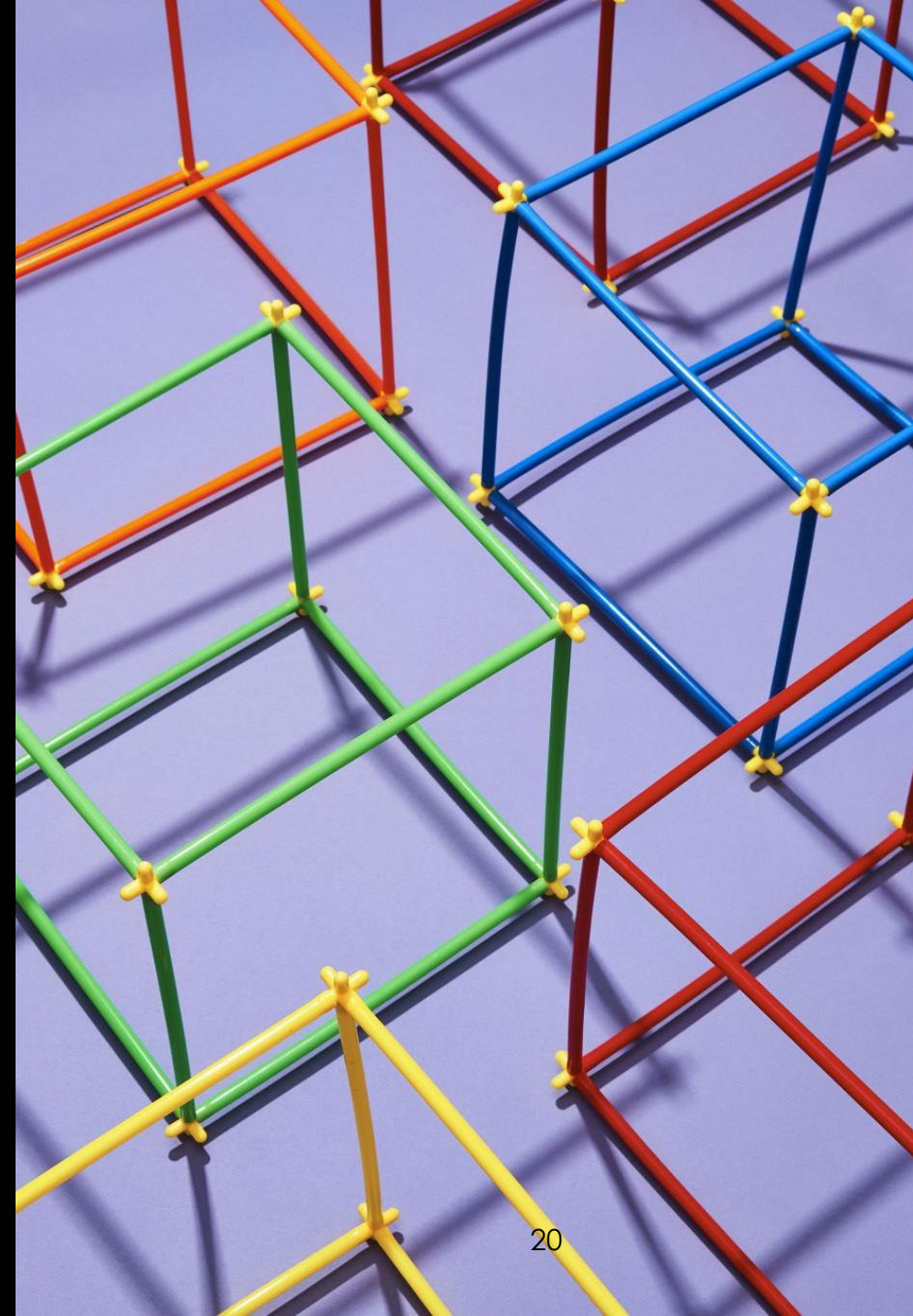The Healthcare Executive
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PROVIDER DISINCENTIVES FOR INFORMATION BLOCKING IN THE HTI-1 RULE - ADDRESSING INFORMATION BLOCKING: PROVIDER DISINCENTIVES

Challenges and Compliance Strategies

- *Understanding the Regulations:* Ensuring comprehensive knowledge of what constitutes information blocking.
- *Implementing Best Practices:* Establishing internal protocols and training to prevent information blocking.

Impact on Healthcare Providers and Systems

- *Promoting Responsible Data Sharing:* Encourages providers to adopt practices that support seamless EHI exchange.
- *Enhancing Transparency and Accountability:* Holds providers accountable for their actions, fostering a more transparent healthcare ecosystem.

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IMPLICATIONS FOR HEALTHCARE PROVIDERS AND PATIENTS - HTI-1 RULE: TRANSFORMING HEALTHCARE FOR PROVIDERS AND PATIENTS

For Healthcare Providers

- *Adaptation to New Standards:* Navigating and integrating the updates like USCDI Version 3 and information blocking regulations into existing systems.

- *Enhanced Responsibility:* Greater accountability in ensuring the secure and efficient use of EHI, and in preventing information blocking.

- *Opportunities for Improvement:* Using the insights from interoperability-focused reporting metrics to enhance health IT solutions and patient care.

IMPLICATIONS FOR HEALTHCARE PROVIDERS AND PATIENTS – HTI-1 RULE: TRANSFORMING HEALTHCARE FOR PROVIDERS AND PATIENTS

For Patients

- *Improved Access to Health Information:* Easier and more comprehensive access to personal health records.

- *Increased Engagement in Healthcare Decisions:* With better access and understanding of their health data, patients can be more actively involved in their healthcare decisions.

- *Trust and Transparency in Healthcare:* Greater transparency in the use of AI and predictive algorithms can increase patient trust in the healthcare system.

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Overall Impact

- *Shift Towards a More Interconnected Healthcare System*: Encourages seamless exchange and use of health data across different platforms and entities

- *Driving Innovation in Health IT*: Motivates the development of more sophisticated, user-friendly, and interoperable health IT solutions.

- *Promoting Patient-Centered Care*: Prioritizes patient needs and preferences in healthcare delivery and decision-making.

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FUTURE DIRECTIONS AND COMPLIANCE STRATEGIES – LOOKING AHEAD: ADAPTING TO THE HTI-1 RULE

Future Directions in Health IT and Regulation

- *Continued Evolution of Standards:* Expect ongoing updates and enhancements in health data standards and interoperability requirements.

- *Increasing Role of AI and Digital Health:* Anticipate further integration of AI, machine learning, and digital health tools in healthcare delivery. Compliance Strategies for Healthcare Entities

  1. *Regular Policy Reviews and Updates*
     - Involve legal and compliance teams in policy updates.

  2. *Investment in Technology and Training*
     - Upgrade health IT systems to comply with new standards like USCDI Version 3.

  3. *Proactive Approach to Information Sharing*
     - Foster a culture that prioritizes open and efficient sharing of electronic health information.

FUTURE DIRECTIONS AND COMPLIANCE STRATEGIES - LOOKING AHEAD: ADAPTING TO THE HTI-1 RULE

Implications for Healthcare Providers and Patients

- *For Providers:* Necessity to adapt to changing technology and regulations to provide optimal care.
- *For Patients*: Greater empowerment and involvement in their healthcare journey.

Preparing for the Future

- *Staying Informed and Agile*: Keep abreast of developments in health IT and regulations.
- *Building Collaborative Networks:* Engage with health IT experts, policymakers, and other stakeholders for shared learning and compliance.

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Q&A SESSION - OPEN FORUM: ADDRESSING YOUR QUESTIONS

Interactive Discussion

- *Open Floor for Queries:* An opportunity for the audience to ask questions and seek clarifications about the HTI-1 Rule and its implications.
- *Engage in Dialogue:* Facilitating a dynamic exchange of ideas and perspectives to deepen understanding.

Guidelines for the Q&A Session

1. *Raise Questions Clearly:* Please state your question concisely and clearly.
2. *Relevant Topics:* Focus questions on the HTI-1 Rule, its components, and its impact on healthcare.
3. *Respectful Interaction:* Maintain a respectful and constructive tone in all questions and discussions.

Closing the Session

- *Final Thoughts and Clarifications*: Summarizing key points and addressing any final queries.
- *Thank You for Participation:* Expressing appreciation for the engagement and insights shared by the audience.

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QUESTIONS FROM AUDIENCE

1.   Q: What does HTI-1 stand for?
   - A: HTI-1 stands for Health Data, Technology, and Interoperability - 1. It's a rule implemented to advance patient access, interoperability, and standards in health IT.

2.   Q: How does the HTI-1 Rule impact Algorithm Transparency?
   - A: The HTI-1 Rule establishes transparency requirements for AI and predictive algorithms in certified health IT. It aims to ensure fairness, appropriateness, and safety in these algorithms, making them more trustworthy and reliable.

3.   Q: What is USCDI Version 3, and why is it important?
   - A: USCDI Version 3 refers to the United States Core Data for Interoperability Version 3. It's important because it introduces enhanced data elements and improves data interoperability, facilitating better patient care and health equity.

4.   Q: What are the challenges healthcare providers may face due to the HTI-1 Rule?
   - A: Providers may face challenges like adapting to new standards, understanding and complying with updated information blocking regulations and investing in technology and training to meet these new requirements.

5.   Q: How does the HTI-1 Rule benefit patients?
   - A: Patients benefit from improved access to their health information, increased engagement in healthcare decisions, and greater trust in the healthcare system due to enhanced transparency, especially in AI use.

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QUESTIONS FROM AUDIENCE

6.   Q: What are some compliance strategies for healthcare entities regarding the HTI-1 Rule?

- A: Compliance strategies include regular policy reviews and updates, investment in technology and staff training, and adopting a proactive approach to information sharing to align with the HTI-1 Rule.

7.   Q: Can you explain the Provider Disincentives for Information Blocking?

- A: Provider Disincentives under the HTI-1 Rule are penalties for healthcare providers who engage in information blocking. These can include financial penalties or corrective actions and are designed to encourage responsible data sharing.

8.   Q: What future directions do you foresee in health IT post-HTI-1?

- A: Future directions include ongoing updates to health data standards, increased integration of AI in healthcare, and continuous evolution in digital health tools and regulations.

9.   Q: How will the HTI-1 Rule change healthcare IT development and usage?

- A: It will drive the development of more advanced, interoperable health IT solutions and encourage healthcare providers to use these technologies more effectively for patient care.

10.   Q: What does the implementation of interoperability-focused reporting metrics entail?

- A: It involves healthcare IT developers reporting specific metrics related to the usage and interoperability of their products. This data helps in understanding the effectiveness of these technologies in healthcare settings and guides continuous improvement.

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11. Q: What is the primary objective of the 21st Century Cures Act?

    A: The primary objective is to accelerate medical product development and bring new innovations in healthcare to patients more efficiently, emphasizing the importance of health data access and interoperability.

12. Q: How does the HTI-1 Rule redefine information blocking?

    A: The HTI-1 Rule revises definitions and exceptions related to information blocking, clarifying what constitutes information blocking and offering guidelines to avoid such practices.

13. Q: What role does AI play under the HTI-1 Rule?

    A: AI plays a crucial role in advancing healthcare delivery, with the HTI-1 Rule establishing requirements for transparency and ethical use of AI and predictive algorithms in health IT.

14. Q: Can you explain the concept of USCDI and its relevance in the HTI-1 Rule?

    A: USCDI, or the United States Core Data for Interoperability, is a set of standard data elements essential for health information exchange. Its relevance in the HTI-1 Rule lies in its latest version, which enhances the scope and quality of data in health IT systems.

15. Q: What are the potential impacts of the HTI-1 Rule on medical research?

    A: The HTI-1 Rule could positively impact medical research by facilitating better data sharing and interoperability, leading to more comprehensive data collection and analysis for research purposes.

QUESTIONS FROM AUDIENCE

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QUESTIONS FROM AUDIENCE

16. Q: How might healthcare providers need to change their practices due to the HTI-1 Rule?

    - A: Providers may need to update their health IT systems, adapt to new data sharing standards, enhance patient data access, and ensure compliance with revised information blocking regulations.

17. Q: What does the future of patient engagement look like under the HTI-1 Rule?

    - A: The future of patient engagement is likely to be more dynamic, with patients having greater access to their health data and being more involved in their healthcare decisions, thanks to improved data transparency and accessibility.

18. Q: How do the HTI-1 Rule updates affect health IT certification?

    - A: The updates affect health IT certification by requiring compliance with new interoperability standards and practices, like adherence to USCDI Version 3 and demonstration of transparent algorithm usage.

19. Q: What kinds of penalties or disincentives can be imposed for information blocking?

    - A: Penalties can include financial fines, corrective action plans, and possible impacts on participation in federal healthcare programs for entities found guilty of information blocking.

20. Q: What should healthcare providers prioritize to effectively adapt to the HTI-1 Rule?

    - A: Healthcare providers should prioritize understanding the new regulations, investing in compliant health IT infrastructure, training staff on these changes, and fostering a culture of open information sharing and transparency.

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CONCLUSION AND KEY TAKEAWAYS - WRAPPING UP: KEY INSIGHTS FROM TODAY'S SESSION

Summarizing the HTI-1 Rule

- *Overview:* A critical update under the 21st Century Cures Act focused on advancing patient access, interoperability, and health IT standards.

- *Components:* Includes Algorithm Transparency, Adoption of USCDI Version 3, Enhanced Information Blocking Requirements, and Interoperability-Focused Reporting Metrics.

Key Takeaways

1. *Enhanced Transparency and Patient Access:* The HTI-1 Rule promotes a more transparent healthcare system, particularly in the use of AI, and enhances patient access to their health data.

2. *Promotion of Interoperability and Innovation:* Encourages seamless data exchange across platforms and fosters innovation in health IT development.

3. *Greater Accountability in Healthcare:* Introduces disincentives for information blocking, emphasizing the need for responsible data sharing.

CONCLUSION AND KEY TAKEAWAYS - WRAPPING UP: KEY INSIGHTS FROM TODAY'S SESSION

Looking Ahead

- *Continuous Adaptation and Compliance:* Healthcare entities must stay informed and adapt to ongoing regulatory changes.

- *Patient-Centered Healthcare Focus:* The rule underscores the shift towards a more patient-centric approach in healthcare delivery and decision-making.

Final Thoughts

- *Embrace Change and Collaboration:* Emphasizing the importance of embracing technological changes and collaborative efforts in healthcare.

- *Thank You for Participation:* Expressing gratitude for active engagement and discussion during the session.

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ADDITIONAL RESOURCES AND REFERENCES - FURTHER EXPLORATION: RESOURCES FOR DEEPENING UNDERSTANDING

Recommended Reading and Resources

- *Official Documentation on the HTI-1 Rule:* Detailed insights and regulatory guidelines from the Office of the National Coordinator for Health Information Technology (ONC).

- *21st Century Cures Act Overview:* Comprehensive information about the Act, its objectives, and implications for healthcare.

- *USCDI Version 3 Resources:* In-depth explanation and analysis of the United States Core Data for Interoperability Version 3.

Online Platforms and Journals

- *Health IT Journals and Publications:* For the latest research, studies, and updates in health IT.

- *Healthcare Policy Blogs and Forums:* Platforms for discussions and insights on healthcare policy and technology.

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ADDITIONAL RESOURCES AND REFERENCES - FURTHER EXPLORATION: RESOURCES FOR DEEPENING UNDERSTANDING

Professional Organizations and Networks

- *Health IT Professional Associations*: Networking and educational opportunities with professionals in the health IT field.
- *Healthcare Policy Advocacy Groups:* Resources for understanding and engaging in healthcare policy advocacy and reform.

Training and Educational Materials

- *Webinars and Online Courses:* Educational resources on health IT, data interoperability, and healthcare regulations.
- **Workshops and Conferences:** Opportunities for learning, networking, and staying updated with the latest trends in healthcare technology.

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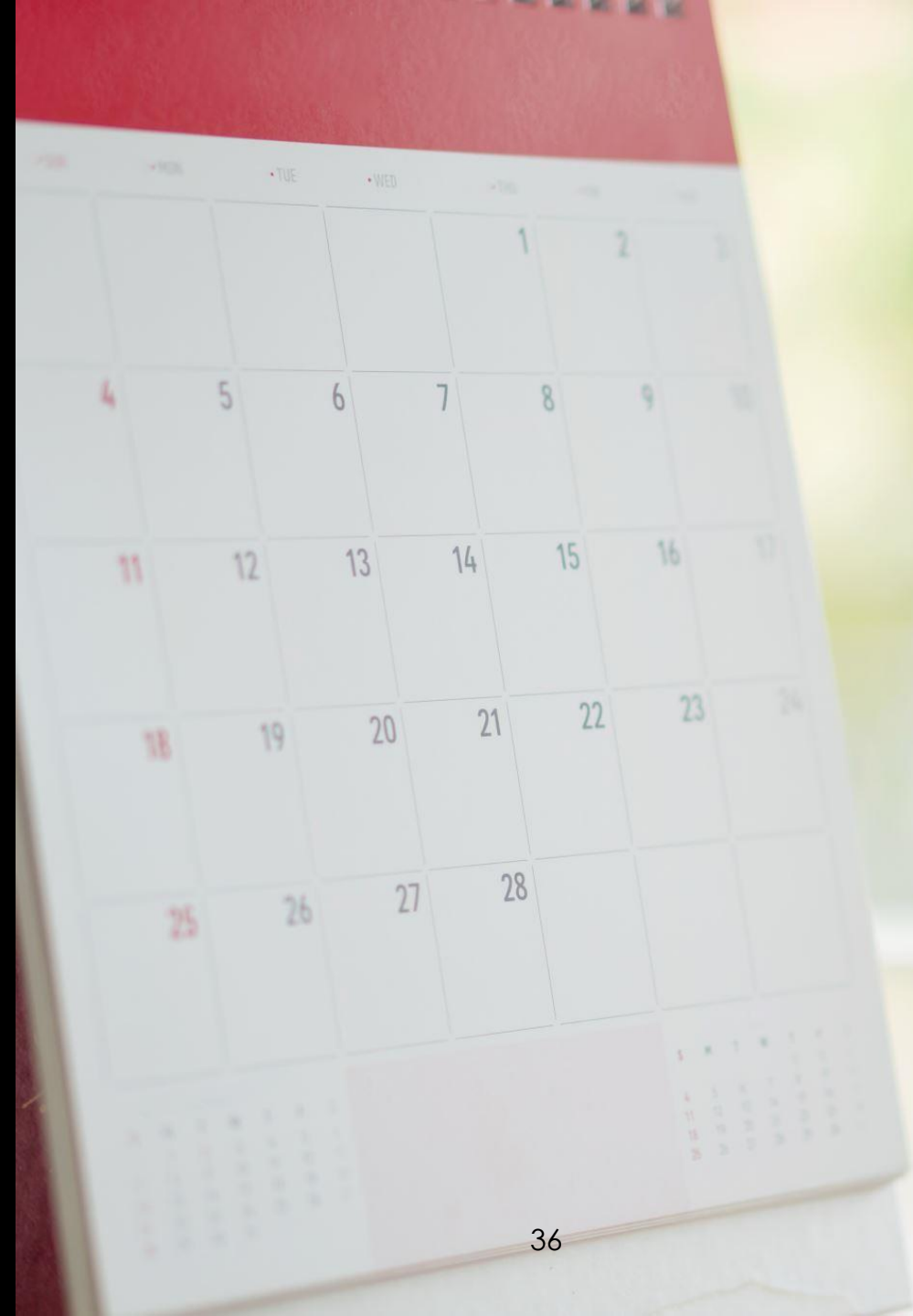# CONTACT INFORMATION AND FOLLOW-UP - STAY CONNECTED: YOUR GATEWAY FOR FURTHER DIALOGUE

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CONTACT INFORMATION AND FOLLOW-UP - STAY CONNECTED: YOUR GATEWAY FOR FURTHER DIALOGUE

Opportunities for Collaboration

- Open to Discussions.
- Future Events and Presentations
- Final Note
- Thank You for Your Engagement
- Encouragement to Reach Out

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ACKNOWLEDGMENTS AND CREDITS - ACKNOWLEDGING CONTRIBUTIONS: A COLLABORATIVE EFFORT

Acknowledgment of Contributions

- Collaborators and Team Members
- Organizational Support

Credits for Information and Resources

- Data and Research Sources
- Visuals and Graphics Credits

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ACKNOWLEDGMENTS AND CREDITS - ACKNOWLEDGING CONTRIBUTIONS: A COLLABORATIVE EFFORT

Special Thanks

- Mentors and Advisors
- Audience Participation

Closing Remarks

- Commitment to Ongoing Learning and Collaboration
- Invitation for Future Sessions

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THANK YOU AND FAREWELL

Gratitude and Appreciation

- A Heartfelt Thank You
- Appreciation for Participation

Final Encouragement

- Encouragement for Continued Learning
- Invitation to Stay Connected

CLOSING SLIDE - THANK YOU AND FAREWELL

Contact Reminder

- *Open Invitation for Feedback:* Encouraging attendees to provide feedback or suggestions about the session.

Closing Message

- *Wishing Well:* Conveying best wishes to all attendees for their future endeavors in health IT and healthcare.

- *Looking Forward to Future Engagements:* Expressing eagerness to interact and collaborate in upcoming events or sessions.

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