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The 21st Century Cures Act: From 20,000 Feet to the Street

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Agenda

- Welcome and Introductions
- Learning Outcomes
- Presentation:
  - MaryBeth Kurland, CAE, CEO, CCMC
  - Janet Marchibroda, MBA, Bipartisan Policy Center
- Question and Answer Session

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Audience Notes

- There is no call-in number for today's event. Audio is by streaming only. Please use your computer speakers, or you may prefer to use headphones. There is a troubleshooting guide in the tab to the left of your screen. Please refresh your screen if slides don't appear to advance.

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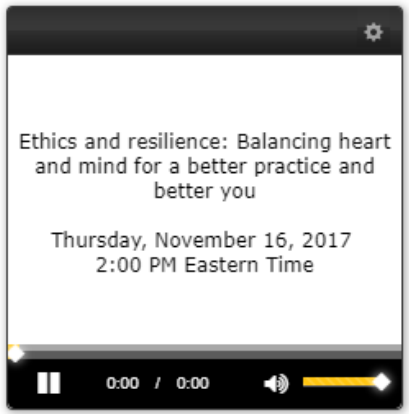
Ethics and resilience: Balancing heart and mind for a better practice and better you
Thursday, November 16, 2017
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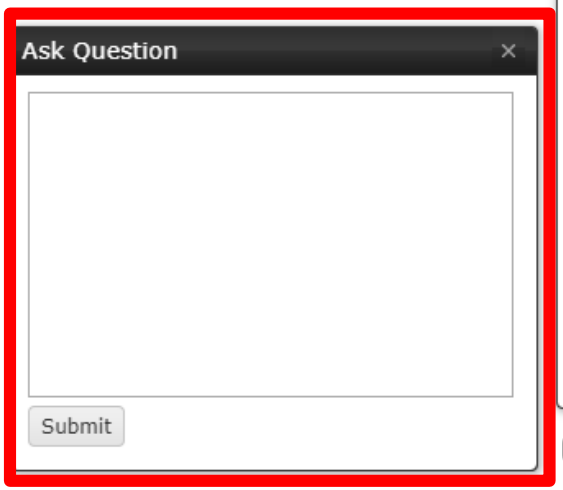
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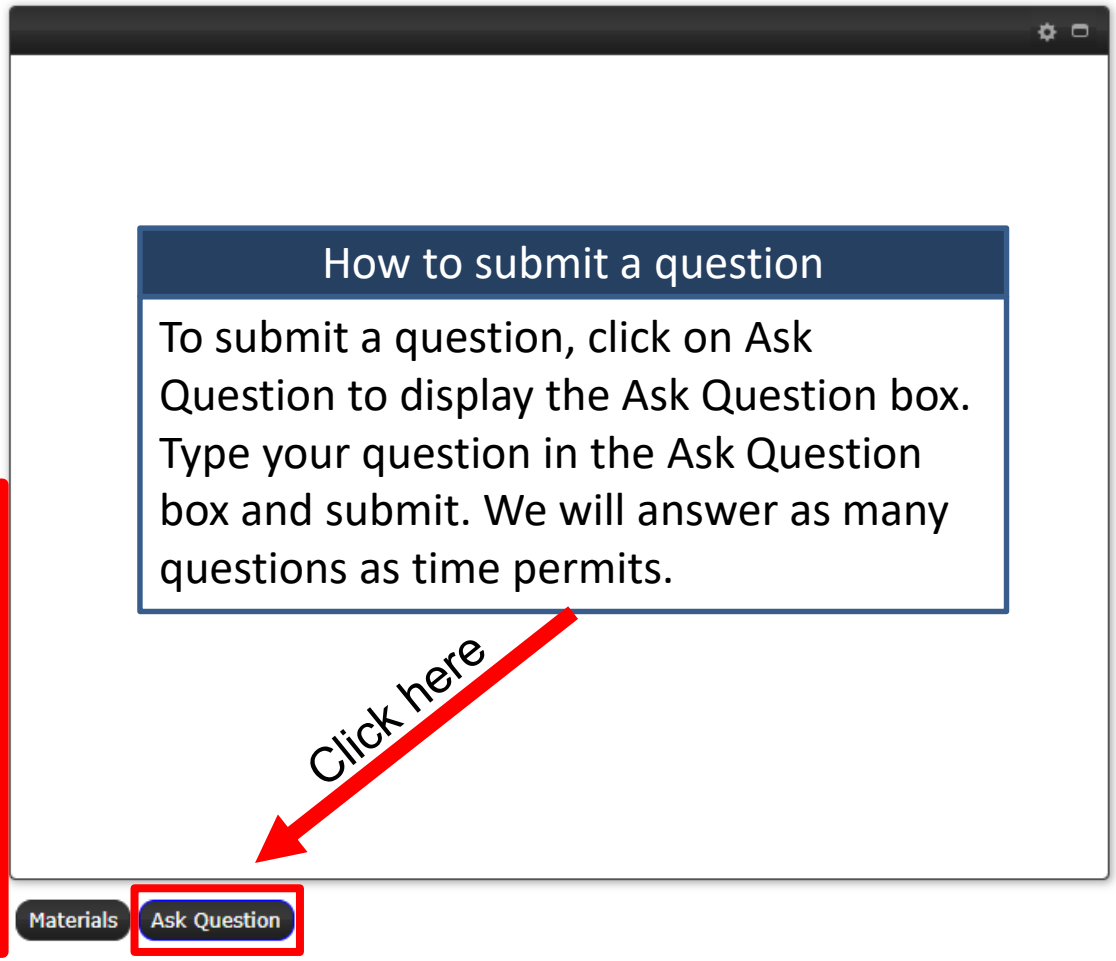
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Audience Notes

- A recording of today's session will be posted within one week to the Commission's website, www.ccmcertification.org
- One continuing education credit is available for today's webinar only to those who registered in advance and are participating today.

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Learning Outcomes Overview

After the webinar, participants will be able to:

1. Summarize three key provisions of the 21st Century Cures Act;
2. Describe three key elements of the 21st Century Cures Act that affect case managers; and
3. Discuss the progress of provisions of the Act already implemented, and what to expect in the coming months.

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Dec. 14, 2016: "An Act to accelerate the discovery, development, and delivery of 21st century cures, and for other purposes."

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Introduction

Janet Marchibroda, MBA

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Bipartisan Policy Center

Bipartisanpolicy.org

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About the Bipartisan Policy Center

Founded in 2007 by Former Senate Majority Leaders

George Mitchell, Howard Baker, Tom Daschle, and Bob Dole

A non-profit organization that drives principled solutions through rigorous analysis, reasoned negotiation and respectful dialogue. With projects in multiple issue areas, BPC combines politically-balanced policymaking with strong, proactive advocacy and outreach.

With guidance from former Senate Majority Leader Bill Frist and former Rep. Bart Gordon, BPC's Health Innovation Initiative focuses on improving health and health care through innovative strategies, accelerating the availability of safe and effective cures and treatments for patients, and effectively using data and technology to improve the lives of individuals

The 21st Century Cures Act

- Comprehensive $6.3 billion medical innovation package that will accelerate **discovery, development, and delivery of safe and effective treatments for patients** ($4.8B NIH research, $500M FDA implementation, and $1B for opioids)
- Also advances mental health reforms and provides grants to states for opioid crisis
- Passed with **nearly unanimous support**, the Act reflects two years of hard work and bipartisan collaboration both in the House and Senate, and with the White House
- **Considerable progress has been made** by key agencies who are in the midst of implementing the Act

The 21st Century Cures Act
WHY WAS THE LAW NECESSARY?

MILLIONS OF AMERICANS HAVE NEITHER CURES OR EFFECTIVE TREATMENTS

- In 2017, there were about 1.7 million new cancer cases diagnosed and more than 600,000 cancer deaths in the U.S.[1]
- About 5.5 million Americans suffer from Alzheimer's disease[2]
- About 1 million Americans live with Parkinson's disease[3]
- Heart disease is the No. 1 cause of death in the U.S., accounting for more than 835,000 deaths (or 1 of every 3 deaths in the U.S.)[4]

WHAT PROBLEMS ARE WE TRYING TO SOLVE?

- It takes more than 10 years and $2 billion – on average – to bring new cures and treatments to patients
- Of the 10,000 known diseases – there are treatments for only 500
- The level of R&D efficiency (e.g., number of new drugs brought to market per billion dollars of U.S. spending) has been declining fairly steadily over the last 60 years

1 Accessed at https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2017.html
2 Accessed at https://www.alz.org/facts/
3 Accessed at http://parkinson.org/Understanding-Parkinsons/Causes-and-Statistics/Statistics
4 Accessed at http://www.heart.org/idc/groups/ahamah-public/@wcm/@sop/@smd/documents/downloadable/ucm_498848.pdf?utm_campaign=sciencenews17-18&utm_source=science-news&utm_medium=heart&utm_content=phd01-31-18

Key Elements of the 21st Century Cures Act
DISCOVERY

1. Provides the National Institutes of Health (NIH) with $4.8 Billion in New Funding
2. Enhances Data Sharing among NIH-Supported Researchers
3. Improves Privacy Protections for Research Volunteers
4. Supports Young Emerging Scientists
5. Reduces Administrative Burden for Researchers
6. Spurs Treatments for Rare Pediatric Diseases
7. Encourages Inclusion of Diverse Populations Represented in Clinical Research

Key Elements of the 21st Century Cures Act DEVELOPMENT

1. Improves Drug Development and Approval
   - Assures patient input into drug development process
   - Improves and expands use of drug development tools that can be used to shorten drug development time and reduce failure rates
   - Modernizes trial design and evidence development
2. Improves Patient Access to Treatments
   - Requires pharmaceutical companies to make compassionate use policies publicly available
   - Enables FDA to grant accelerated approval for regenerative therapies
   - Provides FDA with the flexibility to approve antimicrobial drugs based on a limited population if the drug treats a life-threatening infection

Key Elements of the 21st Century Cures Act DEVELOPMENT

3. Improves Medical Device Regulation, Including Establishment of a Breakthrough Device Pathway
4. Clarifies Regulatory Authority for Medical Devices and Health IT (clarifies that
5. Strengthens FDA Scientific Expertise and Capacity by Offering Additional Flexibility Regarding Hiring
6. Improves Medical Countermeasures
7. Encourages Vaccine Access, Certainty, and Innovation
8. Provides $500 Million in Funding to FDA to Support Implementation

Key Elements of the 21st Century Cures Act DELIVERY

1. Improves Health Information Technology and Information Sharing
   - Improves usability and reduces provider burden
   - Promotes interoperability and discourages information blocking
   - Expands patients' access to their electronic health information
2. Miscellaneous Medicare Provisions
   - Streamlines transfers used for educational purposes
   - Creates new Medicare pharmaceutical and technology ombudsman
   - Improves site-of-service price transparency
   - Requires government actions critical to developing a long-term solution to telehealth services under the Medicare program

Key Elements of the 21st Century Cures Act
MENTAL HEALTH, OPIOID PROVISIONS

1. Strengthens Leadership and Accountability at the Substance Abuse and Mental Health Services Administration (SAMHSA)
2. Ensures Mental and Substance Use Disorder Prevention, Treatment, and Recovery Programs Keep Pace with Science and Technology
3. Improves Mental Health Care for Women, Children, and Adolescents
4. Directs HHS Secretary to Clarify Permitted Uses and Disclosures of Health Information Under HIPAA to Support Coordinated Care
5. Strengthens the Mental Health Workforce
6. Provides $1 billion over 2 years for grants to states to supplement opioid abuse prevention, treatment, and other support

Today We'll Focus on 3 Key Areas That Impact Case Managers

Areas We Will Cover:

1. $4.8B in NIH Research Funding
2. Improving Drug Development at FDA
3. Improving Health IT and Information Sharing

What We Will Cover:

1. What's in the Law and Why It's Important
2. Current Status of Implementation
3. What This Means for Case Managers

BIPARTISAN POLICY CENTER

ADVANCING RESEARCH: NEW NIH FUNDING OF $4.8B

Key 21st Century Cures Act Provisions
NIH RESEARCH FUNDING OF $4.8B

PRECISION MEDICINE INITIATIVE

WHAT'S IN THE LAW

- Provides $1.45 billion in funding for precision medicine research
- Strengthens privacy protections for research volunteers through certificates of confidentiality
- Gives the NIH the authority to require researchers who receive a research grant from NIH, to share their data with the NIH so other researchers can learn and benefit

WHY IT'S IMPORTANT

- "All of Us" Research Program
- One of the largest, most diverse biomedical data sets, with the goal of engaging 1 million individuals – to accelerate research and medical breakthroughs in personalized medicine
- Will further the development of personalized prevention, treatment, and care, based on an individual's genetics, lifestyle, and the environment

Key 21st Century Cures Act Provisions
NIH RESEARCH FUNDING OF $4.8B

PRECISION MEDICINE INITIATIVE
PROGRESS MADE

WHAT'S NEXT
National Roll-out
This Spring

Research

- Began beta phase in May 2017
- Engaged 10 health providers, 6 community health centers, and the VA as partners
- Engaged diverse communities through 4 community partner awards in July
- Created mobile apps to enroll, obtain consent, collect data, and communicate

Privacy Protections

- Issued Guide Notice in Sept to research community, implementing "Certificates of Confidentiality"; every NIH award has this added layer of protection as of Oct 1

Data Sharing

- Made 12 awards to address how to measure usefulness of data sets, where shared data should be stored, how patient protections assured, how interoperability is achieved, and tools needed

Key 21st Century Cures Act Provisions
NIH RESEARCH FUNDING OF $4.8B

BRAIN INITIATIVE

WHAT'S IN THE LAW

- Provides $1.5 billion in funding for Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) Initiative
- Supports efforts to better understand the brain, transforming ability to diagnose and treat neurological/mental disorders such as Alzheimer's

WHY IT'S IMPORTANT

- Understanding brain processes will be instrumental in understanding brain health and ultimately preventing disorders such as Alzheimer's, Parkinson's, schizophrenia, autism, drug addiction, and traumatic brain injury

PROGRESS MADE:
NIH launched 110 new research projects focused on developing powerful new tools to monitor and modulate brain activities in animal models to benefit patients with neurological and psychological disorders

Key 21st Century Cures Act Provisions
NIH RESEARCH FUNDING OF $4.8B

CANCER MOONSHOT

WHAT'S IN THE LAW

- Provides $1.8 billion in funding for former Vice President Biden's *Cancer Moonshot*

WHY IT'S IMPORTANT

- Speeds cancer research, such as the development of cancer vaccines, the development of more sensitive diagnostic tests for cancer, immunotherapy and combination therapies, and other research that has the potential to transform the scientific field

PROGRESS MADE:
In FY 2017, NIH made 142 Cancer Moonshot awards, including advances in immunotherapy, understanding drug resistance, and developing new technologies to characterize tumors and test therapies

What the Act Means for Case Managers
NIH RESEARCH FUNDING OF $4.8B

- **Spurring New Cures and Treatments**
  - Providing the NIH with more than $4 billion in funding will spur innovation, improve U.S. global competitiveness, and accelerate research designed to find new cures and save lives
  - One study has shown that more than 60% of the most important drugs on the market resulted from NIH-funded research grants
  - Case managers will want to be aware of emerging breakthroughs and be prepared to support individuals who may want to pursue clinical trials
- **Precision Medicine is Within Reach**
  - Precision medicine – or developing personalized treatments based on specific genetics, lifestyle, and the environment – is now a therapeutic option for Americans
  - In many cases, reimbursement policies have not caught up with personalized therapies, and the cost of these therapies is not within reach for many Americans
  - Case managers will need to understand reimbursement options available to patients who wish to undergo genetic screening and pursue precision medicine options

BIPARTISAN POLICY CENTER

IMPROVING DRUG DEVELOPMENT

Key 21st Century Cures Act Provisions
IMPROVING DRUG DEVELOPMENT

PATIENT-FOCUSED DRUG DEVELOPMENT

WHAT'S IN THE LAW

Requires FDA to:

- Make public statements regarding patient experience data submitted and reviewed as part of any drug application
- Issue guidances regarding collection of patient experience data and how it will be used in regulatory decision-making
- Prepare a report assessing the use of such data in regulatory decision-making

WHY IT'S IMPORTANT

Patients want to be engaged as partners in the drug development process to:

- Accelerate the identification of new targets in their diseases
- Increase the FDA's acceptance of uncertainty (e.g., benefit-risk assessment)
- This involves incorporating patient input and experiences into the drug development process

Key 21st Century Cures Act Provisions
IMPROVING DRUG DEVELOPMENT

PATIENT-FOCUSED DRUG DEVELOPMENT

PROGRESS MADE

- In May 2017, FDA published a five-year plan for issuing guidance documents related to use of patient experience data
- A new section called "Patient Experience Data" is now included in drug and biologic review documents, requiring reviewers to include a brief statement on how such information was used, if submitted as part of the application
- FDA is on track to complete draft guidance by June 2018, followed by final guidance by June 2020, as required by the law

Key 21st Century Cures Act Provisions
IMPROVING DRUG DEVELOPMENT

DRUG DEVELOPMENT TOOLS

WHAT'S IN THE LAW

- Codifies FDA's ability to qualify biomarkers and other drug development tools, which can accelerate development and approval
- Requires FDA to establish a process and guidance for qualification of drug development tools (including biomarkers and clinical outcome assessments) that can serve as surrogate endpoints, or methods to predict clinical benefit that can be used to support approval

WHY IT'S IMPORTANT

- A biomarker—which is a type of drug development tool—is defined as a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathologic processes, or biological responses to a therapeutic intervention.
- Biomarkers can be used to select patients for inclusion in clinical trials, predict or identify safety problems, or reveal a pharmaceutical activity expected to predict an eventual benefit from a treatment
- Drug development tools can be used to help shorten drug development time and reduce failure rates in development

Key 21st Century Cures Act Provisions
IMPROVING DRUG DEVELOPMENT

DRUG DEVELOPMENT TOOLS
PROGRESS MADE

- FDA is establishing a qualification for drug development tools (i.e., biomarkers, clinical outcome assessments, and animal models)
- FDA has been active with NIH and other stakeholders in the development of evidentiary criteria to support biomarker qualification efforts, having recently held two multi-stakeholder collaborations
- FDA is on track to develop draft guidance, as required by law, by December 2019

Key 21st Century Cures Act Provisions
IMPROVING DRUG DEVELOPMENT

REAL-WORLD EVIDENCE

WHAT'S IN THE LAW

- Real world evidence includes data derived from electronic health records (EHRs), claims and billing systems, registries, and sources of patient-generated data – such as apps and home monitoring
- Act requires FDA to evaluate its use to help support approval of a new indication for an approved drug or support/satisfy post-approval study requirements
- Also requires that FDA develop a framework for implementation and publish guidance describing circumstances under which sponsors and FDA may rely on RWE

WHY IT'S IMPORTANT

- RWE – or data gathered from sources outside of randomized controlled trials, reflecting actual experiences of patients during routine patient care—provides many benefits and opportunities throughout the drug development life cycle
- Improves generalizability of trials with broader, more diverse group of patients in different practice settings
- Provides information on long-term outcomes
- Informs decision-making on value and reimbursement sooner
- Reduces time and cost of post-market monitoring

Key 21st Century Cures Act Provisions
IMPROVING DRUG DEVELOPMENT

REAL WORLD EVIDENCE

PROGRESS MADE

- FDA is developing a framework for a program that will evaluate the use of RWE to support new indications or post-approval study requirements, and is on track to complete its development by December 2018, as required by law
- FDA is gathering input through public workshops, of which two have already been held. Another two workshops are planned
- FDA is supporting numerous demonstration projects to advance a regulatory framework, including:
  - A collaboration with Flatiron Health that is examining how real world data (RWD) can be used to gain insights on safety and effectiveness of new cancer therapies
  - CancerLinQ, ASCO's big data initiative, that is using aggregated data to understand issues related to appropriate use of newly approved therapies, with the initial focus on immunotherapy agents approved for melanoma.

What the Act Means for Case Managers
IMPROVING DRUG DEVELOPMENT

- The FDA is moving drug approvals (including generics) more quickly through the pipeline
  - 46 new drugs were approved in 2017, up from 22 in the previous year
  - 1,027 generic drugs were approved in 2017, the highest annual total in FDA history
- Increasing the availability of drugs – including generic drugs - will help to create more competition in the marketplace, which can help make treatments more affordable and more accessible to patients
- Increased focus on real world evidence is expected to significantly improve the drug development, approval, and post-market monitoring process, and also support decision-making regarding value and effectiveness

BIPARTISAN POLICY CENTER

HEALTH IT AND INFORMATION SHARING

Key 21st Century Cures Act Provisions
HEALTH IT AND INFORMATION SHARING

REDUCING REGULATORY BURDENS

WHAT'S IN THE LAW

HHS – within one year – shall:

- Establish a goal with respect to reduction of regulatory or administrative burdens relating to the use of EHRs
- Develop a strategy and recommendations, prioritizing:
  - CMS Medicare and Medicaid EHR Incentive Programs
  - MIPS
  - Alternative Payment Models
  - Hospital Value-Based Purchasing Program
  - Health IT Certification

WHY IT'S IMPORTANT

- Practicing physicians spend about half of their workdays on EHRs and desk work, including 37% of their time in the examination room with patients, and one to two hours each night[1]
- Emergency physicians spend about 44% of their time on data entry, versus 28% on direct patient care[2]
- Submitting quality data can also be time-consuming and burdensome, taking on average 11 hours and costing $723.50 per eligible clinician[3]
- As a result, EHR and payment-related requirements can lead to lower productivity, higher costs, and physician burnout[4]

[1] Available at: http://www.annfammed.org/content/15/5/419.full.
[2] Available at: https://www.sciencedirect.com/science/article/pii/S0735675713004051
[3] Available at http://www.physiciansfoundation.org/uploads/default/US_Physician_Practices_Spend_More_Than_15.4_Billion_Annually_To_Report_Quality_Measures.pdf
[4] Available at: http://www.americanehr.com/research/reports/Physicians-Use-of-EHR-Systems-2014.aspx

REDUCING REGULATORY BURDENS

PROGRESS MADE

- To reduce regulatory and administrative burdens, with CMS, ONC has established four working groups which address:
  - EHR reporting
  - Documentation, administrative, and reimbursement models
  - Health IT and user-centered design
  - Non-federal payers and other government requirements
- A public meeting on this topic is scheduled for Feb 22, 2018
- ONC now allows health IT developers to self-attest to certain functionality-oriented certification criteria

Key 21st Century Cures Act Provisions
HEALTH IT AND INFORMATION SHARING

NEW REQUIREMENTS FOR EHR DEVELOPERS

WHAT'S IN THE LAW

HHS shall require within one year, as a condition of certification, that health IT developers:

- Not take any actions that constitute information blocking
- Not take any action to inhibit the exchange, access, and use of electronic health information
- Not prohibit or restrict communication regarding usability, interoperability, security, business practices, etc.
- Publish application programming interfaces (APIs) and allow information to be accessed, exchanged, and used without special effort
- Successfully test real world use of technology for interoperability

WHY IT'S IMPORTANT

- Information sharing plays a critical role in supporting delivery system and payment reforms, advances in research and medical innovation, and the ability of individuals to effectively navigate their own health and healthcare
- Being able to communicate challenges associated with usability, security, etc. of health IT facilitates improvement of such systems
- APIs can play a key role in promoting information sharing across disparate health IT systems

PROGRESS MADE:

ONC has stated that it is working to implement these conditions; API provisions are included in the 2015 Edition Health IT Certification

Key 21st Century Cures Act Provisions
HEALTH IT AND INFORMATION SHARING

NEW EHR REPORTING PROGRAM

WHAT'S IN THE LAW

HHS shall:

- Convene stakeholders to develop reporting criteria, including measures that reflect security, usability, interoperability, conformance to certification testing, and performance related to accessing and exchanging information
- Award grants, contracts, or agreements to independent entities that will collect the information required to be reported and report such information to HHS
- Require that health IT developers submit responses to the reporting criteria to the independent entity

WHY IT'S IMPORTANT

- A study conducted by AmericanEHR and the American Medical Association showed that:[1]
  - 43% of physicians have yet to overcome the productivity challenges related to their EHR systems
  - 42% thought that their EHR system's ability to improve efficiency was difficult or very difficult
  - 54% found that that their EHR system increased their total operating costs
  - 72% thought their EHR system's ability to decrease workload was difficult or very difficult

PROGRESS MADE:
ONC has stated that it is unable to move forward on these provisions due to competing priorities

[1] Available at: http://www.americanehr.com/research/reports/Physicians-Use-of-EHR-Systems-2014.aspx

Key 21st Century Cures Act Provisions
HEALTH IT AND INFORMATION SHARING

ACCELERATING INTEROPERABILITY

WHAT'S IN THE LAW

HHS shall:

- Convene stakeholders, establish and publish a trusted exchange framework and a common agreement (TEFCA) for exchange between health information exchange networks
- Provide technical assistance on implementation; provide for pilot testing
- Publish health information networks that have adopted the common agreement and are capable of trusted exchange
- Establish a provider digital contact information index for health professionals and health facilities
- Establish a Health IT Advisory Committee

WHY IT'S IMPORTANT

- Interoperability and information sharing play a critical role in improving health and health care
- Barriers include:
  - Lack of a business case for exchange
  - Costs associated with interfaces and exchange
  - Growing number of data sources
  - Lack of agreement on and adoption of common standards
  - Some concerns about privacy and confidentiality
  - Exchange partner's lack of capability to receive data
  - Difficulty finding provider addresses
  - Difficulty in matching or identifying patients

ACCELERATING INTEROPERABILITY PROGRESS MADE

- ONC has initiated efforts to implement TEFCA, holding two public listening sessions with stakeholders and one round of public comment to gain insights from stakeholders on the policies and practices TEFCA should address
- ONC published a draft TEFCA in January 2018 and is accepting public comments through February 2018
- ONC stood up a new Health IT Advisory Committee, which held its first meeting in January 2018

Key 21st Century Cures Act Provisions
HEALTH IT AND INFORMATION SHARING

INFORMATION BLOCKING

WHAT'S IN THE LAW

- Through rulemaking, and in consultation with the FCC, HHS shall define information blocking
- HHS Office of Inspector General is authorized to:
  - Investigate claims as well as impose penalties on developers, networks, and exchanges that commit information blocking.
  - Refer to other agencies, providers that commit information blocking so that appropriate disincentives can be applied

WHY IT'S IMPORTANT

- Information blocking is the act of providers and HER vendors knowingly and unreasonably engaging in business practices that interfere with electronic health information exchange
- Studies and experience have confirmed that information blocking persists and is a serious impediment to interoperability[1]

PROGRESS MADE:
ONC has not yet published rules that define information blocking; OIG is awaiting ONC's definition

1 Julia Adler-Milstein and Eric Pfeifer, Information Blocking: Is it Occurring and What Policy Strategies Can Address It? 95 Milbank Quarterly, 117, March 2017

Key 21st Century Cures Act Provisions
HEALTH IT AND INFORMATION SHARING

PATIENT ACCESS TO HEALTH INFORMATION

WHAT'S IN THE LAW

- HHS shall encourage partnerships with the goal of offering patients access to their health information
- HHS and OCR shall educate providers on ways to provide patients with access to their health information
- HHS shall promote policies to assure that a patient's electronic information is accessible
- GAO shall conduct a study to review patient access

PROGRESS MADE:
In the past, ONC has published educational information re patient access to information and is currently working with OCR on additional related activities

WHY IT'S IMPORTANT

- Patients and their families or care givers should have access to relevant, usable clinical information directly, via apps and similar technology.
- Such information facilitates patient decision-making and self-care and can also be made available to providers and other patient-designated information recipients.
- Patient access to such information is grounded in a fundamental HIPAA-designated patient right of access to their health information

However, barriers to patient access to their health information, remain

What the Act Means for Case Managers
HEALTH IT AND INFORMATION SHARING

- Electronic information sharing and interoperability of systems among those who deliver, support, and receive care plays a critical role in improving the cost, quality, and patient experience of health care.
- Much of the information about a patient's health and health care resides in the many settings in which care and services are delivered. This information must be delivered to the clinician and the care team, in a usable format, to deliver high-quality, cost-effective, coordinated, patient-centered care.
- Case managers will benefit considerably from the interoperability, information sharing, and information blocking provisions in the Act as they will support their efforts in effectively coordinating and managing their patients' health and health care.

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Question and Answer Session

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Thank you!

- Please fill out the survey after today's session
- Those who signed up for continuing education will receive an evaluation from the Commission.
- A recording of today's webinar and slides will be available in one week at http://ccmcertification.org

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