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The 2019 Healthcare Landscape: A Strategic Scan With A Deep Dive into the Recent ONC Information Blocking and CMS Interoperability Proposed Rules

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eHI Executive Leadership Summit
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About Us

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Health policy, advocacy and data analytics services to health industry clients

Experienced team of 10 professionals bringing to bear diverse backgrounds, including CMS, Capitol Hill, medicine, legal and statistics

Affiliation with McDermott Will & Emery offers seamless, one-stop shopping across clients' lobbying, analytics, policy and legal needs

20 Locations around the globe offering integrated, multidisciplinary approach

120+ dedicated health care attorneys

Tier 1 National Health Rankings in all of the industry's top legal directories

Health Care Practice Group of the Year *Law360* (2018) and *Chambers USA* (2010, 2013, 2017)

HHS Secretary Azar's Four Priorities

- Opioid Crisis – End the crisis of opioid addiction and overdose in America
  - Lead – Admiral Brett Giroir, MD, Assistant Secretary for Health/Senior Advisor to the Secretary for Mental Health and Opioid Policy
- Health Insurance Reform – Improve the availability and affordability of health insurance
  - Lead – James Parker, Senior Advisor to the Secretary for Health Reform
- Drug Pricing – Lower the costs of Rx drugs for all Americans without discouraging innovation
  - Lead – Deputy Assistant Secretary (Health Policy) for Planning and Evaluation John O'Brien, PharmD/ Senior Advisor to the Secretary for Drug Pricing Reform
- Value-Based Care – Transform our health care system to one that pays for value
  - Four focus areas:
    - **Maximizing the promise of health IT, including through promoting interoperability**
    - Boosting transparency around price and quality
    - Pioneering bold new models in Medicare and Medicaid
    - Removing government burdens and barriers, especially those impeding care coordination
  - Lead – CCMI Director Adam Boehler is also Senior Advisor to the Secretary for Value-Based Transformation and Innovation

Administration: "All of Government Approach to Interoperability"

- Series of White House roundtables and summits on interoperability with high level administration attendees – Kushner, Liddell, Verma, Rucker, others
- Verma last December: "interoperability is key to success….data is dormant now…it is not shared…we want it to be accessible….tying payment to some aspects of interoperability/patient access"
- Recent CMS and ONC proposed rules seek to drive interoperability through the use of various levers
  - Complex, multi-faceted proposals
  - Comments due Friday, May 3rd

Who Knew Interoperability Was So Complicated?

- *An Open Ecosystem of Interoperable Applications, Knowledge, Content and Services – An Essential Foundation for Interoperable Decision Support*
- Bring clinicians and HIT engineers together to build an open source library of shared, computable logical information models. When deployed in apps the models provide digital solutions to better health care and lower costs.
- Belief is that without clinical information modeling, we can't achieve seamless, computable clinical data exchange, including sharing of clinical decisions support tools.
- ACS, ACOG, AAFP, ACC and others working on this with the Healthcare Services Platform Consortium.

Congressional Landscape: Senate

- Senate Leadership
  - Majority Leader Mitch McConnell (R-KY)

  - Minority Leader Chuck Schumer (D-NY)

- Ratio Republicans vs Democrats
  - 53 to 47 – gained two seats 2018, but not enough
  - Looking toward 2020 – 34 seats up (22 Rs and 12 Ds)

Key Senate Committee Changes - HELP

Lamar Alexander (R-TN), Chair of the Senate HELP Committee

- Announced he will not seek re-election (last two years as Chair)
- Ranking Member Patty Murray (D-WA); long history of working together with Alexander
- Notable additions from the 116th:
  - New Republican Members: Mitt Romney (R-UT); Mike Braun (R-IN)
  - New Democratic Members: Jacky Rosen (D-NV)
- Health Focus: Health Care Cost/Affordability, Cures Oversight

Key Senate Committee Changes - Finance

Chuck Grassley (R-IA), Chair of the Senate Finance Committee

- Sen. Grassley shifted from Judiciary to Finance
- Republican Senate rules means last two years as Chair
- Ranking Member Ron Wyden (D-OR)
- Experience working with Grassley
- Notable additions from the 116th:
  - New Republican Members: James Lankford (R-OK); Steve Daines (R-MT); Todd Young (R-IN)
  - New Democratic Members: Maggie Hassan (D-NH); Catherine Cortez Masto (D-NV)
- Health Focus: Oversight, Prescription Drug Prices, Rural Health

Congressional Landscape: House

- House Speaker Nancy Pelosi (D-CA)
- Minority Leader Kevin McCarthy (R-CA)
- Ratio of Democrats vs Republicans:
  - 235 Ds to 197 Rs
    - one unresolved election
    - two additional vacancies
      - Pennsylvania's 12th district
      - North Carolina's 3rd district

Congressional Landscape: House Key Health Committees – Energy and Commerce

Frank Pallone (D-NJ), Chair of the Energy and Commerce Committee

- First time as Chair, has been Ranking Member
- Ranking Member Greg Walden (R-OR)
  - First time in the minority as Ranking Member
- Notable additions from the 116th:
  - New Republican Members: Greg Gianforte (R-MT)
  - New Democratic Members: Nanette Barragan (D-CA); Robin Kelly (D-IL); Marc Veasey (D-TX); Tom O'Halleran (D-AZ); Darren Soto (D-FL); Don McEachin (D-VA); Lisa Blunt Rochester (D-DE); Annie Kuster (D-NH)
- Top Health Issues: ACA stabilization, Prescription drug prices, Medicaid expansion, Medicare for All

Congressional Landscape: House Key Health Committees – Energy and Commerce Subcommittee on Health

Anna Eshoo (D-CA)
Chairman Anna Eshoo

- Subcommittee on Health
  - First time as Chair
  - Ranking Member Michael Burgess, MD (R-TX)
    - Long time health subcommittee member
- Subcommittee on Oversight and Investigations
  - Chairman Diana DeGette (D-CO)
    - Active in health policy
  - Ranking Member Brett Guthrie (R-KY)
    - First time Ranking Member for this subcommittee

Congressional Landscape: House Key Health Committees – Ways and Means

Richard Neal (D-MA), Chair of the Ways and Means Committee

- First time as Chair, has been Ranking Member, long-serving
- Ranking Member Kevin Brady (R-TX)
- First time in the minority as Ranking Member
- Notable additions from the 116th:
  - New Republican Members: Jodey C. Arrington (R-TX); Drew Ferguson (R-GA); Ron Estes (R-KS)
  - New Democratic Members: Jimmy Panetta (D-CA); Gwen Moore (D-WI); Dan Kildee (D-MI); Brad Schneider (D-IL); Steven Horsford (D-NV); Stephanie Murphy (D-FL); Don Beyer (D-VA); Brendan Boyle (D-PA); Dwight Evans (D-PA); Tom Suozzi (D-NY)
- Top Health Issues: Pre-existing conditions, Other ACA, Rx Drug Prices, Medicare for All, Health-related tax policies

Congressional Landscape: House Key Health Committees - Ways and Means Health Subcommittee

Chairman Lloyd Doggett (D-TX)

- Subcommittee on Health
  - First time as Chair
  - Ranking Member Devin Nunes (R-CA)
    - First time in the minority as Ranking Member

But Can They Come Together?


BRACE YOURSELVES....
2020 IS HERE
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Divided Government and Election Season

- Administration (Republican); Senate (Republican – not filibuster-proof); House (Democratic)
- Entering 2020 election season:
  - Sen. Cory Booker (announced)
  - ~~Sen. Sherrod Brown (declined)~~
  - Rep. Tulsi Gabbard (announced)
  - Sen. Kristen Gillibrand (announced)
  - Sen. Kamala Harris (announced)
  - Sen. Amy Klobuchar (announced)
  - ~~Sen. Jeff Merkley (declined)~~
  - Sen. Bernie Sanders (announced)
  - Sen. Elizabeth Warren (announced)

What does this divided government mean for health issues?

Three Lenses Impacting the Health Policy Outlook:

+ Oversight

Affordable Care Act

- + Insurance Exchanges
- + State Innovation Waivers
  - 1332 and 1115
- + *Texas v. Azar*

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

TEXAS, et al.,	§	
Plaintiffs,	§	
v.	§	
UNITED STATES OF AMERICA, et al.,	§	**Civil Action No. 4:18-cv-00167-O**
Defendants,	§	
CALIFORNIA, et al.	§	
Intervenors-Defendants.	§	

MEMORANDUM OPINION AND ORDER

The United States healthcare system touches millions of lives in a daily and deeply personal way. Health-insurance policy is therefore a politically charged affair—inflaming emotions and testing civility. But Article III courts, the Supreme Court has confirmed, are not tasked with, nor are they suited to, policymaking.[1] Instead, courts resolve discrete cases and controversies. And sometimes, a court must determine whether the Constitution grants Congress the power it asserts and what results if it does not. If a party shows that a policymaker exceeded the authority granted it by the Constitution, the fruit of that unauthorized action cannot stand.

Here, the Plaintiffs allege that, following passage of the Tax Cuts and Jobs Act of 2017 (TCJA), the Individual Mandate in the Patient Protection and Affordable Care Act (ACA) is unconstitutional. They say it is no longer fairly readable as an exercise of Congress's Tax Power

[1] *See Nat'l Fed'n of Indep. Businesses v. Sebelius (NFIB)*, 567 U.S. 519, 530–38 (2012) (noting the wisdom of legislative policy is entrusted to the Nation's elected leaders).

1

Oversight
Prescription Drug Pricing

Presidential "Blueprint"

- Released in May 2018
- Four multi-agency solutions addressing US drug pricing challenges

Improved competition

Better negotiation

Incentives for lower list prices

Lowering out-of-pocket costs

Positional Positioning Statement Pieces

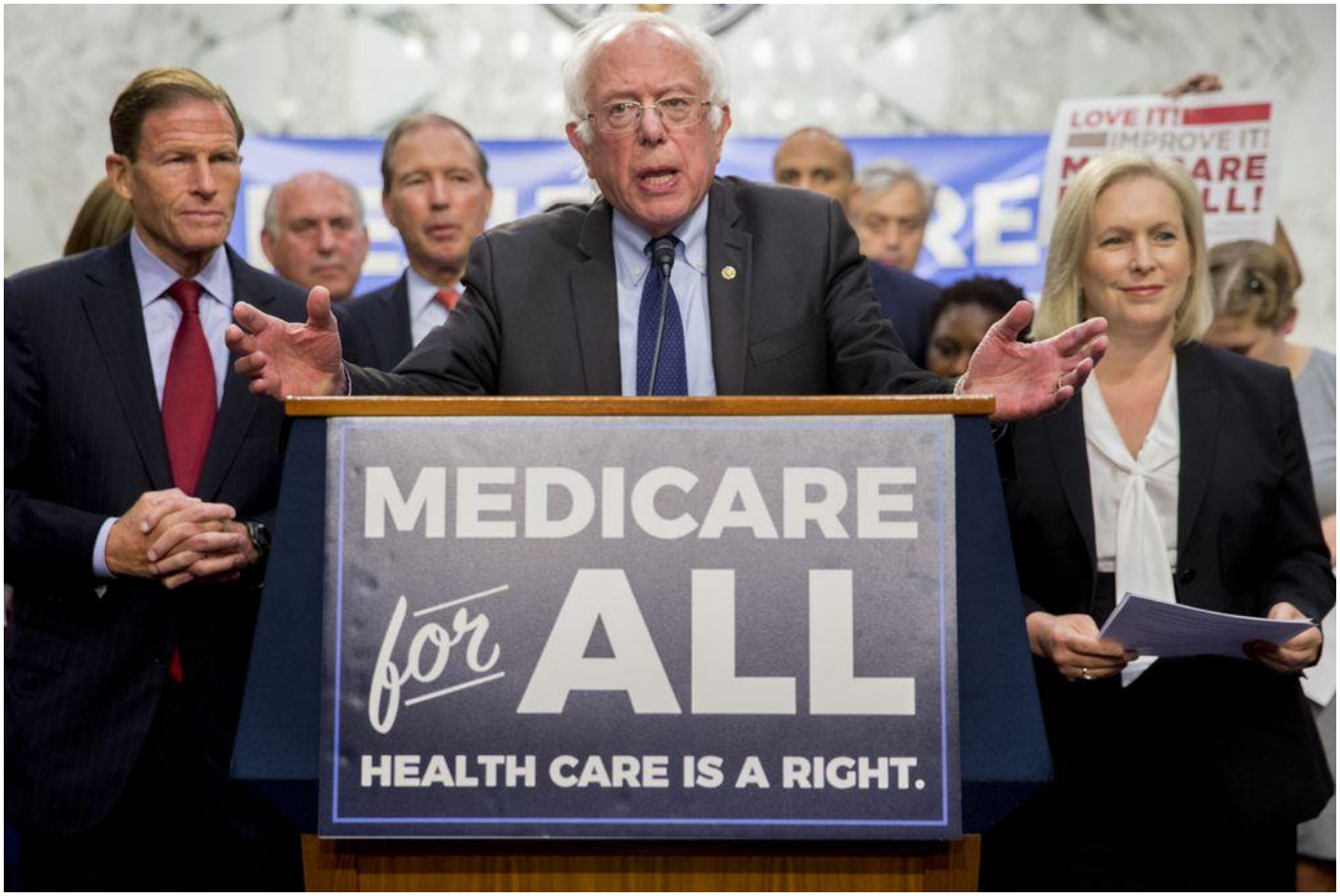
Democrats

- Protecting the ACA
  - Guaranteeing pre-existing condition protections
  - Reversing expanded access to short-term insurance
  - Limiting expanded use of 1332 waivers
- Expanding health care coverage
  - Medicare/Medicaid
- Lowering Drug Prices
  - Part D Negotiations

Republicans

- Reducing regulatory burden
- State flexibility and waivers

Medicare For All



Ambiguity of Medicare For All

- Medicare for All
- Medicare for More
- Medicaid/Medicare Buy-In
- Universal health care
- Single payer
- Socialized medicine
- All payer rate setting

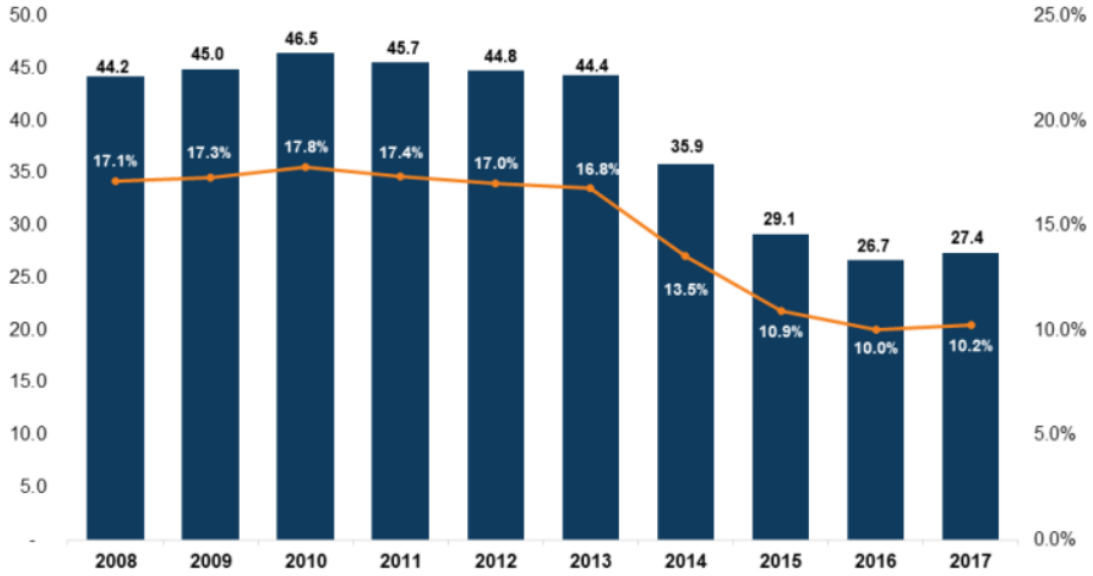
Potential for Bipartisan Action

ACA Market Stabilization	Regulatory Sprint	Health Transformation
Prescription Drug Prices	Price Transparency and Surprise Billing	Industry Consolidation
Rural Health Care	Miscellaneous Medicare Provisions	Innovation

ACA Market Stabilization

Alexander-Murray

- Cost-sharing reduction subsidy payments
- Outreach and enrollment education funding
- Catastrophic (copper) option



Number of Uninsured / Uninsured Rate in Non-elderly Population 2008-2017

Source: Kaiser Family Foundation

Regulatory Sprint to Coordinated Care

Requests for Information

- Stark Law
- Anti-Kickback Statute
- HIPAA

Center for Medicare and Medicaid Innovation

- Administration increased activity in 2019
- Up to 15 models to be released 2019 - 2020
  - Direct Contracting
  - Social Determinants of Health

Key issue to watch: **Mandatory** vs. **Voluntary**

Prescription Drug Pricing

- This is a key potential area for bipartisan cooperation
- This is a major administrative priority
- Politics pose a big potential barrier to making policy progress
- At least 8 congressional hearings thus far

Prescription Drug Prices

CREATES Act
Prevents brand drug makers from withholding samples from generic makers in an effort to delay or prevent generics from coming to market

Pay-for-delay
Limits patent settlement payments from brands to generic makers to not compete

Safe and Affordable Drugs from Canada Act
Allows re-importation from Canada

Right Rebate Act
Prevents purposeful misclassification of drugs by drug makers

Price Transparency and Surprise Billing

- **Senate Price Transparency Working Group**
- **End Surprise Billing Act of 2019**
  H.R. 861, 116th congress

Hospital Charges $4,700 For A Fainting Spell

A 39-year-old man fainted after getting a flu shot at work, and a colleague called 911. He turned out to be fine, but the trip to the ER cost him his whole deductible.

That's A Lot Of Scratch: The $48,329 Allergy Test

A California college professor never imagined that trying to figure out what was causing her rash could add up to such a huge bill.

Source: Kaiser Health News, 2019

- **No More Surprise Medical Bills Act**
  - S. 3592, 115th Congress
- **The Reducing Costs for Out-of-Network Services Act**
  S. 3541, 115th Congress

Industry Consolidation
Potential Scrutiny

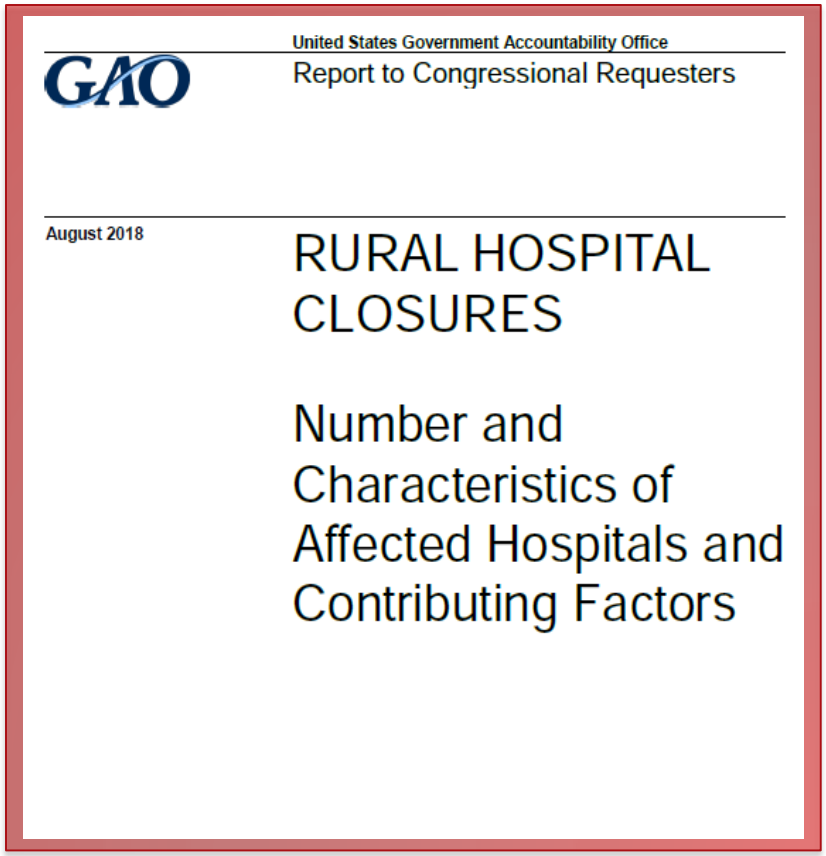
340B

Reproductive health

Price increases

Tax-exempt status/community benefit

Rural Health Care
Viable Proposals



United States Government Accountability Office

GAO

Report to Congressional Requesters

August 2018

RURAL HOSPITAL CLOSURES

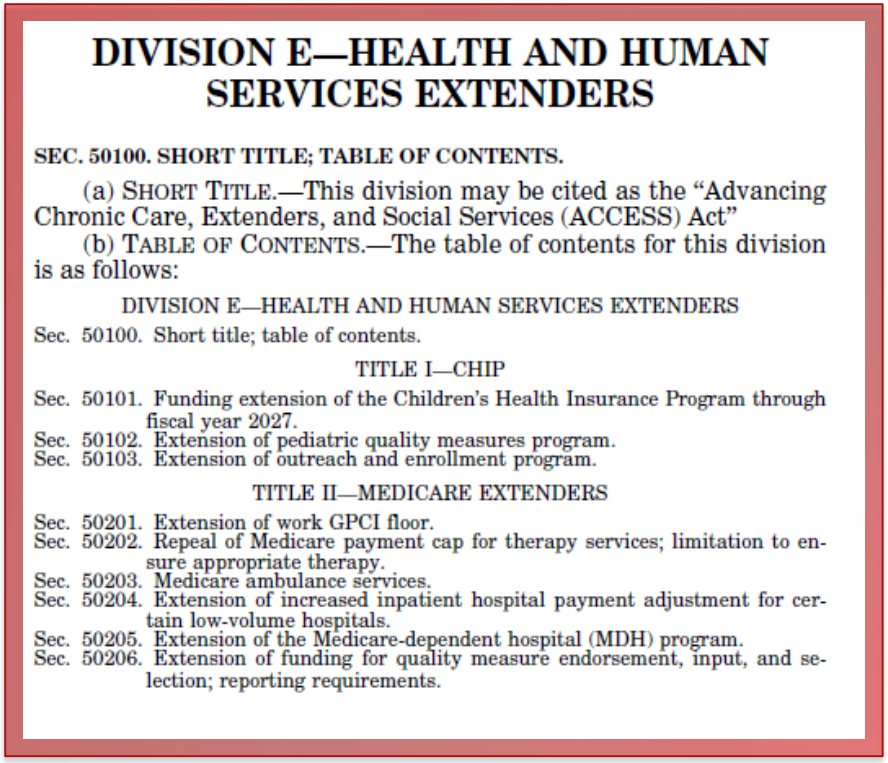
Number and Characteristics of Affected Hospitals and Contributing Factors

- **Increased** Medicare and Medicaid **reimbursement**
- **Strengthened workforce programs** focused on rural areas hardest hit by provider shortages
- **Expanded access** to telehealth services
- **New models of care** for rural providers

Miscellaneous Medicare/Other Provisions

Expect a significant extenders package

- Community Health Centers
- Teaching Health Centers
- Geographic Practice Cost Index
- Radiation Therapy transition payments
- Long-term Care Hospitals
- Medicaid DSH
- National Health Service Corps



DIVISION E—HEALTH AND HUMAN SERVICES EXTENDERS

SEC. 50100. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This division may be cited as the "Advancing Chronic Care, Extenders, and Social Services (ACCESS) Act"

(b) TABLE OF CONTENTS.—The table of contents for this division is as follows:

Health Care Innovation/Interoperability

- Health Care Innovation Caucus:
  - Launched in May 2018 by Founding Co-Chairs: Rep. Mike Kelly (R-PA); Rep. Ron Kind (D-PA); Markwayne Mullin (R-OK); Ami Beri, MD (D-CA)
- Actions:
  - Summer 2018 - Request for public input on how innovation can improve health care quality and lower costs
  - Health Care Innovation Showcase – March 7, 5:00 – 7:30pm
    - Showcase the latest innovations in the health sector
    - Highlight products and ideas that seek to transform or disrupt different segments of the health sector

Congressional Health Care Innovation Caucus Co-Chairs

Rep. Mike Kelly (R-PA-16)

Rep. Kelly serves on the House Ways and Means Committee Health Subcommittee and Chairs the Oversight Subcommittee

Rep. Ron Kind (D-WI-3)

Rep. Kind serves on the House Ways and Means Health Subcommittee

Rep. Markwayne Mullin (R-OK-2)

Rep. Mullin serves on the Energy and Commerce Health Subcommittee

Rep. Ami Bera (D-CA-7)

Rep. Bera serves on the Science, Space and Technology Committee. He is a physician

Senate HELP Committee Tackles Health Care Costs --- Seeks Input, Including on Health IT, and Plans Hearing on Interoperability/Proposed Rules March 26

- Senate Health, Education, Labor and Pensions Committee – Chairman Alexander (Rep-TN)/Ranking Member Murray (Dem-WA)
  - Series of hearings on how to reduce America's rising health care costs in 2018
  - Alexander December 11, 2018 request for input on the following questions:
    - What specific steps can Congress take to lower health care costs, incentivize care that improves the health and outcomes of patients, and increase the ability for patients to access information about their care to make informed decisions?
    - What does Congress or the administration need to do to implement those steps? Operationally, how would these recommendations work?
    - Once implemented, what are the potential shortcomings of those steps, and why are they worthy of consideration despite the shortcomings?
  - Input due March 1, 2019
    - Can't transform health and reduce costs while improving quality without leveraging health IT
  - What next?
    - Interoperability hearing focused on ONC/CMS proposed rules March 26, 2019
    - After that?

Cybersecurity in Congress

- Senate Commerce Committee announced a new Security Subcommittee chaired by Sen. Dan Sullivan (R-AK).
- Senator Mark Warner (D-VA) issued an RFI February 21, 2019 seeking information from stakeholders on improving oversight and identifying gaps in infrastructure and data. Comments due March 22, 2019
- The White House released a National Cyber Strategy in September 2018.
  - While not health focused, it does show importance the Administration is placing on the broader issue.

Aligning HIPAA and 42 CFR Part 2

- Alignment of privacy requirements relating to certain substance use disorder treatment records with HIPAA requirements that allow the use of patient information for treatment, payment and health care operations NOT included in HR 6, opioid legislation enacted in October 2018
- Efforts continue in the 116th, with a greater focus on regulatory change
  - March 5, 2019 bipartisan Senate letter to HHS spearheaded by Senators Capito (R-WV) and Joe Manchin (D-WV)

Administrative Action on 42 C.F.R. Part 2

- On January 3, 2018, SAMHSA released a final rule that further modifies the confidentiality rules ("42 CFR Part 2") that apply to patient identifying information generated by federally assisted substance abuse treatment programs ("Part 2 Records")
- The final rule clarified that when patients consent for persons or entities to receive Part 2 Records, these persons or entities may re-disclose the Part 2 Records to contractors, subcontractors, and legal representatives to assist in performing payment and health care operations activities, provided that they have entered into a written contract meeting certain requirements
- Lawful holders of Part 2 have until February 2, 2020 to enter into contracts with contractors, subcontractors, and legal representatives that comply with the final rule
- According to the Fall 2018 Unified Agenda, additional rulemaking by SAMHSA on 42 C.F.R. Part 2 is anticipated this year

HHS Draft Strategy to Reduce Health IT Burden

- As required by Cures, HHS/ONC issued a report November 28, 2018 entitled, "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs"
- Report includes strategies and recommendations in four categories of EHR-related burden
  - Clinical documentation
  - HIT usability and the user experience
  - EHR reporting
  - Public health reporting

EHRs Contributing to Physician Burnout – A Public Health Crisis

- Three primary objectives to reduce clinician burden:
  1. Reduce the effort and time required to record health information in EHRs for clinicians
  2. Reduce the effort and time required to meet regulatory reporting requirements for clinicians, hospitals, and health care organizations
  3. Improve the functionality and ease of use of EHRs
- Comments were due January 28

CMS Proposed MA/Part D Rule for CY 2020

- Public comment period closed January 25, 2019
- Of interest to HIT community –
  - Proposal to accelerate the use of real-time benefit tools (RTBTs) in the Part D program
  - CMS proposes that each Part D plan make one or more RTBT tools available to prescribers
  - Importantly, the RTBT must be capable of integrating with providers' e-prescribing and EMR systems and deliver complete, accurate, timely and clinically appropriate patient-specific real time formulary and benefit information on or before January 1, 2020.

Expanded Medicare Coverage and Reimbursement for Technology-Enabled Health Care Services

- Telehealth
  - Bipartisan Budget Act of 2018
    - Patients with stroke symptoms presenting at hospitals or mobile stroke units may receive a timely telehealth consult with a neurologist (geographic restriction that limits originating sites to rural areas eliminated)
    - Patients with ESRD who receive home dialysis (geographic restriction eliminated)
    - Opportunities for ACOs to expand their telehealth services
    - Opportunities for MA Plans to provide medical care via telehealth technologies
  - SUPPORT Act
  - Beginning 7/1/2019, Medicare benes may receive coverage for telehealth services related to substance use disorders in any location, including their homes
  - GAO to report to Congress on barriers to the delivery of services to children via telehealth
  - Allows incentive payments to behavioral health providers for adoption of CEHRT
  - Requires the AG to promulgate, prior to 10/1/2019, final regulations specifying circumstances in which certain providers may be issued special registrations to prescribe controlled substances via telehealth
- Other Technology-Based Services
  - Certain provider-to-provider consultations
  - Review of patient images or videos

CMS Interoperability Proposed Rule

- Key Proposals and Requests for Comment:
  - Application Programming Interface (API) requirement for Medicare, Medicaid and CHIP health plans
  - Medicare Condition of Participation: electronic patient event notifications
  - Public posting of hospitals and professionals for information blocking non-attestation
  - Principles for promoting interoperability through new CMMI models
  - Incentivizing adoption of interoperable health IT at long-term and post-acute care settings
  - Strategies to improve patient matching

CMS Interoperability Proposed Rule

- Application Programming Interface (API) requirement for Medicare, Medicaid and CHIP health plans
  - Applies to Medicare Advantage plans, Medicaid state agencies, Medicaid managed care plans, CHIP agencies, CHIP Managed Care entities, and issuers of QHPs in Federally-Facilitated Exchanges
  - API must allow the third-party application, at direction of the beneficiary, to retrieve:
    - Data concerning adjudicated claims
    - Clinical data, if managed by the plan
    - For MA plans, provider directory of contracted providers
  - API technology must meet health information technology standards established by ONC

CMS Interoperability Proposed Rule

- Medicare Condition of Participation: electronic patient event notifications
  - New condition of participating in Medicare for hospitals, critical access hospitals, and other hospital classifications that have adopted EHRs
  - Requirement to send electronic patient event notifications upon a patient's transition to another provider or care setting
  - CMS would require hospitals to include the patient's basic personal information as well as his or her diagnosis (to the extent not prohibited by other applicable law)
  - Would establish a separate requirement from existing Promoting Interoperability measures

CMS Interoperability Proposed Rule

- Public posting of hospitals and professionals for information blocking non-attestation
  - CMS proposes to publically report on applicable CMS websites (e.g., Physician Compare) which Medicare hospitals and health care providers have refused to affirmatively attest that they are not engaging in information blocking.

CMS Interoperability Proposed Rule

- Principles for promoting interoperability through new CMMI models
  - CMS is requesting public comment on general principles for interoperability within Innovation Center models for integration into new models
  - The three principles identified by CMS are:
    - Provide patients access to their own electronic health information
    - Promote trusted health information exchange; and
    - Adopt leading health IT standards and pilot emerging standards
  - CMS also requests public comment on ways to further promote interoperability among model participants and other health care providers

CMS Interoperability Proposed Rule

- Incentivizing adoption of interoperable health IT at long-term and post-acute care settings
  - CMS notes that hospitals frequently transition Medicare patients to post-acute care facilities such as a skilled nursing facility (SNF) and, based on a national survey, only 29 percent of SNFs can send or receive health information
  - CMS is seeking input on how it can more broadly incentivize the adoption of interoperable health IT systems and the use of interoperable data across long-term and post-acute care settings
  - Considering whether standardized patient assessment data elements defined by CMS under the IMPACT Act would be appropriate to incorporate into the United States Core Data for Interoperability (USCDI)

CMS Interoperability Proposed Rule

- Strategies to improve patient matching
  - CMS is also seeking public comment on potential strategies to improve patient matching between health information technology systems
  - CMS is particularly interested in public comment on the security and privacy risks associated with patient matching through algorithms versus the risks inherent with use of a unique patient identifier (UPI)
  - CMS is considering leveraging the newly established Medicare ID, which has replaced Social Security Numbers on Medicare ID cards, to help match records of dually eligible beneficiaries who are enrolled in Medicaid and CHIP plans

What is Information Blocking?

- A practice that, except as required by law or covered by an exception, is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI.
  - There are different knowledge standards for different “actors” under the law
- 5 categories of practices that are “likely to interfere” according to ONC:
  - Restrictions on access, exchange, or use
  - Limiting or restricting the interoperability of health IT
  - Impeding innovations and advancements in access, exchange, or use of health IT-enabled care delivery
  - Rent-seeking and other opportunistic pricing practices
  - Non-standard implementation practices

Actors Subject to the Information Blocking Prohibition

- Health Care Provider
- Health IT Developer of Certified Health IT
- Health Information Exchange (HIE)
- Health Information Network (HIN)

What Information is Covered?

- The information blocking prohibition applies to “electronic health information” or EHI
- ONC proposes to define EHI as:
  - EPHI (as defined in the HIPAA regulations) and
  - “Any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted or maintained in electronic media, … that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.”

Information Blocking: Investigations and Enforcement

- How might the government learn about alleged information blocking?
  - Complaints
    - Cures Act Complaint Process/ONC
    - OIG Hotline
    - No Wrong Door
  - In connection with other investigations
- OIG Information Blocking Investigations
  - Could include informal requests for information and formal subpoenas for documents
- What about penalties?
  - Up to $1,000,000 Civil Monetary Penalties
  - "Appropriate Disincentives"
- When will enforcement begin?

The 7 Proposed Exceptions to Information Blocking

1. Preventing Harm
2. Promoting Privacy of EHI
3. Promoting the Security of EHI
4. 4. Recovering Costs Reasonably Incurred
5. Responding to Requests that are Infeasible
6. Licensing of Interoperability Elements and Rand Terms
7. Maintaining and Improving Health IT Performance

Preventing Harm Exception

- ONC proposes to protect practices that reduce the likelihood of patient harm or harm to others.
- A practice must meet both:
  - General conditions
    - Actor has a reasonable belief that the practice will directly and substantially reduce the likelihood of harm to a patient or someone else
    - Harm arises from:
      - Corrupt/inaccurate data in a patient's EHR
      - Misidentification of a patient or their EHI or
      - Disclosure where, in the professional judgment of a licensed health care professional, that disclosure is reasonably likely to present a danger to the life or physical safety of the patient or another person, and
- The requirements for either:
  - organizational policies or
  - case-by-case determinations

Preventing Harm Exception *cont'd*

- **Organizational Policy**: An organizational policy must be:
  - In writing
  - Based on relevant clinical, technical, and other appropriate expertise
  - Implemented in a consistent and non-discriminatory manner and
  - Only as broad as is necessary to mitigate the risk of harm

- **Case-by-Case Determination**: If a practice does not implement an organizational policy, the actor must make a finding in each case, based on the particular facts and circumstances, and based on, as applicable, relevant clinical, technical, and other appropriate expertise, that:
  - The practice is necessary and
  - No broader than necessary to mitigate the risk of harm

Promoting the Privacy Of EHI Exception

- ONC proposes to protect practices that meet one of the following four separate and limited sub-exceptions designed to promote the privacy of EHI:
  1. Precondition not satisfied
  2. Health IT developer of certified health IT not covered by HIPAA
  3. Denying request for EPHI under HIPAA Privacy Rule
  4. Respecting an individual's request not to share information

Precondition Not Satisfied Sub-Exception

- This sub-exception would protect actors that choose not to provide access, exchange, or use of EHI when a state or federal privacy law requires the actor to satisfy a precondition and that precondition has not yet been satisfied. The practice must be:
  - Tailored to the specific privacy risk or interest being addressed
  - Implemented in a consistent and non-discriminatory manner and either:
    - Conform to organization policies and procedures that meet certain requirements, or
    - Have been documented, on a case-by-case basis, identifying the criteria used to determine when the precondition would be satisfied, any criteria not met, and the reason why the criteria were not met
- For preconditions that rely on the provision of consent or authorization from an individual, the actor:
  - Must have done all things reasonably necessary within its control to provide the individual with a meaningful opportunity to provide the consent or authorization and
  - Must not have improperly encouraged or induced the individual to not provide the consent or authorization

Health IT Developer of Certified Health IT Not Covered by HIPAA Sub-Exception

- This sub-exception would protect health IT developers of certified health IT that are not covered by the HIPAA Privacy Rule when they engage in practices that promote the privacy interests of individuals
- The practice must:
  - Comply with applicable state and federal privacy laws
  - Implement a process that is described in the actor's organizational privacy policy
  - Have previously been meaningfully disclosed to the persons or entities that use the actor's product or service
  - Be tailored to the specific privacy risk or interest being addressed and
  - Be implemented in a consistent and non-discriminatory manner

Denying Request for EPHI under HIPAA Privacy Rule Sub-Exception

- This sub-exception would protect actors that deny an individual's request for access to their EPHI in instances when the HIPAA Privacy Rule would specifically permit such a denial under 45 CFR 164.524(a)(1), (2), and (3)

- Examples of permissible denials include:
  - Requests for psychotherapy notes
  - Certain requests for information created or obtained in the course of research and
  - Certain requests for information obtained from a non-health care provider under a promise of confidentiality

Respecting an Individual's Request Not to Share Information Sub-Exception

- This sub-exception would protect an actor that honors an individual's request that their information not be shared
- Protection would only be available if:
  - The individual requests that the actor not provide such access, exchange, or use
  - That request is initiated by the individual without any improper encouragement or inducement by the actor
  - The actor or its agent documents the request within a reasonable time period and
  - The actor's practice is implemented in a consistent and non-discriminatory manner
- Note: This sub-exception would not allow an actor to refuse to provide access, exchange, or use of EHI when providing such access, exchange, or use is required by law

Promoting Security Of EHI Exception

- ONC proposes an information blocking exception that seeks to balance need for reasonable information security with Cures Act goals of promoting patient access to EHI and exchange of EHI for care coordination and other permissible purposes
- Actors and their security-related practices may satisfy proposed exception through:
  - Written organizational policies or
  - Determinations on a case-by-case basis under particular facts and circumstances
- A practice must meet both:
  - General conditions and
  - Either the requirements for organizational policies or case-by-case determinations

Promoting Security Of EHI Exception *cont'd*

- **General Conditions:** A practice is not Information Blocking if it is:
  - Directly related to safeguarding the confidentiality, integrity and availability of EHI
  - Tailored to the specific security risk being addressed and
  - Implemented in a consistent and non-discriminatory manner
- **Organizational Security Policy**. An organizational security policy must:
  - Be in writing
  - Be based on, and directly respond to, security risks identified and assessed by the actor (e.g., a HIPAA security risk assessment)
  - Align with consensus-based standards or best practices (e.g., NIST or ISO standards) and
  - Provide objective timeframes and other parameters for identifying and responding to security incidents

Promoting Security Of EHI Exception *cont'd*

- **Case-by-Case Determination.** If a practice does not implement an organizational security policy, the actor must have made a determination in each case, based on the particular facts and circumstances that:
  - The practice is necessary to mitigate security risk to the EHI and
  - There are no reasonable and appropriate alternatives that address security risk that are less likely to interfere with, prevent, or materially discourage access, exchange or use of EHI
- ONC's examples of practices that may meet exception:
  - Request triggers malicious software detection alert and actor denies access for appropriate timeframe
  - Temporary suspension of EHI access due to known software vulnerability
  - Practice directly related to verifying identity before granting EHI access
  - Refusal to grant access because individual cannot prove identity
  - Role-based access controls
  - Request comes from blacklisted website

Cost Recovery Information Blocking Exception

- Because information blocking may include fees that interfere with the access, exchange or use of EHI, ONC proposes an exception that permits actors to recover costs reasonably incurred for such access, exchange or use
- In preamble, ONC states, "We note that complying with requirements of this exception would not prevent an actor for making a profit in connection with the provision of access, exchange or use of EHI. Indeed, the costs recoverable under this proposed exception could include a reasonable profit, provided that all applicable conditions were met."
- ONC seeks to balance goal of incentivizing investment in interoperable technologies with Cures Act's goal of facilitating access, exchange and use of EHI for proper purposes

Cost Recovery Exception *cont'd*

- Exception is limited to actor's costs reasonably incurred to provide access, exchange, or use of EHI
- Method by which the actor recovers its costs must
  - Be based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests
  - Be reasonably related to the actor's costs of providing the type of access, exchange, or use to, or at the request of, the person or entity to whom the fee is charged
  - Be reasonably allocated among all customers to whom technology or service is supplied, or for whom the technology is supported
  - Not be based in any part on whether requestor or other person is a competitor, potential competitor, or will be using the EHI in a way that facilitates competition with the actor AND
  - Not be based on the sales, profit, revenue, or other value that the requestor or other persons derive or may derive from the access to, exchange of, or use of EHI, including the secondary use of such information, that exceeds the actor's reasonable costs for providing access, exchange, or use of EHI

Specifically Excluded Costs

- Costs that the actor incurred due to the health IT being designed or implemented in non-standard ways that unnecessarily increase the complexity, difficulty or burden of accessing, exchanging, or using EHI
- Costs associated with intangible assets (including depreciation or loss of value), other than the actual development or acquisition costs of such assets
- Opportunity costs, except for the reasonable forward-looking cost of capital
- A fee prohibited by the HIPAA Privacy Rule's PHI access fee restrictions at 45 CFR § 164.524(c)(4)
- A fee based in any part on the electronic access by an individual or their personal representative, agent, or designee to the individual's EHI
- A fee to perform an export of EHI via the export capability of health IT certified to the ONC's certification criterion at §170.315(b)(10) for the purposes of switching health IT or to provide patients their EHI or
- A fee to export or convert data from an EHR technology, unless such fee was agreed to in writing at the time the technology was acquired

Coordination With Health IT Certification Criteria

- **APIs Certified to §170.315(g)(7) – (11)**
  - If the actor is a developer of a Health IT Module certified to any of the certification criteria for APIs at §170.315(g)(7) – (11), the actor (i.e., the API Technology Supplier) must comply with API fee limitations and other Conditions of Certification at §170.404
  - If actor is an API Data Provider, the actor is only permitted to charge the same fees that an API Technology Supplier is permitted to charge to recover costs consistent with the permitted fees specified in the Condition of Certification at §170.404

- **Export Capability Certified to §170.315(b)(10)**
  - Condition of Certification at § 170.402(a)(4) requires health IT developer that manages EHI to certify to health IT certification criterion for export capability at §170.315(b)(10)
  - As noted on previous slide, the exception specifically prohibits any fee to perform an export of EHI via the export capability at §170.315(b)(10) for the purposes of switching health IT or to provide patients their EHI

Responding to Infeasible Requests Exception

- ONC proposes an information blocking exception that would recognize that there may be practical challenges beyond an actor's control that may limit the actor's ability to comply with requests for access, exchange, or use
- In order to receive protection for a practice, the actor must:
  - Demonstrate that complying with the request in the manner requested would impose a substantial burden on the actor that is unreasonable under the circumstances
  - Timely respond to all request relating to access, exchange, or use of EHI, including but not limited to requests to establish connections and to provide interoperability elements
  - Provide the requestor with a detailed written explanation of the reasons why the actor cannot accommodate the request and
  - Work with the requestor in a timely manner to identify and provide a reasonable alternative means of accessing, exchanging, or using the EHI
- ONC would not consider providing access, exchange, or use in the manner requested to be a burden merely because it would have facilitated competition with the actor or prevented the actor from charging a fee

Licensing Interoperability Elements Exception

- Information blocking may include Interoperability Element licensing terms with persons who require Interoperability Element to develop and provide interoperable technologies or services
- ONC proposes exception that seeks to balance an actor's legitimate interest in protecting the value of its innovations and earning a return on the investment with Cures Act's goal of facilitating access, exchange and use of EHI for permitted purposes
- Examples of practices implicating Information Blocking prohibition:

• Actor refuses to negotiate a license after receiving request from developer	• Actor offers a license to developer at a royalty rate that exceeds reasonable and non-discriminatory rate
• Actor offers a license to a competitor at royalty significantly higher than was offered to a party not in direct competition with the actor	• An actor files a patent infringement lawsuit against a developer without first offering to negotiate a license on reasonable and non-discriminatory terms

What is an Interoperability Element?

- Health IT hardware or software functional element that could be used to access, exchange, or use EHI for any purpose, including EHI transmitted or maintained in disparate media, information systems, HIEs or HINs
- Technical information that describes functional elements (such as a standard, specification, protocol, data model, or schema) and that a person of ordinary skill in the art may require to use the functional elements of the technology, including to develop compatible technologies that incorporate or use the functional elements
- Any technology or service required to enable the use of a compatible technology in production environments, including any system resource, technical infrastructure or HIE or HIN element
- License, right, or privilege that may be required to commercially offer and distribute compatible technologies and make them available for use in production environments
- Any other means by which EHI may be accessed, exchanged, or used

Handling Requests to License Interoperability Elements

Upon receiving a request to license or use Interoperability Elements, actor must respond to the requestor within 10 business days from receipt of the request by:

- Negotiating with the requestor in a reasonable and non-discriminatory (RAND) fashion to identify the interoperability elements that are needed and
- Offering an appropriate license with RAND terms

Required Scope of Rights Under License

- Actor must license the needed Interoperability Elements on RAND terms
- License must provide all rights necessary to access and use the Interoperability Elements for the following purposes, as applicable:

Developing products or services that are interoperable with actor's health IT, health IT under the actor's control, or any third party who currently uses the actor's Interoperability Elements to interoperate with the actor's health IT or health IT under the actor's control	Marketing, offering, and distributing the interoperable products and/or services to potential customers and users *E.g.*, access to the actor's app store/marketplace, but not preferred status	Enabling the use of the interoperable products or services in production environments, including accessing and enabling the exchange and use

Permissible Royalty Terms

- If actor charges a royalty for use of Interoperability Element, the royalty must be:
  - Reasonable (including base and rate)
  - Non-discriminatory (discussed below)
  - Based solely on independent value of actor's technology to the licensee's products, not on any strategic value stemming from actor's control over essential means of accessing, exchanging, or using EHI
- ONC references antitrust and IP law authorities establishing requirements for "standard-essential technologies"
- If actor has licensed the Interoperability Element through a standards development organization in accordance with such organization's policies regarding the licensing of standard-essential technologies on RAND terms, the actor may charge a royalty that is consistent with such policies

Maintaining and Improving Health IT Performance Exception

- ONC proposes to protect practices that balance accessibility and usability of EHI with the need to ensure that health IT performs properly and efficiently
- An actor may make health IT under its control temporarily unavailable to perform maintenance or improvements, so long as the practice is:
  - For a period of time no longer than necessary to achieve the maintenance or improvements for which the health IT was made unavailable
  - Implemented in a consistent and non-discriminatory manner and
  - If the unavailability is initiated by a health IT developer of certified health IT, HIE, or HIN, agreed to by the individual or entity to whom the health IT developer of certified health IT, HIE, or HIN supplied the health IT
- If an actor initiates the unavailability of health IT for maintenance or improvements in response to a risk of harm to a patient or another person or a security risk, then this exception would not be available to the actor and the actor would instead have to meet the requirements of the harm- or security-specific exception, as applicable

ONC's Information Blocking Rule

- Other Proposals and Requests for Information
  - Updating the 2015 Certification Criteria
  - Conditions and Maintenance of Certification
  - Standards Version Advancement Process
  - HIT for Pediatric Care Settings
  - RFIs
    - Price Information
    - Exchange with Registries
    - Trusted Exchange Framework and Common Agreement
    - HIT and Opioid Use Disorder Prevention and Treatment
    - Patient Matching

Looking to keep up with all the changes?

- McDermottPlus Resource Centers:
- http://mcdermottplus.com/news/resource-centers
  - PAYMENT INNOVATION
  - DIAGNOSTICS INSURANCE COVERAGE
  - PRESCRIPTION DRUG PRICING

+McDermott+Consulting Diagnostics Forum April 3rd

McDermott +CONSULTING | HEALTH LOBBYING ANALYTICS POLICY

celebrating 5 years

+Dx Diagnostics Forum

APRIL 3, 2019 | WASHINGTON, DC

SAVE THE DATE | APRIL 3, 2019

Date	Wednesday, April 3, 2019
Time	8:00 am – 4:30 pm EDT
	Networking cocktail reception to follow
Venue	**The McDermott Building** 500 North Capitol Street, NW Washington, DC 20001

Add to Calendar

Click here to add this event to your calendar.

Please contact Jenny Randles to be added to our mailing list if you would like to receive registration announcements, agenda and speaker updates.

Celebrating its fifth year, McDermott+Consulting's +Dx Diagnostics Forum is widely regarded as the premier annual program for the laboratory diagnostics community. We are excited to announce that next year's program will be held on April 3, 2019.

The +Dx agenda will feature a comprehensive discussion and analysis of pending pertinent regulatory and reimbursement issues. The event will focus on the transformative nature of the laboratory diagnostics field and explore how the industry is addressing regulatory and business challenges, all while embracing new and exciting technology in an ever-evolving health policy landscape.

The +Dx Forum will tackle these important issues and more with a faculty comprising industry innovators, lawmakers and leading regulators who will provide in-depth analysis, thoughtful guidance and strategic insights.

+Dx will once again offer unparalleled networking opportunities, including a reception following the Forum where attendees will be able to interact with regulators, industry leaders and colleagues.

For more information, please contact Jennifer Randles at +1 202 204 1461 or jrandles@mcdermottplus.com. Look for registration information and program details soon at mcdermottplus.com.

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