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The 2018 Health Care Landscape: A Strategic Scan

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January 25, 2018

Where to Begin?

Congressional Focus in 2018: Elections

Senate: 34 Seats in play

- Republicans hold distinct advantage with 8 seats up compared to 24 seats held by Democrats and 2 seats held by Independents

House: Fight for Control Heats Up

- Republicans seeing increasing retirements; primaries and presidency likely to have impact

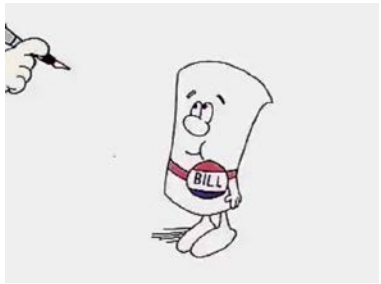
ACA Lives to Fight Another Day…Sort of

House Activity

March 24, 2017:
First AHCA Vote
WITHDRAWN

May 4, 2017
Second AHCA Vote
PASSED

AHCA Sent to Senate for Consideration



It's Not Dead Yet?
Select Concepts Likely to Resurface in 2018

Senate Activity

Late June 2017
BCRA Pulled

July 25, 2017
Amended BCRA Vote
FAILED 43-57
July 27, 2017
Straight Repeal Vote
FAILED 45-55
July 28, 2017
Skinny Repeal Vote
FAILED 49-51

September 2017
Graham Cassidy Pulled

Framework for ACA Repeal and Replace

Continued Desire for Repeal, Stabilization Concerns Drive Discussion

Provisions Targeted for Repeal or Change:

Exchange Infrastructure
- -Premium Subsidies (tax credits)
- -Cost Sharing reductions
- -Mandates (individual, employer)
- -Some market reforms (but not all)

Revenue Provisions
- -Insurer, Drug and Device taxes
- -Income Tax surcharge
- -Cadillac Tax
- -IPAB
- -Medicaid Expansion Funds

Provisions Remaining In Effect:

Select Insurance Reforms
- -Guaranteed Issue*
- -Coverage Up To Age 26 on Parent's Plan

CMMI
- -Funding
- -Waiver Authority

Medicare Payment Cuts
- Productivity Adjustments for Hospitals, Post-Acute Providers, etc.
- Medicare Advantage Changes

Biosimilars and Public Health Measures

Political Calculation Difficult; Legislative Success Less Likely Due to Election

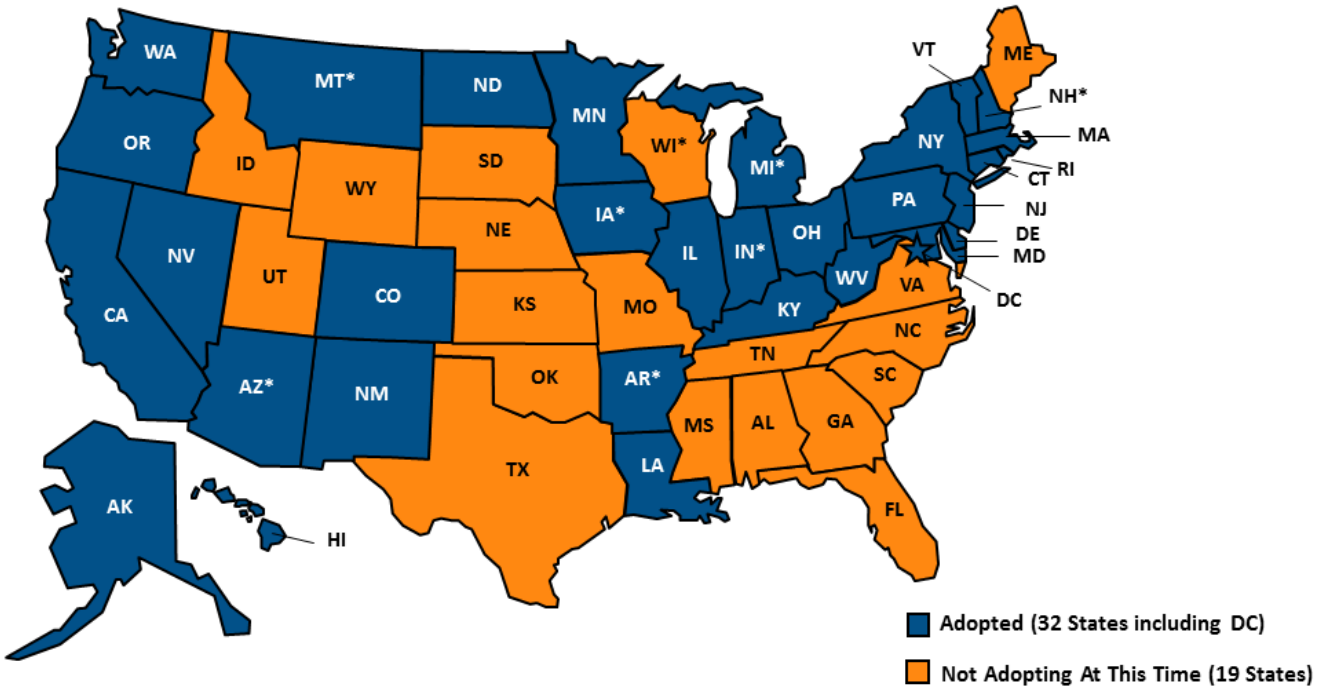
* May be waived by states in some circumstances under proposals

Role of Medicaid Growing In Recent Years

- Emerging role as dominant source of coverage, funding
  - 1 in 5 Americans covered by Medicaid
  - Single largest coverage source in market
  - Nearly half of all births covered by Medicaid
  - Lowest cost per capita compared to other coverage sources
  - Beneficiary satisfaction favorable
- Growth in spending; ideology driving discussion
  - 2015 program spending roughly $545 billion
  - Third largest domestic program in federal budget
    - 9% of federal spending
  - Rapidly displacing education as largest growing state spending item on average

Medicaid Enrollment Expanding in Many States

Current Status of State Medicaid Expansion Decisions



NOTES: Current status for each state is based on KCMU tracking and analysis of state executive activity. *AR, AZ, IA, IN, MI, MT, and NH have approved Section 1115 waivers. WI covers adults up to 100% FPL in Medicaid, but did not adopt the ACA expansion.
SOURCE: "Status of State Action on the Medicaid Expansion Decision," KFF State Health Facts, updated January 1, 2017.
http://kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/

THE HENRY J. KAISER FAMILY FOUNDATION

Can't We All Just Get Along?

Entitlement reform poses political conundrum

Problem is too much spending, not too little revenue
- Reduce entitlement spending
- Reduce taxes
- Private market should lead with government support

Problem is too little revenue, not too much spending
- Increase tax revenue
- Support entitlement spending
- Government should lead with private market support

Broad Range of Considerations in Pursuing Entitlement Reform:
- Complexity of Developing Consensus
- Constituent Impact and Election Considerations
- Legislative Bandwidth
- Cost Considerations
- Stakeholder Engagement
- Legislative process requirements

More likely to be campaign issue at home than legislation on floor

Tough Dynamics Complicate Legislative Efforts

- House and Senate process dictate different approach
  - Senate make-up and rules on the floor mean individual members have much more ability to impact movement
  - Supermajority vote threshold in Senate means reconciliation is only option to pass partisan health care proposals
  - Equal representation rather than proportional distribution of members yields differing strategies in House and Senate
  - Wide gulf between Republican conservatives and moderates poses challenges to finding consensus without losing votes
  - Unclear where the vote count will end up in both parties- is the pathway to the left or the right?
  - Looming 2018 elections likely to polarize discussions
    - Though moderates will try to demonstrate ability to govern

HHS "Reboot" and Evolution Underway

Alex Azar
Secretary of HHS

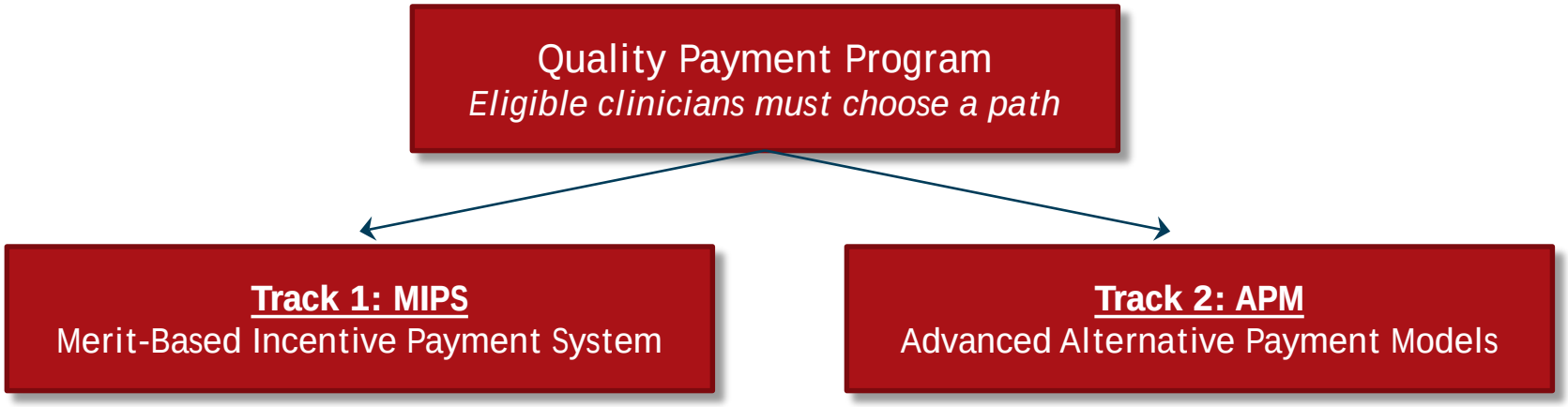
- Former President of US division of Eli Lily confirmed yesterday with 55-43 vote
- Served as Deputy Secretary and General Counsel at HHS under Bush II
- Policy wonk and experienced HHS official likely to take new approach

Seema Verma
CMS Administrator

- Focused on Medicaid reform, regulatory burden and payment reform
- Thumbprint becoming more apparent
- Pragmatic but political; gained credibility with ACA repeal activity

MACRA Implementation Moving Forward

- MACRA implements a new payment methodology for items and services furnished by eligible clinicians under the Part B Physician Fee Schedule
- Payment under MACRA begins on **Jan. 1, 2019** but provider performance reporting that determines 2019 rate began **this year**
- QPP links payment rates and incentives to performance in areas such as quality measurement, electronic health record use, cost and care coordination



- Providers choosing the MIPS pathway will have payments increased or decreased based on performance relative to their peers
- Physicians choosing the APM pathway will receive an incentive payment for participation

Understanding MIPS vs. APM Track

Details	MIPS	Advanced APMs
FFS Adjustments (Adjustment to annual update)	**Yes** (+/- 4% beginning in 2019; goes up to +/- 9% by 2022)	**Not Applicable**
Bonuses and Other Payments	**Bonus to Top 25%** Providers in top 25% of all aggregate scores receive additional positive adjustment factor (2019 – 2025); bonus capped at 10% per eligible provider	**5% Incentive Payment** (2019-2024)
Annual Update* (Beginning in 2026)	**0.25%**	**0.75%**
Criteria for Participation	**MIPS Reporting Requirements in Four Performance Categories**	**Participation Thresholds Related to APMs Involving More Than "Nominal" Risk or Select Medical Home Model**

* Annual Update Amount is 0.5% until 2019 and 0.0% (frozen) in 2020-2025

MIPS Performance Categories

Category	Reporting Criteria	2019-2020 Weight
Quality (Replaces Physician Quality Reporting System and Value Modifier Program)	• Six measures with at least one cross-cutting measure • Outcome measure if available • If no outcome measure, one other high priority measure • Quality measures can be reported either individually or from a specialty-specific measure set	**60%**
Advancing Care Information (Replaces the Meaningful Use program)	• Significant changes from current Meaningful Use program (*e.g.*, no longer requires reporting on the Clinical Decision Support and the Computerized Provider Order Entry measures) • Report on six objectives and measures proposed by CMS (Base Score) • Report on select measures that emphasize patient care and information access (Performance Score)	**25%**
Clinical Practice Improvement Activities	• Measures a provider's participation in clinical improvement-related activities (*e.g.*, expanded practice access, such as same-day appointments for urgent needs) • CMS generally encourages but does not require a minimum number of CPIAs	**15%**
Resource Use (Replaces the cost component of the Value Modifier Program)	• Continues two measures from the Value Modifier program: total costs per capita for all attributed beneficiaries, and Medicare Spending per Beneficiaries with minor technical adjustments • Episode-based measures, as applicable to the MIPS eligible clinician	**0%***

Advanced APM Track Overview

For Payment Years 2019 and 2020, clinicians qualify for the Advanced APM track through their participation in Medicare models designated by CMS as Advanced APMS

Beginning in 2021, clinicians can qualify based upon their participation in both Medicare and other payer models designated by CMS

To qualify for the Advanced APM track in 2020, an APM entity must have sufficient payment or patient volume in Medicare models meeting three specified criteria for Advanced APMs:

1. Certified electronic health record technology (CEHRT) use requirements
2. Quality reporting and/or performance requirements
3. Financial and nominal risk requirements

Drug Pricing Yields Much Talk, Little Action

- President Trump Promises Administrative Action
  - Consistently criticizes industry for price gouging; lack of competition and “getting away with murder”
  - Has voiced support for price negotiation; reimportation; regulatory relief; FDA reform and tax reform
  - Inconsistent in his stance on specific policy proposals
  - HHS, CMS pursuing initial strategies while working to develop comprehensive proposal (OPPS, CMMI activity)
- Bipartisan Criticism Continues in Congress
  - Oversight and calls for action on both sides of aisle
  - Wide range of legislation introduced by both R’s and D’s
  - Republicans more wary of price controls while Democrats want more government intervention

State Flexibility Also Early Focus of HHS; CMS

March 2017 Price and Verma Letter to Governors

"Today, we commit to ushering in a new era for the federal and state Medicaid partnership where states have more freedom to design programs that meet the spectrum of diverse needs of their Medicaid population. "

"The expansion of Medicaid…to non-disabled, working age adults without dependent children was a clear departure from the core, historical mission of the program…We are going to work with both expansion and non-expansion states on a solution that best uses taxpayer dollars to serve the truly vulnerable."

"It is our intent to use existing Section 1115 demonstration authority to review and approve meritorious innovations that build on the human dignity that comes with training, employment and independence."

January 2018 SMDL on Required 'Community Engagement'

"[A] new policy designed to assist states in their efforts to improve Medicaid enrollee health and well-being through incentivizing work and community engagement among non-elderly, non-pregnant adult Medicaid beneficiaries who are eligible for Medicaid on a basis other than disability."

1115 Waivers Likely to Become the Focus

Longstanding Authority Remains Foundation for Innovation

Section 1115 Waiver Basics

OBRA established authority in 1981

Section 1115 allows Secretary to authorize "any experimental, pilot or demonstration project likely to assist in promoting the objectives" of Medicaid or CHIP

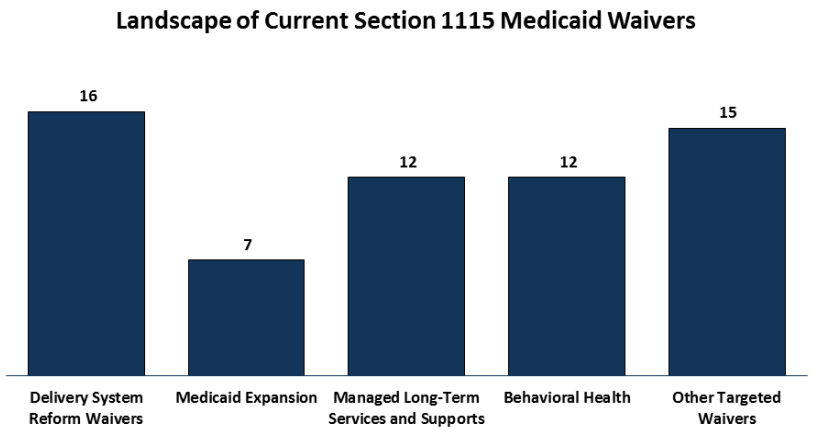
Secretary can waive many, but not all, program requirements under research and demonstration authority

CMS generally requires 1115 waiver arrangements to be budget neutral

Waiver typically structured for 3-5 year time period

Figure 1

States with Section 1115 Medicaid demonstration waivers in place, February 2017



Source: The Kaiser Family Foundation

While Others Tackle Broader Reforms





Pay-for-Performance	Patient-Centered Medical Homes	Bundled Payments	Population-Based, ACOs	Total Cost of Care
• **New Jersey** Private hospitals receive funding to complete projects focused on one of eight conditions • **New York** Provider coalitions receive incentive payments to complete delivery reform projects	• **Arkansas** PMPM payments with opportunity to earn shared savings if cost and quality performance thresholds are met • **Colorado** PMPM payments to cover enhanced services like care coordination	• **Arkansas and Tennessee** Accountable physicians can earn shared savings if cost and quality performance thresholds are met or must pay back excess costs	• **Alabama** Regional Care Organizations • **Minnesota** Integrated Health Partnerships • **Oregon** Coordinated Care Organizations • **Vermont** Accountable Care Organizations	• **Maryland** Global budget caps for hospital services

Upside Risk Only → **Potential for Downside Risk**

Source: The Advisory Board Company

HHS Statement of Regulatory & Deregulatory Priorities for FY2018

HHS is committed to a regulatory agenda that is focused on better meeting the needs of the individuals served by its programs, empowering individuals and communities by reducing the burden of compliance, and maximizing the impact of federal investments, streamlining regulations, improving transparency, flexibility, and accountability of its regulatory processes, to realize a future where science, health care, and human services are fundamentally person-centered.

- More Effectively Meeting the Needs of Individuals
  - **Improving Service Delivery through Meaningful and Appropriate Information Sharing**
    - **stronger and clearer regulatory systems that promote the judicious sharing of personally identifiable information among care teams, individuals, and families, while protecting the confidentiality and security of that information.**
  - Supporting Consumer Autonomy
    - person-centered approach to health care is the concept of autonomy and personal responsibility: providing consumers with the information they need and choices so they can take responsibility for their health and better direct their own care
  - Aligning Programs with Scientific Advancements
    - it is crucial that HHS regulations and programs reflect current science
- Empowering Individuals and Communities Through **Reducing Regulatory Burden**
  - Minimizing Duplication and Burdensome Requirements
  - Eliminating Outdated Restrictions and Obsolete Regulations
  - Providing Necessary Regulatory Clarity to Industry Stakeholders
- Maximizing the Impact of Every Federal Dollar Spent
  - Protecting the Integrity of HHS Programs
  - **Promoting Flexibility** for States, Grantees, and Regulated Entities

Regulatory Reduction – Trump Administration Activity

- **Early 2017** – Regulatory reform has been a priority since day one of the Trump Administration
  - Regulatory freeze memo from then-Chief of Staff Reince Priebus on Trump's first day in office, followed by Executive Orders (EOs) related to regulatory reform matters
  - January 20 – EO on "minimizing the economic burden" of the ACA
  - January 30 – EO on "Reducing Regulation and Controlling Regulatory Costs"
    - EO required that for every one new regulation issued, at least two prior regulations be identified for elimination.
  - February 24 – EO on "Enforcing the Regulatory Reform Agenda"
    - Required agency heads to designate a Regulatory Reform Officer (RRO), who would "oversee the implementation of regulatory reform initiatives and policies to ensure that agencies effectively carry out regulatory reforms"
- **Spring/Summer 2017** – Ongoing work at agency level, with RFIs on reducing regulatory burdens included in several annual rules issued by CMS in 2017 (including IPPS, OPPS and PFS rules)
- **October 2017** – CMS kicked off "Patients Over Paperwork" initiative, seeking to modify/eliminate regulations that impose "unnecessary regulatory obstacles," create burdens, increase costs and limit time spent with patients
- **October 2017** – CMS announced "Meaningful Measures" effort to assess quality measures across all programs
- **December 2017** – President Trump gave speech touting the regulatory reform efforts
  - The President stated: "Within our first 11 months, we cancelled or delayed over 1,500 planned regulatory actions—more than any previous President by far"
  - Regarding the requirement from his January EO that for every one new regulation issued, at least two prior regulations be identified for elimination, President Trump noted that his agencies have far exceeded that goal: "And instead of eliminating two old regulations, for every one new regulation we have eliminated 22—22—that's a big difference. We aimed for two for one, and, in 2017, we hit twenty-two for one"
  - "I want every Cabinet Secretary, agency head, and federal worker to push even harder to cut even more regulations in 2018. And that should just about do it. I don't know if we'll have any left to cut, but we'll always find them"
- **December 2017** – Office of Information and Regulatory Affairs (OIRA)—part of OMB—released its updated Unified Agenda, the listing of pending regulatory actions at each federal agency that is updated twice yearly
  - New title—the *Unified Agenda of Regulatory and Deregulatory Actions*—stresses Administration's focus on reduction
  - OIRA overview notes that the Unified Agenda represents the "next step in fundamental regulatory reform and a reorientation toward reducing unnecessary regulatory burden on the American people" and notes that the two-for-one goal of 2017 is being increased to three deregulatory actions for every new regulatory action in FY2018
  - Overview also notes that 1,579 regulations have been withdrawn or delayed under the Trump Administration

White House Listening Session on EMR Interoperability December 2017

Administration Officials (10)

- Scott Blackburn - VA
- Andrew Bremberg – White House
- Eric Hargan - HHS
- Kristen Honey – White House
- Jared Kushner – White House
- Chris Liddell – White House
- Don Rucker – ONC
- Seema Verma - CMS
- Captain John Windom - VA
- Ashwini Zenooz – VA

Invited Private Sector Guests (24)

- Kyle Armbrester - athenahealth
- Christine Bechtel – X4 Health
- Cynthia Bens – Personalized Medicine Coalition
- Ricky Bloomfield – Apple (HealthKit/ResearchKit)
- Adam Boehler* - Landmark Health
- Ed Cantwell - Center for Medical Interoperability
- Aneesh Chopra (attended portion of listening session) - Hunch Analytics
- John Doerr - Kleiner Perkins Caufield & Byers
- Marc Harrison – Intermountain Healthcare
- Ryan Howells - Leavitt Partners
- Stan Huff - Intermountain Healthcare
- John Kansky –IN Health Information Exchange, Inc.
- Christopher Klomp - Collective Medical Technologies
- Bob Kocher - Lyra health, Inc.
- Joshua Mandel - Verily (Google Life Sciences)
- Kenneth D. Mandl - Boston Children's Hospital
- Joel Minton - Login.gov
- Farzad Mostashari - Aledade, Inc.
- Frank Opelka - American College of Surgeons
- Marc Overhage - Cerner Health Services
- Ryan Panchadsaram - Kleiner Perkins Caufield & Byers
- Mike Polcari - 23andMe
- Josh Rosenfield - ECO1
- Mariann Yeager - Sequoia Project

- Boehler nominated to lead CMMI December 22, 2017
  - Administration wants to "empower beneficiaries as consumers, provide price transparency, increase choices and competition to drive quality, reduce costs and improve outcomes"

White House Listening Session on EMR Interoperability: Themes

- Interoperability is an important issue for the administration.
- Interoperability is key to increasing the quality and decreasing the cost of healthcare.
- The patient should be at the center of interoperability. Patients over paperwork.
- Many of the challenges of interoperability would be resolved by the marketplace if there were proper incentives for providing high quality care.
- Usability of EHR systems needs to be improved.
- Standard RESTFUL APIs, especially HL7 FHIR, are gaining traction. The government should continue to support the development and implementation of open consensus standards.
- Information blocking is a concern, but it needs to be sharply defined and then proper behavior should be actively enforced.
- Certification criteria and Meaningful Use measures for EHRs should be revisited. Relief from the yearly increase in the stringency of the measures would be a welcome legislative action.
- There should be education and clarification about HIPAA. Too often, HIPAA is used as an excuse for not sharing data.
- The definition of interoperability should be further clarified so that we all have the same understanding and a common vision.
- Narrative text in EHRs should not be neglected. Discharge summaries, progress notes, operative notes, and imaging studies contain invaluable information and should be included in the standards.
- Images should be included as part of interoperability.

Health Information Technology Advisory Committee

- Created by the 21st Century Cures Act (8 pages of the statute)
- Replaces the HITPC and HITSC
- Tasked with making recommendations to ONC relating to the implementation of national and local HIT infrastructure.
  - Recommendations to include "policies, standards, implementation specifications, and certification criteria" that advance the electronic access, exchange, and use of health information
  - Priority Target Areas, Additional Target Areas, Authority for Temporary Additional Target Areas are specified in HITECH
- Inaugural meeting January 18, 2018; additional meetings scheduled monthly through November with the exception of July and August
- Two HITAC Advisory Committee task forces are accepting applications:
  - Trusted Exchange Framework Task Force
  - U.S. Core Data for Interoperability Task Force

HITAC Membership

- 3 HHS Appointees:
  - Leslie Lenert, M.D. – Medical University of South Carolina
  - Clem J. McDonald, M.D. – National Center for Biomedical Communications
  - Robert Wah, M.D. – DXC Technology
- 15 GAO Appointees:
  - Michael Adcock – University of Mississippi Medical Center
  - Christina Caraballo – Get Real Health
  - Tina Esposito – Advocate Health Care
  - Brad Gescheider – PatientsLikeMe
  - John Kansky – Indiana HIE
  - Kensaku Kawamoto – University of Utah Dept of Biomedical Informatics
  - Denni McColm – Citizens Memorial Healthcare
  - Brett Oliver – Baptist Health
  - Terrence O'Malley – Massachusetts General Hospital
  - Carolyn Petersen – Mayo Clinic
  - Raj Ratwani – MedStar Health
  - Tasha TerMaat – Epic
  - Sheryl Turney – Anthem Blue Cross Blue Shield
  - Andrew Truscott – Accenture
  - Denise Webb – Marshfield Clinic Health System
- 8 Congressional Appointees:
  - Cynthia Fisher – WaterRev, LLC
  - Dr. Anil Jin – IBM Watson Health
  - Dr. Steven Lane – Sutter Health
  - Arien Malec – RelayHealth
  - Steven Ready – Norton Healthcare
  - Dr. Patrick Soon-Shiong – NantWorks
  - Aaron Miri – Imprivata
  - Valerie Grey – New York eHealth Collaborative

Information Blocking

- In the 21st Century Cures Act, Congress established new civil monetary penalties of up to $1 million per “information blocking” violation
- 21CC defined information blocking (see next slide)
- OIG empowered in 21CC to investigate claims that HIT developers, providers and others engage in information blocking
- OIG met quietly with more than a dozen stakeholders; ONC was represented at these meetings. OIG also consulted the FTC.
- Information blocking was a topic of keen interest at Senate HELP October 2017 hearing on implementation of HIT provisions in 21CC
- ONC and the HHS Office of the Inspector General (OIG) expect to release a proposed rule in April 2018
- The rule is expected to provide examples of reasonable and necessary activities that do NOT constitute information blocking
- OIG is already reviewing cases and preparing to take action when rulemaking is complete
- While the Trump Administration in general is seeking to reduce regulatory/administrative burdens and simplify HHS/CMS programs, this proposed rule may be an exception
- While some in the HIT community do not see information blocking as a problem, ONC views information blocking as a persistent problem and a serious impediment to interoperability (See, e.g., ONC’s Jon White statement at HELP hearing)

21CC Definition of Information Blocking

'Information blocking' means a practice that:

"(A) except as required by law or specified by the Secretary pursuant to rulemaking under paragraph (3), is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and

"(B)(i) if conducted by a health information technology developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or

"(ii) if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

"(2) PRACTICES DESCRIBED.—The information blocking practices described in paragraph (1) may include—

"(A) practices that restrict authorized access, exchange, or use under applicable State or Federal law of such information for treatment and other permitted purposes under such applicable law, including transitions between certified health information technologies;

"(B) implementing health information technology in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using electronic health information; and

"(C) implementing health information technology in ways that are likely to—

"(ii) lead to fraud, waste, or abuse, or impede innovations and advancements in health information access, exchange, and use, including care delivery enabled by health information technology.

"(3) RULEMAKING.—The Secretary, through rulemaking, shall identify reasonable and necessary activities that do not constitute information blocking for purposes of paragraph (1).

21CC Calls for Trusted Exchange Framework to Advance Data Exchange and Interoperability

- In 21CC, Congress directed ONC to develop **or support** a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks – a "network of networks of networks"
- More than 100 regional health information networks exist today as well as broader efforts like Sequoia, Carequality, etc.
- ONC put forth its Draft Trusted Exchange Framework January 5; comments due February 20
- A Recognized Coordinating Entity (RCE), selected by ONC from industry in mid-2018, will act as governance body that will operationalize trusted exchange
- Final TEFCA expected late 2018
- RCE will incorporate trusted exchange framework into a single all-encompassing Common Agreement, which Qualified Health Information Exchange Networks (HIN) may **voluntarily** agree to abide by.
- A Qualified HIN is a network of organizations working together to share data. Qualified HINs will connect directly to each other to ensure interoperability between the networks they represent. Qualified HINs that agree to voluntarily adopt the final TEFCA will be included in ONC's online TEFCA directory. Qualified HINs may withdraw from participation at any time.
- ONC has lofty goals for TEFCA, including "single on-ramp" to interoperability, but how feasible?

Accounting of Disclosures

- HITECH requirement Section 13405(c) – new patient right to AOD of TPO disclosures
- NPRM May 31, 2011 – proposed controversial new right to an "access report"
- HITPC Tiger Team examined the issue, held a virtual hearing, and recommended no requirement for AOD until ONC did successful pilots. None were done.
- 21CC includes AOD as a "Priority Target Area" - requires HITPC to make recommendations for "technologies that allow for an AOD and protections against disclosures of individually identifiable health information made by a CE for purposes of treatment, payment and health care operations"
- Fall 2016 Unified Agenda and Regulatory Plan - AOD Final Rule - "To Be Determined"
- Fall 2017 – Current Regulatory Plan and the Unified Agenda of Regulatory and Deregulatory Actions
  - ANPRM Expected November 2018 – "This advance notice of proposed rulemaking would solicit the public's views on modifying the HIPAA Privacy Rule as necessary to implement the accounting of disclosures provisions of section 13405(c) of the Health Information Technology for Economic and Clinical Health Act (title XIII of the American Recovery and Reinvestment Act of 2009) and on certain workability changes to the accounting requirement. The previous NPRM (76 FR 31426) will be withdrawn in November 2018."

Meaningful Use Reform

- Trump Administration
  - Provided flexibility through rulemaking
  - Eric Hargan statement at listening session
  - Current CMS activity
- Congress
  - H.R. 3120
    - Introduced June 29, 2017 by Rep. Burgess
    - Bipartisan - – Dingell, Thompson, ~~Tiberi~~
    - Removes the escalator clause
    - CBO Score: "*Enacting H.R. 3120 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply*."
    - Energy and Commerce Health Subcommittee Hearing July 20, 2017
    - Approved by Energy and Commerce Committee October 4, 2017
  - S. 2059, EHR Regulatory Relief Act – Introduced by REBOOT group:
    - Senator Thune (R-SD), Chair, Senate Commerce Committee
    - Senator Alexander (R-TN), Chair, Senate HELP Committee
      - » "MU Stage 1 was useful; MU Stage 2 is difficult and MU Stage 3 is terrifying "
    - Senator Burr (R-NC), Chair, Senate Intelligence Committee
    - Senator Enzi (R-WY), Chair, Senate Budget Committee
    - Senator Roberts (R-KS), Chair, Senate Agriculture Committee
    - Senator Cassidy (R-LA), Member, Finance and HELP Committee
    - Removes the escalator clause
    - 90-day reporting period for hospitals and physicians
    - Removal of all-or-nothing approach to Meaningful Use
      - Hospitals – would be required to meet no more than 70% of MU metrics
      - Physicians – directs HHS to consider forthcoming GAO recommendations regarding flexibility in assessing ACI requirements
    - Hardship exception flexibility expanded for 2019 payment year for hospitals
    - CBO Score: S. 2059 reportedly scores at $5M/10-years for ALL of its provisions
  - Congress likely to advance at least H.R. 3120 as a "member priority" in forthcoming government funding bill

"The Secretary shall seek to improve the use of electronic health records and health care quality over time ~~by requiring more stringent measures of meaningful use selected under this paragraph~~".

-HITECH

New Medicare Beneficiary Identifier: A Solution to Patient Matching?

- Currently, Medicare ID cards use the beneficiary's Social Security Number as the ID number
- Congress required CMS in MACRA to remove SSNs from all Medicare cards by April 2019
- CMS intends to replace the SSN with a Medicare Beneficiary Identifier (MBI) on new Medicare cards, which will begin to be mailed to beneficiaries in April 2018. The mailing will occur in phases by geographic location
- Could the creation of a new health-specific ID number for Medicare help pave the way for the adoption of a national patient identifier?
- GAO Patient Matching Study Due to Congress December 2018

Cybersecurity

- Congress, in the "Cybersecurity Information Sharing Act of 2015" called for a report on health care cybersecurity from the Health Care Industry Cybersecurity Task Force.
- That report, entitled "Report on Improving Cybersecurity in the Health Care Industry", released in June 2017, made clear that:
  - "health care cybersecurity is a key public health concern that needs immediate and aggressive attention"
  - "health care industry cybersecurity issues are, at their heart, patient safety issues" and
  - "as health care becomes increasingly dependent on information technology, our ability to protect our systems will have an even greater impact on the health of the patients we serve."
- One of the six high-level imperatives identified by the report is: "Increase the security and resilience of medical devices and health IT"
- The report concluded that "the ever-increasing volume of connected medical devices and automated medication delivery systems, if not protected, could pose a risk to patient safety."

42 CFR 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 clarifies 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
- While the final rule will become effective on February 2, 2018, lawful holders of Part 2 Records will have until February 2, 2020 to enter into contracts with contractors, subcontractors, and legal representatives that comply with the final rule
- In addition to releasing the final rule, SAMHSA announced that it would be hosting a public listening session on January 31, 2018 in-person at its headquarters in Rockville, Maryland and via webcast
  - **Without changes to 42 CFR Part 2, substance use disorder treatment programs are unlikely to be able to participate in efforts to promote health information exchange and interoperability**
  - **Session will provide an opportunity for stakeholders to communicate difficulty in managing 42 CFR Part 2's requirements**

Health Care Clearinghouse Proposal

- Congresswoman McMorris Rodgers (R-WA) reintroduced legislation (H.R. 4613) in December 2017 that would prevent health care clearinghouses from being considered “business associates” and instead permit them to use and disclose all PHI they receive for any purpose permitted under HIPAA
- According to its supporters, the Proposal would enhance patient access to their PHI by creating an opportunity for individuals to directly request longitudinal claims data held by clearinghouses
- Detractors contend that the Proposal would provide health care clearinghouses with special treatment under HIPAA as compared to other business associates that maintain and transmit PHI on behalf of health care providers and health plans
- The bill was referred to the Health Subcommittee of the House Committee on Energy and Commerce
- Senator Cassidy may reintroduce a similar proposal
- Committee staff acknowledge HIPAA needs changes but don’t expect HIPAA to be re-opened anything soon. Do consider cataloging needed changes.

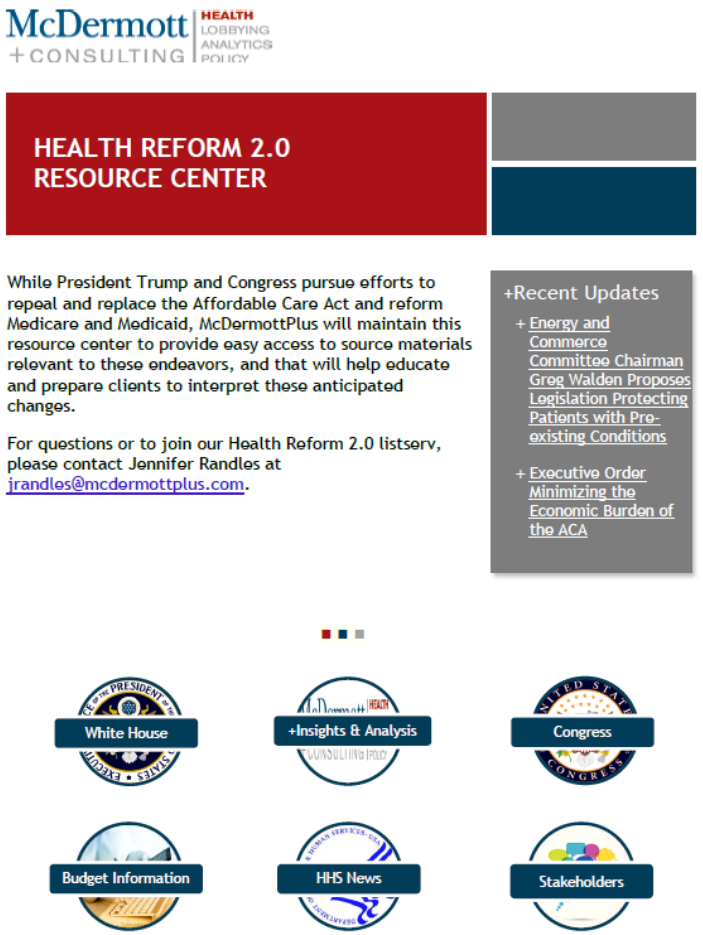
Artificial Intelligence and Health Care

- ONC and AHRQ, with support from the Robert Wood Johnson Foundation, turned to JASON, an independent group of scientists and academics, to consider how AI might shape the future of public health, community health, and healthcare delivery given the digitization of health data
- In a report released in December 2017, JASON outlined three reasons why the time may be ripe for AI in health:
  - 1) Frustration with the existing – or legacy – medical systems among patients and health professionals
  - 2) Ubiquity of networked smart devices in society
  - 3) Comfort with at-home services like those provided through Amazon and other technology companies
- ONC noted that "without access to high quality, reliable data, the promise of AI will not be realized: the increased availability of digital health data could allow for the use of AI in clinical practice, though issues regarding the quality of existing data must be addressed"
- ONC and AHRQ say they will work closely with other agencies to define and identify possible opportunities for the use of AI in efforts to improve biomedical research, medical care, and outcomes

Looking to keep up with all the changes?

- McDermottPlus Resource Centers:

- http://mcdermottplus.com/news/resource-centers
  - Health Reform and Repeal/Replace
  - MACRA
  - PAMA



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