# HHS Hart Health Strategies Inc.

2016

Jan. 29	•Deadline for providing input: Senate Finance/House Ways and Means Committees on the Stark Law; Senate HELP Committee's Bipartisan Legislation to Improve Health Information Technology for Patients and Families; Senate Finance Committee's Chronic Care Options Paper
Feb. 1	•MA and Part D Advance Notice and Draft Call Letter; 2017 Notice of Benefit and Payment Parameters final rule; Final Letter to Issuers in the FFM
Feb. 4	•President Obama formally signs the TPP; the legislative clock for consideration will not begin until the Administration sends final legislative text to Capitol Hill
Feb. 5	•FDA posts agenda for Public Hearing on Draft Guidances Relating to the Regulation of Human Cells, Tissues or Cellular or Tissue-Based Products (HCT/Ps)
Feb. 9	•President's FY 2017 budget released; First markup of Senate HELP Committee medical innovation bills
March 1	•MIPS/APM proposed rule is expected in spring of 2016
March 9	Second markup of Senate HELP Committee medical innovation bills
March 11	•Presentations for Public Hearing on Draft Guidances Relating to the Regulation of HCT/Ps due to the FDA
March 17	•FDA's Patient-Focused Drug Development Public Meeting on Psoriasis
April 1	•IPPS proposed rule published; Medicaid Managed Care final rule published; MA and Part D Rate Announcmenet and Final Call Letter; Hospice Wage Index proposed rule expected in April/May

•Third/final markup of Senate HELP Committee medical innovation bills Public Hearing on Draft Guidances Relating to the Regulation of HCT/Ps; will include a live webcast • Comments due on Draft Guidances Relating to the Regulation of HCT/Ps 29 •MPFS and OPPS/ASC proposed rules published; Hospice Wage Index final rule expected in July/August •IPPS final rule published •End of FY 2016, deadline for federal appropriations to be completed; Expiration of Nursing Workforce Development (Title VIII of Public Health Services Act); Expiration of establishment and support of the Office of Minority Health in the Office of the Secretary 30 •MPFS and OPPS/ASC final rules published; MIPS/APM final rule expected to be included in the MPFS; Marketplace/Health Insurance Exchanges Notice of Benefit and Payment Nov. Parameters proposed rule published • Election Day Scheduled Lame Duck Session

• Early preview of MA growth rates; 2018 Draft Letter to Issuers in the FFM

•House/Senate adjourn for the calendar year



# **Key 2016 Legislative/Regulatory Dates** and Health Policy Overview

Hart Health Strategies Inc. compiled key dates and deadline for the 2<sup>nd</sup> session of the 114<sup>th</sup> Congress. An overview of health policy issues and an election outlook are provided.

## 2016

January 1	The Secretary shall develop and post a draft plan for development of quality measures and accept comments through March 1, 2016. Secretary must post final plan for measure development no later than May 1, 2016.*
January 29	Submission deadline for comments on Senate Finance Committee's Chronic Care Options Paper (extended from Jan 26)
January 29	Deadline for providing input to Senate Finance Committee and House Ways and Means Committee on the Stark Law
January 29	Deadline for commenting on Senate Health, Education, Labor and Pensions (HELP) Committee's Bipartisan Legislation to Improve Health Information Technology for Patients and Families
February 1	The Secretary shall make publicly available the number and characteristics of opt-out physicians and practitioners and update annually.

<sup>\*</sup>Italicized items indicate those related to the implementation of the Medicare Access and CHIP Reauthorization Act (MACRA).

<sup>\*\*</sup>Denotes dates both the House and the Senate have a scheduled recess. Document does not capture other additional dates on which only one chamber is in recess.

~February 1	Medicare Advantage (MA) and Part D Advance Notice and Draft Call Letter
~February 1	2017 Notice of Benefit and Payment Parameters final rule
~February 1	Final Letter to Issuers in the Federally-Facilitated Marketplace (FFM)
February 4	President Obama formally signs the Trans-Pacific Partnership (TPP); the legislative clock for consideration will not begin until the Administration sends final legislative text to Capitol Hill.
February 5	The Food and Drug Administration (FDA) posts agenda for Public Hearing on Draft Guidances Relating to the Regulation of Human Cells, Tissues or Cellular or Tissue-Based Products.
February 9	President's fiscal year (FY) 2017 budget released.
February 9	First markup of Senate HELP Committee medical innovation bills
February 15	Congressional Budget Office (CBO) submits budget and economic outlook report to Budget Committees.
<b>February 15 - 19</b>	House/Senate recess**
February 15 - 19 ~March 2016	House/Senate recess**  The Secretary shall post a draft list of patient relationship categories and codes for episode attribution methodology purposes ("Not later than one year after the date of enactment"); the Secretary shall seek comment for 120 days; not later than 240 days after comment period the Secretary shall post an operational list of patient relationship categories and codes.
-	The Secretary shall post a draft list of patient relationship categories and codes for episode attribution methodology purposes ("Not later than one year after the date of enactment"); the Secretary shall seek comment for 120 days; not later than 240 days after comment period the Secretary shall post an operational list of patient relationship
~March 2016	The Secretary shall post a draft list of patient relationship categories and codes for episode attribution methodology purposes ("Not later than one year after the date of enactment"); the Secretary shall seek comment for 120 days; not later than 240 days after comment period the Secretary shall post an operational list of patient relationship categories and codes.  The Secretary shall conduct a study and submit a report to Congress on the feasibility of mechanisms (e.g. a Website) that would allow users to compare the interoperability of EHR products ("not later than 1 year after the date of
~March 2016  ~March 2016	The Secretary shall post a draft list of patient relationship categories and codes for episode attribution methodology purposes ("Not later than one year after the date of enactment"); the Secretary shall seek comment for 120 days; not later than 240 days after comment period the Secretary shall post an operational list of patient relationship categories and codes.  The Secretary shall conduct a study and submit a report to Congress on the feasibility of mechanisms (e.g. a Website) that would allow users to compare the interoperability of EHR products ("not later than 1 year after the date of enactment").  Merit-based Incentive Payment System (MIPS)/Alternative Payment Model (APM) proposed rule is expected in spring of

March 11	Presentations for Public Hearing on Draft Guidances Relating to the Regulation of Human Cells, Tissues or Cellular or Tissue-Based Products due to the FDA
March 17	FDA's Patient-Focused Drug Development Public Meeting on Psoriasis
March 21- April 1	Senate spring recess
March 22	Committees submit views and estimates to Budget Committees.
March 24 - April 11	House spring recess
April 1	Senate Budget Committee reports concurrent resolution on the budget.
~April 1	Medicaid Managed Care final rule published
~April 1	MA and Part D Rate Announcement and Final Call letter
~April 1	Inpatient Prospective Payment System (IPPS) proposed rule published
~April 1	Skilled Nursing Facility PPS proposed rule published
~April 1	Hospice Wage Index proposed rule expected in April/May
April 6	Third markup of Senate HELP Committee medical innovation bills
April 13	Public Hearing on Draft Guidances Relating to the Regulation of Human Cells, Tissues or Cellular or Tissue-Based Products; will include a live webcast
April 15	Congress completes action on the concurrent resolution on the budget. If not, Chairman of House Budget Committee files 302(a) allocations; Ways and Means is free to proceed with pay-as-you-go measures.
April 29	Comments due on Draft Guidances Relating to the Regulation of Human Cells, Tissues or Cellular or Tissue-Based Products
May 2 - 6	House/Senate recess**
May 15	Annual appropriation bills may be considered in House.

<b>May 30 - June 3</b>	House/Senate recess**
June 10	House Appropriations Committee reports last annual appropriations bill.
June 15	Congress completes action on reconciliation legislation (if required by the budget resolution).
June 30	House completes action on annual appropriation bills.
~July 1	Medicare Physician Fee Schedule (MPFS) proposed rule published
~July 1	Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) proposed rule published
~July 1	Home Health Agency PPS proposed rule published this month
~July 1	Skilled Nursing Facility PPS final rule published this month
~July 1	Hospice Wage Index final rule expected in July/August
July 1	Secretary must submit a report to Congress on the feasibility of including participation in Alternative Payment Models into the Medicare Advantage payment system; this should include feasibility of including a value-based modifier and whether such modifier should be budget neutral.
July 1	Qualified Entities (QEs) may use combined data to conduct additional non-public analyses for the purposes of assisting providers to develop and participate in quality and patient care improvement activities including developing new models of care.
July 1	Qualified Clinical Data Registries (QCDRs) may request Medicare claims data (and in certain circumstances Medicaid data) to link with clinical outcomes data and perform risk-adjusted, scientifically valid analyses and research to support quality improvement or patient safety. Costs of providing the data apply.
July 1	The Secretary shall establish metrics to determine whether the national objective of achieving widespread EHR interoperability is being met.
July 15	President submits mid-session review.
July 18 - 21	Republican Convention (Cleveland, OH)

July 18 - September 6 House/Senate recess\*\*

July 25-28 Democratic Convention (Philadelphia, PA)

**~August 1** IPPS final rule published

**September 2016** GAO Report on alignment of quality measures between public and private programs with recommendations on how to

reduce administrative burden of reporting ("not later than 18 months after the date of enactment").

September 26 First presidential debate (Dayton, OH)

**September 30** End of FY 2016, deadline for federal appropriations to be completed.

September 30 Expiration of Nursing Workforce Development (Title VIII, Public Health Services Act)

**September 30** Expiration of establishment and support of the Office of Minority Health in the Office of the Secretary

**\*October 2016** The Secretary shall post a draft list of care episodes and patient condition codes ("270 days after the end of the

comment period"); The Secretary shall accept comments for 120 days; within 270 days the Secretary shall post an

operational list of care episode and patient condition codes (and the criteria and characteristics assigned to such code).

October 4 Vice presidential debate (Farmville, VA)

October 9 Second presidential debate (St. Louis, MO)

October 10 - House/Senate recess\*\*

**November 11** 

October 19 Third presidential debate (Las Vegas, NV)

**November 1** The Secretary, through notice and comment, shall establish criteria for physician-focused payment models including for

specialist physicians (that could also be used by the Physician-Focused Payment Model Technical Advisory Committee on

which to make comments and recommendations).

**November 1** MPFS final rule published; MIPS/APM final rule expected to be included in the MPFS.

~November 1 OPPS/ASC final rule published ~November 1 Home Health Agency PPS final rule published ~November 1 Marketplace/Health Insurance Exchanges Notice of Benefit and Payment Parameters proposed rule published **November 8 Election Day** ~December 1 Early preview of MA growth rates ~December 1 2018 Draft Letter to Issuers in the FFM **November 21 - 25** House/Senate recess\*\* November 29 -Scheduled Lame Duck Session **December 16 December 16** House/Senate adjourn for the calendar year. 2016 The Secretary shall post physician data ("similar to the type of information in the Medicare Provider Utilization and Payment Data: Physician and Other Supplier Public Use File released by the Secretary with respect to 2012") available on Physician Compare by 2016.

\* \*

## HEALTH ISSUES OVERVIEW

#### **Mental Health**

Congress plans to make progress on a number of mental health initiatives during the coming year.

- The Helping Families in Mental Health Crisis Act (H.R. 2646): The legislation would reform and reorganize the lead federal agency responsible for improving the nation's mental health and substance use treatment and prevention system, the Substance Abuse and Mental Health Services Agency (SAMHSA). Sponsored by House Energy and Commerce Committee member Tim Murphy (R-Pa.), the bill is heading for full committee markup with dozens of Democratic cosponsors.
- The Mental Health Reform Act of 2015 (S. 1945): The bill aims to make critical reforms to address a lack of resources, enhance coordination, and develop meaningful solutions to improve outcomes for families dealing with mental illness. Sponsored by Sens. Chris Murphy (D-Conn.) and Bill Cassidy (R-La.), a hearing has been held by the Senate HELP Committee on the legislation, though an official markup has yet to be scheduled.
- The Mental Health and Safe Communities Act of 2015 (S. 2002): This bill, sponsored by Sen. John Cornyn (R-Texas), would enhance and reauthorized programs that promote collaboration between federal, state and local criminal justice systems to improve responses to people with mental illnesses. The Senate Judiciary Committee has held a hearing on the legislation, which faces Democratic opposition due to the included language on guns.
- The Excellence in Mental Health Act: Sens. Debbie Stabenow (D-Mich.) and Roy Blunt (R-Mo.) have announced that they will introduce legislation to expand upon the Excellence in Mental Health Act, which would increase funding for community health clinics. The Senators previously championed this bill in 2014. The law currently provides funding for a trial program for states to create community mental health centers that offer services such as 24-hour crisis and psychiatric care. The new bill would expand funding under the law from 8 states to 24 states estimated at \$1.7 billion in new funding.

#### **Innovations/21st Century Cures**

Chairman of the Senate HELP Committee Lamar Alexander (R-Tenn.) announced that HELP will not be working on a Senate version of the House's 21<sup>st</sup> Century Cures Act, but will instead vote separately on a range of medical innovation bills. Chairman Alexander announced three scheduled markups to consider legislation: February 9, March 9 and April 6. The Committee will consider at least seven bipartisan bills during its first markup in February:

- Bipartisan HELP Committee legislation to improve electronic health records. (Comments due on draft legislation no later than Jan. 29)
- The FDA Device Accountability Act of 2015 (S.1622), sponsored by Sens. Burr (R-N.C.) and Franken (D-Minn.);
- The Advancing Targeted Therapies for Rare Diseases Act of 2015 (S.2030), sponsored by Sens. Bennet (D-Colo.), Burr (R-N.C.), Warren (D-Mass.), and Hatch (R-Utah);
- The Advancing Research for Neurological Diseases Act of 2015 (S.849), sponsored by Sens. Isakson (R-Ga.) and Murphy (D-Conn.);
- The Next Generation Researchers Act (S.2014), sponsored by Sens. Baldwin (D-Wisc.) and Collins (R-Maine);
- The Enhancing the Stature and Visibility of Medical Rehabilitation Research at the NIH Act (S. 800), sponsored by Sens. Kirk (R-III.), Bennet (D-Colo.), Hatch (R-Utah), Murkowski (R-Alaska), Isakson (R-Ga.), and Collins (R-Maine); and
- Legislation regarding FDA regulation of duodenoscopes.

Additional bipartisan bills to modernize the FDA and the National Institutes of Health (NIH) and provide congressional support for the president's Precision Medicine Initiative will be considered by the Committee in March:

- The Advancing Hope Act of 2015 (S. 1878), sponsored by Sens. Casey (D-Pa.), Isakson (R-Ga.), Brown (D-Ohio) and Kirk (R-III.);
- The Medical Electronic Data Technology Enhancement for Consumer's Health (MEDTECH) Act (S. 1101), sponsored by Sens. Bennet (D-Colo.) and Hatch (R-Utah);
- The Medical Countermeasures Innovation Act of 2015 (S. 2055), sponsored by Sens. Burr (R-N.C.), Casey (D-Pa.), Isakson (R-Ga.), and Roberts (R-Kan.);
- The Combination Products Innovation Act of 2015 (S.1767), sponsored by Sens. Isakson (R-Ga.), Casey (D-Pa.), Roberts (R-Kan.) and Donnelly (D-Ind.);
- The Advancing Breakthrough Medical Devices for Patients Act of 2015 (S. 1077), sponsored by Sens. Burr (R-N.C.), Bennet (D-Colo.), Hatch (R-Utah), and Donnelly (D-Ind.); and
- Legislation to support the president's Precision Medicine Initiative and ensure that the NIH has the tools it needs to research treatments that are individualized for patients.

A final markup in April is planned for the Committee to complete its work on the Innovations Initiative. The House's medical innovation bill, **the 21**<sup>st</sup> **Century Cures Act (H.R. 6)**, passed the chamber in July by a 344 - 77 vote.

#### **Medicaid**

Toward the end of 2015, Chairman of the House Energy and Commerce Committee Fred Upton (R-Mich.) announced the creation of a Medicaid Task Force to examine potential changes to strengthen and sustain the program. The Republican group is chaired by Health Subcommittee Chairman Brett Guthrie (R-Ky.), and the following members were appointed to serve on the Task Force: Rep. Marsha Blackburn (R-Tenn.), Rep. Susan Brooks (R-Ind.), Rep. Larry Bucshon (R-Ind.), Rep. Michael C. Burgess, M.D. (R-Texas), Rep. Chris Collins (R-N.Y.), Rep. Bill Flores (R-Texas, and Rep. Markwayne Mullin (R-Ok.). Task Force membership comes from both Medicaid expansion and non-expansion states. Democrats have criticized the Task Force for not including representatives from both sides of the aisle. Last year, the Energy and Commerce Committee held six Medicaid-related hearings. Additionally, the issue of poverty is of particular interest for Speaker of the House Paul Ryan (R-Wis.). Reforming Medicaid and other entitlement programs could be high on his agenda for the coming year.

#### **Cancer MoonShot**

During the State of the Union Address in January, the President committed to finding a cure for cancer once and for all. Obama announced that Vice President Joe Biden would lead this effort. Accelerating a cure for cancer has been a focus of the Vice President since he lost his oldest son to brain cancer last year. Almost immediately following the President's State of the Union challenge to the nation, Vice President Biden began work on the effort. The Vice President has said that his priority will be increasing both public and private dollars to fight cancer, and on breaking down the silos that prevent the sharing of cancer data and research. Biden has said that he will convene the first meetings with administration officials in February, and that he will continue meetings with leaders in cancer research and advocacy. The President is also expected to announce a presidential memorandum that allows Biden to convene a task force on the subject.

#### **Hospital Payment**

In 2015, House Ways and Means Committee Chairman Kevin Brady (R-Texas) developed a broad package of hospital and post-acute care payment reforms. Chairman Brady has said that he is now looking for opportunities to craft a bill and advance it to the floor. The bill could include the following measures, which were considered during the reform efforts last year:

- The Medicare Crosswalk Code Development Act of 2015 (H.R. 3291) would help translate diagnosis codes between inpatient and outpatient systems.
- The Medicare IME Pool Act of 2015 (H.R. 3292) would give teaching hospitals lump-sum payments for Indirect Medical Education (IME) costs.
- The Strengthening DSH and Medicare Through Subsidy Recapture and Payment Reform Act of 2015 (H.R. 3288) would begin reimbursing disproportionate share hospitals (DSH) through lump sum payments. H.R. 3288 would also increase DSH funding to those hospitals that are located in states that have not expanded their Medicaid programs under the Affordable Care Act (ACA) by recouping overpayments for subsidies under the law.

These bills took into account comments received on Rep. Brady's Hospital Improvements for Payment discussion draft.

#### **Antibiotics**

The problem of antibiotic resistant bacteria is on the radar of both the Administration and Congress. The Presidential Advisory Counsel on Antibiotic-Resistant Bacteria (CARB) will hold several meetings during the coming year. The tentative dates for these meetings are March 30-31, June 21-22, and September 19-20. Legislation that has seen congressional activity and is under discussion includes:

- The Promise for Antibiotics and Therapeutics for Health (PATH) Act (S. 185), introduced by Sen. Orrin Hatch (R-Utah) and Sen. Michael Bennet (D-Colo.) would create a limited population pathway for the approval of certain antibacterial drugs. This legislation continues to be under discussion as a part of the HELP Committee's work on medical innovation.
- The Antibiotic Development to Advance Patient Treatment (ADAPT) Act (H.R. 2629), introduced by Rep. John Shimkus (R-III.) and Rep. Gene Green (D-Tex.) was included as a part of the House-passed 21<sup>st</sup> Century Cures Act. It directs the FDA to approve new antibiotic and antifungal drugs for limited populations of patients for whom no other suitable treatment options exist.

#### **Interoperability**

The following legislation is likely to see action during 2016:

- The MEDTECH Act (S. 1101): In the Senate, Sens. Hatch (R-Utah) and Bennet (D-Colo.) have introduced the Medical Electronic Data Technology Enhancement for Consumer's Health Act, or MEDTECH, which seeks to clarify medical device accessories based upon their intended function, rather than on a classification of the medical device with which it is used. The loosening of FDA's grip on low-risk consumer applications to spur innovation has become a central focus of key champions of health information technology (HIT) on the Hill and we expect to see a strong effort to clarify the role of the FDA, which has traditional oversight of such products, and the Federal Trade Commission (FTC), which has taken on enforcement actions against manufactures of devices making particular health claims. This bill will be considered by the HELP Committee as a part of its work on the Innovations Initiative.
- The Electronic Health Fairness Act (H.R. 887): Introduced by Rep. Diane Black (R-Tenn.), the Electronic Health Fairness Act, H.R. 887, seeks to exempt certain ambulatory care surgical center visits from meaningful use definition. A similar version of this bill in the Senate, S. 1347 sponsored by Sen. Johnny Isakson (R-Ga.), has already passed the Senate this year and the bill is back in the House for consideration.

- The TRUST IT Act (S. 2141): The Transparent Ratings in Usability and Security to Transform Information Technology Act, or TRUST IT, was introduced by Sen. Bill Cassidy (R-La.) in October. TRUST IT seeks to better define interoperability of electronic health records (EHRs) and address performance reporting and security requirements.
- The Cybersecurity Information Sharing Act of 2015 (CISA) (S. 754): Introduced by Sen. Richard Burr (R-N.C.), the CISA bill passed the Senate in late October. The bill addresses cybersecurity, data breach and notification. The House passed its own version of the bill in April and the two bills are expected to be reconciled in conference and sent to the President for signature in early 2016. Several other bills in Congress address information sharing among and between the private sector and government as well as issues around liability protection. A bill introduced by Representative Joe Pitts (R-PA), the Health Exchange Security and Transparency Act requires notification when a breach has occurred under the ACA exchanges, which have been vulnerable to theft of personally identifiable information.

Additionally, the Senate HELP Committee released bipartisan legislation focused on decreasing unnecessary physician documentation; enabling patients to have easier access to their own health records; and making EHRs more accessible to the entire health care team, such as nurses. The Committee identifies stopping information blocking – or intentional interference with access to personal health information, ensuring the government's certification of a records system means what it says it does, and improving standards as the most critical steps to developing systems that achieve interoperability. As mentioned above, the Committee is seeking comments on this draft and plans to consider the bill on February 9.

The Office of the National Coordinator for Health Information Technology (ONC) has issued **A Shared Nationwide Interoperability Roadmap**, with milestones for achieving the goal of sending, receiving, finding, and using priority data domains to improve health care quality and outcomes by the year 2017:

- Supportive Payment and Regulatory Environment: The Centers for Medicare and Medicaid Services (CMS) will aim to administer 30 percent of all Medicare payments to providers through alternative payment models that reward quality and value, and encourage interoperability by the end of 2016.
- Shared Decision-Making, Rules of Engagement and Accountability: At least 50 percent of electronic health information sharing arrangements, including
  health information service provides (HISPs), adhere to recommended policies and business practices such that electronic health information can be
  exchanged by participants across organizational boundaries.
- Ubiquitous, Secure Network Infrastructure: 100 percent of Technology developers should follow best practice guidance for "building security in" their health IT products and services. Security considerations should be incorporated at all phases of the software development lifecycle, including penetration testing. Health IT products and services should be deployed with secure defaults enabled, such as encryption, and easily patched when security issues are identified.
- Verifiable Identity and Authentication of All Participants: 65 percent of health care organizations permit patient access to patient portals via username and password plus knowledge-based attributes or emerging technologies in lieu of passwords to reduce vulnerabilities in identity theft.
- Consistent Representation of Authorization to Access Data or Services: 30 percent of health care organizations convey information on user attributes and
  authentication using agreed upon assertion technology, such as SAML, Organization for the Advancement of Structured Information Standards (OASIS), or
  other nationally recognized standards, when requesting electronic health information across organizational boundaries.
- Consistent Understanding and Technical Representation of Permission to Collect, Share, and Use Identifiable Electronic Health Information: The health IT ecosystem understands and promotes that in general, HIPAA enables the interoperable exchange of electronic health information for TPO without first needing to seek and individual's permission.

- Industry-wide Testing and Certification Infrastructure: ONC and industry-led testing and certification programs develop a standard set of best practices and policies that ensure consistency across testing and certification bodies.
- Consistent Data Semantics: Clinical care providers are able to collect data elements associated with priority data domains once and use them for a variety of purposes, including sharing with individuals, sending during referral, and leveraging for quality measurement.
- Consistent Data Formats: By the end of 2017, SDOs align semantic standards (vocabulary, code set, value set, and structure where applicable) across common electronic health information format standards with semantic standards adopted in ONC's 2015 Edition for priority data domains and associated data elements.
- Secure, Standard Services: Certification approaches that encourage the adoption of specific APIs or consistently functioning APIs in a manner that does not prevent the adoption of innovative new APIs are developed and implemented by ONC and other industry stakeholders.
- Consistent, Secure Transport Techniques: The majority of hospitals, ambulatory providers, and individuals are able to send and receive data elements associated with priority data domains with their trading partners of choice, using at least the Direct transport protocol.
- Accurate Individual Data Matching: All organizations that match electronic health information have an internal duplicate record rate of no more than 2 percent at the end of 2017.
- Health Care Directories and Resource Location: A glide path for moving from current provider directories to future resource location techniques is developed via a public, transparent process, and widely disseminated.
- Individuals have access to longitudinal electronic health information, can contribute to that information, and can direct it to any electronic location: A majority of individuals are able to securely access their electronic health information and direct it to the destination of their choice.
- Provider Workflows and Practices Include Consistent Sharing and Use of Patient Information From All Available and Relevant Sources: Providers evolve care processes and information reconciliation to ensure essential health information is sent, found and/or received to support safe transitions in care.
- Measuring Success: ONC, federal partners and stakeholders develop a set of measures assessing interoperable exchange and the impact of interoperability on key processes that enable improved health and health care.

#### Physician Payment/MACRA

During 2016, the Centers for Medicare and Medicaid Services (CMS) will be focused on developing the new physician payment methodology stemming from the Medicare Access and CHIP Reauthorization Act (MACRA) of April 2015. As is detailed in our MACRA timeline, CMS is in the process of transitioning Medicare physician payments into an incentive based system, known as the Merit-Based Incentive Payment System (MIPS). Under MACRA, providers participating in alternative payment models (APMs) won't be judged under MIPS and will receive a five percent bonus payment between 2019 and 2024. CMS has already published a request for information (RFI) and solicited additional comments through the 2016 Medicare Physician Fee Schedule (MPFS).

This year will be the critical year for MACRA rulemaking. While Medicare physician reimbursements won't be based on MIPS until 2019, physician performance in 2017 will be used for scoring. CMS will be developing specific metrics used to determine bonus payments and penalties under MIPS. Payments will be based on quality, resource use, clinical practice improvement activities and meaningful use.

MACRA authorizes \$15 million/year for five years to fund MIPS measure development. No funding has been allocated yet. On December 18, 2015, CMS published for comment its draft Quality Measure Development Plan (MDP): Supporting the Transition to the MIPS and APMs. CMS's goal is to produce a patient-centered measure portfolio that addresses crucial measure gaps; facilitates alignment across federal, state, and private programs; and promotes efficient data collection to reduce provider burden. The MDP builds on the existing set of clinician quality measures used in current CMS programs, prioritizing the development of outcome measures, measures that are relevant for specialty providers, and other measure and performance gaps. Measures developed under this plan will hold individual clinicians and group practices accountable for care and promote shared accountability across multiple providers. CMS also notes the importance of incorporating the patient and consumer voice throughout the measure development process to ensure that the measures yield publicly reported results that patients and consumers can use to make informed decisions about their health care. The MDP provides expectations for future measure development given the fact that MACRA-funded measure developers must follow the principles outlined in the MDP. The MDP also describes tools and resources that can facilitate the development of measures applicable to a wide variety of stakeholders. The plan is open for public comment through March 1, 2016. The final MDP will be posted online by May 1.

While CMS is working to develop the new payment system, providers are still subject to the current set of quality programs.

Physician Quality Reporting System (PQRS): Providers who did not satisfactorily report data on quality measures in 2014 will be subject to a two percent cut in 2016. Quality reporting in 2016 will be used to determine whether providers will receive a two percent cut in 2018.

- Value Based Modifier (VBM): Physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists are subject to a two percent cut in 2018 based on 2016 performance. Providers in groups of 10 or more may be subject to a four percent cut in 2018.
- Meaningful Use: At the end of 2015, Congress passed legislation to make it easier for eligible professionals to apply for hardship exemptions for the 2015 reporting period for the 2017 payment adjustments.



## **Key 2016 Election Dates/Political Overview**

## 2016

January 28	Republican Debate, Iowa Events Center, Des Moines, Iowa (Fox News)
February 1	Iowa Caucuses - First Caucus in the Nation
February 6	Republican Debate, St. Anselm's College, Goffstown, NH (ABC News, IJReview)
February 9	New Hampshire Primary - First Primary in the Nation
February 11	Democratic Debate, Milwaukee, WI (PBS)
February 13	Republican Debate, Peace Center, Greenville, SC (CBS News)
February 20	SC Republican Primary, NV Democratic Caucus, WA Republican Caucus
February 23	NV Republican Caucus
February 13	Republican Debate, University of Houston, Houston, TX (CNN/Telmundo/Salem Radio)
February 27	SC Democratic Primary
March 1	"Super Tuesday" Primaries/Caucuses held in AL, AR, CO, GA, MA, MN, OK, TN, TX, VT, VA, and GOP caucus in AK, ND & WY, American Samoa Democratic Caucus
March 1-8	Democrats Abroad Primary
March 5	KS, NE Caucuses, LA primary, KY/ME Republican caucuses
March 6	Puerto Rico Primary, ME Democratic Caucus

March 8 HI Republican Caucus, ID Republican Primary, MI, MS primaries

March TBD Republican Debate, TBD (Fox News)

March 9 Democratic Debate, Miami, FL (Univision/Washington Post)

March 10 Republican Debate, FL (CNN/Salem Radio/Washington Times)

March 12 Guam territorial convention, DC convention

March 15 FL, IL, MO, NC, OH Primaries, Northern Mariana Islands caucuses

March 5 Virgin Islands caucus

March 22 AZ Primary, UT caucus, ID Democratic Caucus, American Samoa Republican territorial convention

March 26 AK, HI, WA Democratic Caucus

April 5 WI Primary

April 9 WY Democratic Caucus

**April 19** NY Primary

**April 26** CT, DE, MD, PA, RI primaries

May 3 IN primary

May 10 NE Republican Primary, WV Primary

May 17 KY Democratic Primary, OR Primary

May 24 WA Republican Primary

June 7 CA, MT, NJ, NM, SD primaries, ND Democratic Caucus

July 18 - 21 GOP Convention (Cleveland, OH)

**July 25-28** Democratic Convention (Philadelphia, PA)

**September 26** First presidential debate (Dayton, OH)

October 4 Vice presidential debate (Farmville, VA)

October 9 Second presidential debate (St. Louis, MO)

October 19 Third presidential debate (Las Vegas, NV)

November 8 Election Day

November 29 - Scheduled Lame Duck Session

December 16

## 2017

**January 3** First Day of 115th Congress

January 20 Inauguration Day

January 20 - First 100 Days of new presidency April 29

- \* A Primary or Caucus listed is for both parties unless noted as "Republican" or "Democratic".
- \*\* The National Parties select the manner in which the delegates to their nominating convention are chosen. Delegates are often assigned according to the results of a presidential primary or caucuses. Technically, the voter or caucus goers are electing delegates pledged to their particular candidate. Depending on the rules set forth by the party, these delegate may be bound or unbound to their candidate at the convention.

\* \* \*

## 2016 POLITICAL/ELECTIONS OVERVIEW

#### **Presidential Primaries:**

The 2016 Presidential primary race has proven to be anything but dull on the Republican side, with Donald Trump unexpectedly dominating the top of the polls longer than most veteran handicappers ever anticipated, and at one moment in time, neurosurgeon Ben Carson, was leading the pack. As things have settled out, it has been Trump, Ted Cruz, and Marco Rubio who appear to have staying power in the days ahead. While it hasn't exactly been a barn-burner on the Democratic side, excitement has picked up significantly in the new year, with the long-presumed nominee, Hillary Clinton, seemingly under more pressure than we have seen since 2008, as Senator Bernie Sanders continues to demonstrate tremendous political skill in rallying the liberal base to a fervor that Hillary Clinton has yet to inspire. Nevertheless, it's a long climb for Sanders to undo the inevitability of her nomination without the broader appeal that characterized President Obama's success.

- On the road to the Democratic nomination. While the polls are often imperfect at this juncture because they fail to capture the enthusiasm and in this case experience certain caucus-goers and/or primary voters carry with them into meetings and booths, nevertheless, the numbers are telling us at this moment roughly a week out from the first-in-the-nation caucus and two weeks from the first-in-the-nation primary Bernie Sanders has a slight lead over Hillary Clinton in Iowa, and a sizable one in New Hampshire. Still, few analysts believe Sanders will end up as the Democratic nominee. Poll numbers in Iowa possibly miss the degree to which Clinton's more experienced caucus-goers will outperform Sanders's first-timers. That said, there is a more palpable anti-Clinton Machine sentiment in the air than just a few months, even weeks, ago, as evident as it may have been in the tremendous numbers attracted to Sanders' events. Democrats had kept these inner anxieties a tad more subdued until recently.
- On the road to the Republican nomination. Donald Trump and Senator Ted Cruz are getting all of the attention ahead of the first-in-the-nation-caucus. With what appears to be too-close-to-call in lowa, Trump has taken the lead in a few recent polls, outside the poll's margin of error, while Cruz leads in a few others, although inside the margin of error. Some believe Cruz has a better organization in lowa and more fitting support for the Caucus style, and there is a question of whether Trump supporters will turn out to the degree reflected in polls. In New Hampshire, Trump maintains a solid lead. Although yet to be tested in a real polling place, Trump's sustained lead in national opinion polls over several months on the back of weak policy credentials and what some consider all-too-recent conversion to conservative philosophy, has caused great apprehension, and downright discord, among a number of true "movement" conservatives. Many leading conservative intellectuals, and GOP faithful, who no doubt shudder at Trump's at times impertinent remarks (i.e. insults toward war hero Senator John MccCain/comments regarding Carly Fiorina's looks), exhibit great unease over nominating a political novice who they believe knows very little about national security, lacks detailed understanding of just about any policy, shows only passing regard for Constitutional limitations, and expresses insufficient desire to limit governmental power. The influential Wall Street Journal editorial page, for example, has been among those to take issue with Trump's apparent protectionist rhetoric, cursory knowledge of facts, and lack of experience in national security. The disquiet within Republican ranks was evidenced quite prominently recently with the late father of modern conservative thought, William F. Buckley's publication, National Review cover story "Against Trump" outlining deep anxiety of treating the presidency as an entry-level political position. Somewhat ironically, Buckley was one of the prominent New York conservatives Tru
- The meaning of IA and NH. A more important question may be: Does winning lowa or New Hampshire matter in 2016? What does it mean? Taken individually, IA or NH are not reliable predictors of the party's nominee. However, for 40 years since 1976, the Republican nominee has won at least one of the first two contests. Could this year be different? Anything is possible, but it would add one more improbable to a list of improbables that have already occurred.

- The Democratic nominees have followed a similar fate: They've won either IA or NH since 1976, with one notable exception, Bill Clinton in 1992. In 1992, Bill Clinton did not win either IA or NH (with 24% of the vote in NH he earned as many delegates as the winner, Paul Tsongas). In fact, then-little-known-Governor Clinton did not win anything until his victory in the Southern state of Georgia on Super Tuesday, March 3, 1992. He also took no other contests that day. From March 7 on, Clinton swept most every contest with only a few exceptions.
- Momentum out of lowa can alter NH dramatically in just a few short hours, it can help raise funds for those who exceed expectations, and it can create an aura of success not available before real voting starts. However, the ability to capitalize on any momentum derived from IA has to be matched with an organization, if not by NH, at least by Super Tuesday. As you can see from the timeline above, Super Tuesday this year is two-and-a-half weeks after NH. We can expect one or two more candidates to get a lift if they surprise in IA. However, by and large for Republicans, if Trump takes New Hampshire and then South Carolina as expected, he will be a difficult train to stop. For Democrats, because of the make-up of the electorate in the Super Tuesday states, it is a little different: Hillary Clinton can likely recover from any strong showing by Sanders early on.
- What it takes. Primaries and caucuses, and in some cases statewide conventions, allocate delegates to the national nominating convention, who then choose the nominee. There are 2,472 Delegates to the Republican Convention. The magic number needed to become the Republican nominee is 1,236 (50% of 2,472 +1). Democrats have a slightly different process. Unlike the GOP, 713 of Democrats' 4,764 convention delegates (15 percent) are un-pledged "Super Delegates." Super Delegates are party and elected officials who are automatically made delegates but not necessarily pledged to a candidate. Based on endorsements, Clinton has a sizable lead among Super Delegates over Sanders, unless they can somehow be convinced to support Sanders by the Convention. According to the Cook Political Report, Clinton is expected to have earned 380 of these delegates already, to Sanders' 11, an enormous gap for Sanders. Still, the remaining 4,051 pledged delegates allocated through the primary and caucus process are key to securing the Democratic nomination. The pledged and un-pledged delegates needed to clinch the Democratic nomination is 2,383.
  - **Delegate Selection.** Each state party is responsible for deciding how to select its delegates to the nominating conventions, and each state party is subject to the rules of its national party committee and its state election laws. Most states have instituted primary contests, while others have employed a caucus system, and still others statewide conventions. Some states utilize a hybrid form. Each state has "at-large" delegates attributable to the statewide vote and district delegates attributable to the number of Congressional Districts in that state. The chart below illustrates significant dates along the road to the nomination, which taken together would be enough to secure the nomination if a candidate could win them all. However, delegates are often awarded proportionally and therefore it is not possible for candidates to win all of the delegates represented below. The chart provides a perspective, but not the whole picture:
    - The Democratic National Committee mandates that all of its delegates be awarded on a *proportional* basis, provided that a candidate earns above a certain threshold. This rule is applied to the statewide total vote, as well as to the vote within each Congressional District. In other words, the candidate receives the percentage of delegates according to the percentage of vote received, statewide and at the district level. If Hillary Clinton receives 55% of the statewide vote and Bernie Sanders receives 45%, and no other candidates therefore receives above a 15% minimum threshold, Clinton and Sanders will receive 55% and 45% of the statewide at-large delegates respectively. That process would also be applied to each Congressional District vote total.
    - The Republican National Committee Republicans does not have a blanket requirement that delegates be awarded on a proportional basis. However, beginning in 2016, all states holding primaries or caucuses before March 15 are required to use proportion allocation. Starting on March 15, states may award the winner of the popular vote all of their delegates. However, many states still award delegates proportionally or combine the two systems. Some states have winner-take-all by Congressional District, with different candidates able to win all of the delegates from differing districts. The RNC allows states to award delegates proportionally while also instituting a threshold after which the

system turns to winner-take-all. For example, a state may decide that if a candidate receives over 50% of the statewide vote, or the same at the district level, he or she could earn all of the delegates within that political unit. Ten states hold true "winner-take-all" primaries in which the statewide winner regardless of percentage receives all of the delegates. Florida for example now awards all of its 99 delegates to the statewide vote winner.

#### **Road to the Democratic Nomination**

#### **Road to the Republican Nomination**

Key Dates	# of Delegates	Key Dates	# of Delegates
February 1, Iowa Caucus	44	Feb 1, Iowa Caucus	30
March 1, Super Tuesday	859	March 1, Super Tuesday	632
March 15 (FL et al.)	691	March 15 (FL et al.)	367
April 18 (NY)	247	April 19 (NY)	95
June 7 (CA et al.)	676	June 7 (CA et al.)	303
Total:	2,517	Total:	1,427
# of un-pledged "Super Delegates"	713		
Total # of Delegate Votes	4,764	Total # of Delegates	2,472
# of Delegates needed to secure Nomination	2,383	# of Delegates needed to secure nomination	1,236

• **Brokered Convention?** It is conceivable, though it has not happened since 1932 when it produced FDR, that we get to one of the conventions without a clear winner and the candidates in second or third place not conceding defeat, which means another campaign can ensue — one for the hearts and minds, and support, of delegates who are pledged but not necessarily bound to the candidate for which they were pledged on primary/caucus day. This so-called "Brokered Convention" was common before primaries were instituted. Indeed, the party getting together to choose a nominee used to be what Conventions

were all about. In the modern age conventions have been a celebration of the nominees and an opportunity to demonstrate the solidarity of the party behind their new leader.

#### **U.S. Senate**

Number of U.S. Senate Seats up in 2016: 34

Seats up held by Democrats: 10 Seats up held by Republicans: 24 **Current Balance of Power in the U.S. Senate:** 

54 Republicans44 Democrats

2 Independents (both caucus with the Democrats and includes Democratic presidential candidate Bernie Sanders)

**Balance of power.** The current balance of power in the Senate is 54 Republicans and 44 Democrats, and 2 Independents. It takes 51 to have control, and a 50-50 split is decided by the Vice President. Therefore, control of the Senate may be determined by who takes the White House.

- Each election cycle (every 2 years) a third of the Senate seats are up. There are 34 seats up in the Senate in 2016, and 24 of those are currently held by Republicans. That's a huge disadvantage for Republicans. More incumbent seats up means having to defend more and a higher probability that the other party can pick some off, particularly in states that lean Democratic. Fewer seats up in the cycle means a lower probability that the balance can shift away from you and more opportunities for your party to pick up seats. With Democrats having only 10 seats up, they have to defend fewer seats and can spend fewer resources on Red States, those leaning Republican, and greater resources on vulnerable Republicans in Blue States, those leaning Democratic, or even in Purple states, those where there is a more event split between Republicans and Democrats and could go either way with an effective campaign.
- According to the National Journal/Hotline, in 2016 it is not a question of whether the Democrats will pick up seats, but how many. The Hotline and Politico, two respected sources of election analysis, both see the top five most vulnerable seats, enough for Democrats to get to 50, in Illinois, Wisconsin, New Hampshire, Florida, and Pennsylvania. All of these seats are currently held by Republicans. If Maine Independent Senator Angus King continues to caucus with the Democrats in the Senate, this would hand Democrats the Majority. National Journal/Hotline ranks Ohio and Nevada 6th and 7th most vulnerable, while Politico puts them at 7th and 6th respectively. Ohio is currently a Republican-held seat (Rob Portman), while Nevada is held by retiring Democratic Leader Harry Reid.
- In 2012, Illinois, Wisconsin, New Hampshire, Florida, Pennsylvania, Ohio, and Nevada all went for Barack Obama. Illinois, Wisconsin and Pennsylvania are considered solid Blue states, having gone for the Democratic presidential candidate in each of the past four elections. Ohio, Nevada, and Florida could be considered "Purple" states having been won two out of the past four elections by both parties. New Hampshire has gone Democratic 3 out of the last 4 presidential elections.
- To put in recent historical context, the last time Republicans had an imbalance in seats up like this, 2008, when 23 were held by Republicans and 12 by Democrats, and it was an open Presidential election year, Democrats picked up 8 Senate seats. That election turned a 49-49 Senate with a 2-seat Majority held by Democrats because the two Independents caucused with them, to a 9-seat advantage. Of course, with the election of Barack Obama after eight years of a Republican presidency, there were considerable coattails and discernible change in the national mood. For the record, the largest Senate swing by the Democrats dates back to 1958, the mid-term election of President Eisenhower that followed a recession, when Democrats picked up 13 seats, 10 from those that had been held by Republicans.

### 2016 Senate Races 34 Seats — 24 Republicans, 10 Democrats

(6 Open seats — 3 held by outgoing Democrats, 3 held by outgoing Republicans)

Source: Cook Political Report

Solid Dem	Likely Dem	Lean Dem	Toss-up	Lean Rep	Likely Rep	Solid Rep
Blumenthal (D-CT)	CA (Open Seat - Boxer)	Bennet (D-CO)	NV (Open Seat-Reid)	Burr (R-NC)	Murkowski (R-AK)	Shelby (R-AL)
Schatz (D-HI)			FL (Open seat - Rubio)	Portman (R-OH)	McCain (R-AZ)	Boozman (R-AR)
MD (Open Seat - Mikulski)			Kirk (R-IL)	Toomey (R-PA)	Isakson (R-GA)	Crapo (R-ID)
Schumer (D-NY)			Ayotte (R-NH)		IN (Open seat - Coats)	Grassley (R-IA)
Widen (D-OR)			Johnson (R-WI)		Blunt (R-MO)	Moran (R-KS)
Leahy (D-VT)						Paul (R-KY)
Murray (D-WA)						LA (Open seat - Vitter)
						Hoeven (R-ND)
						Lankford (R-OK)
						Scott (R-SC)
						Thune (R-SD)
						Lee (R-UT)

#### **U.S. House of Representatives**

Number of U.S. House Seats up in 2016: All 435

Seats up held by Democrats: 188 Seats up held by Republicans: 247

#### Balance of power.

The current balance of power in the U.S. House of Representatives is 247 Republicans to 188 Democrats. With 435 total members, it takes 218 to gain control of the chamber. With a differential of 59 seats, Democrats will need to pick up 30 seats to regain the Majority in 2016.

- Every seat in the U.S. Congress is up for re-election each cycle (two years). Of the 435 seats, 377 are considered "safe" this time around nearly 87% of Members.
- To put it in some recent historical perspective, Democrats won 31 seats during the second midterm of President George W. Bush in 2006 giving them the Majority. The largest swing to the majority by the Democrats before 2006 was back in 1954 during the midterm of President Eisenhower, 19 seats. Prior to 1954, it was 1948, when they gained a whopping 75 seats coinciding with Harry Truman's re-election. While obtaining 30 seats is very achievable in swing elections, it usually requires a larger catalyst a wave election of some kind, and/or a presidential candidate/President with considerable coattails. In 2010, the first mid-term election of the Obama presidency, Republicans picked up 63 seats, bringing it to 242 -193. In 2012, when President Obama was re-elected, Republicans lost 8 seats, maintaining a 33 seat Majority, 234 -201. In 2014, Republicans gained an additional 13 seats, raising their total to the current 247, the largest Majority held by Republicans in the House since 1928.
- According to political analyst Charlie Cook, 207 Republican seats and 170 Democratic seats are considered safe. That leaves 58 seats that he believes are truly competitive. Of those 58 competitive races, 25 Republican seats are regarded by Cook to be either "likely" or "lean" Republican, but only one of those likely or leaning Republican seats is held by a Democrat. Of those 58 races, 17 are viewed to be "likely" or "lean" Democratic, with 4 of those occupied by Republicans. Together, the likely/lean category reflects a possible pick-up of 3 seats, net, (4-1) for Democrats.
- According to Cook, of those 58 competitive races, 16 are viewed as a toss-up, where either party is just as likely to win. Of those 16 seats, 12 are currently held by Republicans and 4 currently held by Democrats. For the sake of argument, if Democrats were to sweep the toss-up races and gain all 16 seats, plus the 3 net seats from the likely-lean category, we'd see a pick-up of 19 seats for Democrats, slightly shy of what is needed to regain the Majority.
- Larry Sabato of the University of Virginia Center for Politics has 19 races that are viewed as "toss-ups," 15 Republican and 4 Democratic, and a net four seats if Democrats were to win every likely/lean seats currently held by Republicans. Again, assuming Democrats sweep these races assuming a bad night for Republicans this would give Democrats a pick-up of potentially 23 seats ....close, but still short of the 30 seats needed to regain the Majority.
- Depending on the political narrative at the time of the election on November 8, 2016, races can shift in and out of the toss-up category and often do. A few, though rare, can shift from toss-up to likely/lean.
- Nevertheless, the bulk of the expectations around the House are solidly that the House will remain in Republican hands in the next Congress. The Senate, as noted above, given the dynamics of the races more Republicans up for re-election this cycle is much more difficult to predict and a Democratic take-over certainly possible if Republicans stumble or world/political events shift perspectives in their favor.

### 2016 Competitive House Races — 58 of 435 Seats — 247 Republicans, 188 Democrats

(58 competitive with 6 open seats —3 held by outgoing Democrats, 3 held by outgoing Republicans)

Source: Cook Political Report

Likely Democratic	Lean Democratic	Democratic Toss-up	Republican Toss-up	Lean Republican	Likely Republican
AZ-09 Sinema (D)	CA-07 Bera (D)	AZ-01 OPEN (D)	CO-06 Coffman (R)	AZ-02 McSally (R)	FL-02 Graham (D)
CA-16 Costa (D)	FL-13 OPEN (R)	FL-18 OPEN (D)	FL-26 Curbelo (R)	CA-10 Denham (R)	IL-12 Bost (R)
CA-24 OPEN (D)	MN-08 Nolan (D)	NE-02 Ashford (D)	IL-10 Dold (R)	CA-21 Valadao (R)	IL-13 Davis (R)
CA-31 Aguilar (D)	NV-04 Hardy (R)	NY-03 OPEN (D)	IA-01 Blum (R)	CA-25 Knight (R)	MI-08 Bishop (R)
CA-36 Ruiz (D)	VA-04 Forbes (R)		ME-02 Poliquin (R)	FL-07 Mica (R)	NJ-03 MacArthur (R)
CA-52 Peters (D)			MN-02 OPEN (R)	IA-03 Young (R)	NY-21 Stefanik (R)
CT-05 Esty (D)			NV-03 OPEN (R)	MI-01 OPEN (R)	NY-23 Reed (R)
FL-10 Webster (R)			NH-01 Guinta (R)	MI-07 Walberg (R)	NC-09 Pittenger (R)
MD-06 Delaney (D)			NY-19 OPEN (R)	NJ-05 Garrett (R)	PA-06 Cotello (R)
MN-07 Peterson (D)			NY-22 OPEN (R)	NY-01 Zeldin (R)	PA-07 Meehan (R)
NY-18 Maloney (D)			PA-08 OPEN (R)	NY-24 Katko (R)	VA-02 OPEN (R)
NY-25 Slaughter (D)			TX-23 Hurd (R)	UT-04 Love (R)	VA-10 Comstock (R)
					WV-02 Mooney (R)



# Medicare and CHIP Reauthorization Act of 2015: Timeline of Implementation

	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026+
Base Update	Jan-Jun: 0 July-Dec: 0.5	0.5%	0.5%	0.5%	0.5%	Bas	e Conversio	on Factor U <sub>l</sub>	odate of 0.0	)% each ye	ar	0.25%*
Electronic Health Record Incentive Program	EHR Incentives continue under current law EHR Meaningful Use Incorporated into MIPS											
Physician Quality Reporting System	PQRS continues under current law				Quality reporting incorporated into MIPS							
Physician Value- Based Payment Modifier	VBM Continues under current law					Pa	arts of VBM	incorporate	ed into MIP	S		
"Merit Based" Incentive Payment System (MIPS)**, ***	N/A				(+/-) 4%	(+/-) 5%	(+/-) 7%			(+/-) 9%		
Alternative Payment Models	N/A				5% lump sum b servic	oonus on the es for "qual	•		•	onal	0.0%	0.75%

- \* In 2026 and subsequent years, the non-APM conversion factor will be set as "equal to the respective conversion factor for the previous year (or, in the case of 2026, equal to the single conversion factor for 2025) multiplied by the update established under paragraph (20) for such respective conversion factor for such year."
- \*\* The Secretary has the authority to create additional MIPS bonuses for "exceptional performers" through 2024.
- \*\*\* "Partial Qualifying APM Participants" (as defined in the legislation) who report on applicable MIPS measures are considered to be a "MIPS eligible professional" in that year. The Secretary may also base the determination by using "counts of patients in lieu of using payments and using the same or similar percentage criteria . . .as the Secretary determines appropriate."
- "APM Qualifying Participant": 2019-2020: 25% of Medicare revenues furnished as part of an eligible APM; 2021-2022: 50% of Medicare revenues furnished as part of an eligible APM; or professionals with at least 25% of Medicare revenues from services furnished as part of an eligible APM AND at 50% of all payer revenues (excluding VA and DOD) for services provided as part of an APM (provided that the professional is willing to provide data to CMS to be able to make that determination). 2023 and subsequent years: 75% of Medicare revenues furnished as part of an eligible APM; or professionals with at least 25% of Medicare revenues from services furnished as part of an eligible APM AND at 75% of all payer revenues (excluding VA and DOD) for services provided as part of an APM (provided that the professional is willing to provide data to CMS to be able to make that determination). 2021 and subsequent years: The Secretary may also base the determination by using "counts of patients in lieu of using payments and using the same or similar percentage criteria . . .as the Secretary determines appropriate."

#### **ADDITIONAL DATES & DEADLINES:**

#### 2015

January 1, 2015: The Secretary shall make payments "for chronic care management services furnished on or after January 1, 2015 . . ."

**STATUS**: Via previous Physician Fee Schedule Final Rules, CMS has provided payment rules under the Chronic Care Management Codes. This will likely fulfill the subsequently enacted provision to pay for chronic care management services, although CMS reiterated its policies designed to pay for these services as part of the CY 2016 Medicare Physician Fee Schedule proposed rule.

~ May 2015: Statutory change that automatically renews Medicare opt-out period for additional two year periods unless "not later than 30"

days before the end of the previous 2-year period" provides notice to the Secretary. (Effective date "shall apply to affidavits

entered into on or after the date that is 60 days after the date of enactment.")

STATUS: CMS is implementing this provision via a proposal made in the CY 2016 Medicare Physician Fee Schedule proposed rule.

**Cottober 2015:** The **Secretary** and **CMS** must make public a list of **episode groups** and related descriptive information ("not later than 180 days

after the date of enactment"); the **Secretary** shall accept public input for 120 days after posting (eventually for resource use

analysis).

~October 2015: Make appointments to the Physician-Focused Payment Model Technical Advisory Committee, which will provide

recommendations on moving providers into alternative payment models ("180 days after date of enactment").

STATUS: On June 9, 2015, the Federal Register published a GAO request for nominations to the PTAC. Nomination materials

were due on July 22, 2015 for the October 2015 appointments.

**~October 2015:** The <u>Secretary</u> and <u>HHS OIG</u> shall submit a report to Congress with legislative recommendations to amend fraud and abuse laws

(e.g. Stark and Anti-Kickback Statute) in order to allow gainsharing arrangements that can improve care and reduce waste and

inefficiency ("Not later than 6 months after the date of enactment.").

January 1, 2016:	The <u>Secretary</u> shall develop and post a <u>draft plan for development of quality measures</u> and accept comments through March 1, 2016. Secretary must post final plan for measure development no later than May 1, 2016.
February 1, 2016:	The <b>Secretary</b> shall make publicly available the number and characteristics of <b>opt-out physicians and practitioners</b> and update annually.
~March 2016	The <u>Secretary</u> shall post a draft list of <u>patient relationship categories</u> and <u>codes</u> for <u>episode attribution methodology</u> purposes ("Not later than one year after the date of enactment"); the <u>Secretary</u> shall seek comment for 120 days; not later than 240 days after comment period the <u>Secretary</u> shall post an operational list of <u>patient relationship categories</u> and <u>codes</u> .
~March 2016:	The <u>Secretary</u> shall conduct a study and submit a report to Congress on the feasibility of mechanisms (e.g. a Website) that would allow users to <u>compare the interoperability of EHR products</u> ("not later than 1 year after the date of enactment").
July 1, 2016:	<u>Secretary</u> must submit a report to Congress on the feasibility of including participation in <u>Alternative Payment Models into the Medicare Advantage</u> payment system; this should include feasibility of including a value-based modifier and whether such modifier should be budget neutral.
July 1, 2016:	<b>Qualified Entities (QEs)</b> may use combined data to conduct additional non-public analyses for the purposes of assisting providers to develop and participate in quality and patient care improvement activities including developing new models of care.
July 1, 2016:	<u>Qualified Clinical Data Registries (QCDRs)</u> may request <u>Medicare claims data</u> (and in certain circumstances Medicaid data) to link with clinical outcomes data and perform risk-adjusted, scientifically valid analyses and research to support quality improvement or patient safety. Costs of providing the data apply.
July 1, 2016:	The <b>Secretary</b> shall establish metrics to determine whether the national objective of achieving widespread EHR interoperability is being met.
~September 2016:	<u>GAO Report</u> on alignment of quality measures between public and private programs with recommendations on how to reduce <u>administrative burden of reporting</u> ("not later than 18 months after the date of enactment").
~October 2016:	The <u>Secretary</u> shall post a draft list of <u>care episodes</u> and <u>patient condition codes</u> ("270 days after the end of the comment period"); The <u>Secretary</u> shall accept comments for 120 days; within 270 days the Secretary shall post an operational list of <u>care episode</u> and <u>patient condition codes</u> (and the criteria and characteristics assigned to such code).

November 1, 2016: The <u>Secretary</u>, through notice and comment, shall establish criteria for <u>physician-focused payment models</u> including for

specialist physicians (that could also be used by the **Physician-Focused Payment Model Technical Advisory Committee** on which

to make comments and recommendations).

**2016:** The <u>Secretary</u> shall post physician data ("similar to the type of information in the Medicare Provider Utilization and Payment

Data: Physician and Other Supplier Public Use File released by the Secretary with respect to 2012") available on **Physician** 

Compare by 2016.

2017

January 1, 2017: GAO Report on whether entities that pool financial risk for physician practices (i.e. independent risk managers) can play a role

in supporting physician practices.

~April 2017: The Secretary (in consultation with the OIG) shall conduct a study and send a report to Congress on fraud and abuse laws and

impact on Alternative Payment Models ("not later than 2 years after enactment").

~April 2017: The GAO shall submit a report to Congress on studies on telehealth and remote patient monitoring, which shall include

legislative and administrative recommendations ("not later than 24 months after the date of enactment").

May 1, 2017: The Secretary shall post a report on the progress made in measure development (to be conducted annually).

July 1, 2017: The Secretary shall make available timely ("such as quarterly") performance feedback reports for MIPS participants. The

current Physician Feedback Reports requirements will end in 2017.

**July 1, 2017:** Initial MedPAC Report on total and rate of growth of physician and healthcare profession expenditures.

December 31, 2017: The Secretary shall submit a report to Congress on the use of chronic care management services by individuals living in rural

areas and by racial and ethnic minority populations.

#### 2018

July 1, 2018: The <u>Secretary</u> shall make available to MIPS participants data about items and services that are furnished to that MIPS' patients by other providers and suppliers.

**December 31, 2018:** Congressional declaration that it is a national objective to achieve widespread exchange of health information through interoperable certified EHR technology nationwide.

#### 2019

July 1, 2019: <u>MedPAC Report</u> on spending on professional services from 2015-2019 and its impact on efficiency, economy, quality of care, access, and recommendations for future payment updates.

The <u>Secretary</u> shall submit a report to Congress in the event the Secretary makes a determination that we have not achieved national widespread EHR interoperability identifying the barriers to adoption and making recommendations that the Federal government can take to achieve adoption.

#### 2021

**July 1, 2021:** Final MedPAC Report on total and rate of growth of physician and healthcare profession expenditures.

October 1, 2021: GAO Report on the MIPS program including the distribution of performance and performance scores of participants,

recommendations for improvement, and the impact of technical assistance on the ability of professionals to transition to APMs

(particularly for practices in HPSAs and MUAs).

October 1, 2021: GAO Report on transition of professionals in rural areas, HPSAs, and MUAs into APMs.

\* \* \*