eHealth Initiative (eHI) 2016 Government Affairs Retreat
February 2, 2016
8:00 a.m. – 11:30 a.m. ET

Alfred Nobel Room
House of Sweden
2900 K Street NW
Washington, DC 2007

AGENDA

Goals

1. To expand understanding of and gain input on eHI policy and member priorities for 2016.
2. To share important, breaking intelligence on key HIT policy and regulatory issues.
3. To receive critical membership input on eHI's action agenda for policy engagement with Congress and the Administration.
4. To explore policy priorities and opportunities in the eHI *2020 Roadmap*.

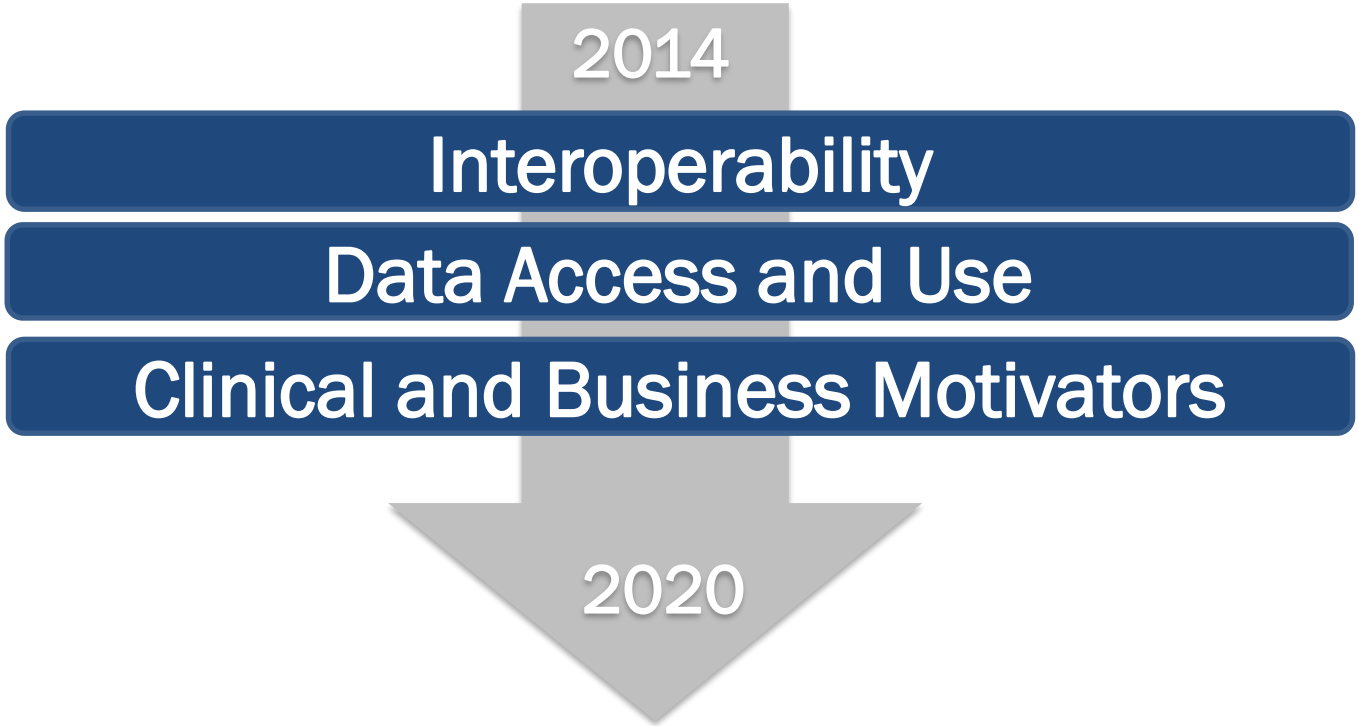
8:00 – 8:15 am	**Welcome and Overview of Day's Policy Discussions** • Laura McCrary, EdD, Executive Director, Kansas Health Information Network, Inc.; Chair, eHI Policy Steering Committee • Erin A. Mackay, Associate Director of Health Information Technology Programs, National Partnership for Women & Families; Vice Chair, eHI Policy Steering Committee **Member Welcome and eHI *2020 Roadmap* Notables** • Jennifer Covich Bordenick, Chief Executive Officer eHealth Initiative & eHealth Initiative Foundation
8:15 - 8:30 am	**Potential Policy Intersections: eHI's *2020 Roadmap*** • Virginia Riehl, Healthcare Management Consultant; Facilitator, eHI Interoperability Workgroup
8:30 – 9:15 am	**Perspectives from the Congress** *Facilitated by Ticia Gerber **2016 Congressional Agenda, Health and HIT** • Stuart Portman, MPH, Professional Staff Member (Healthcare Legislative and Health IT Specialist), Office of the Honorable Orrin Hatch (R-UT) - **(Confirmed)** Note: Audience Q&A will follow remarks
9:15 – 10:15 am	**Key Administration Activity** *Facilitated by Laura McCrary and Erin Mackay **ONC**

	Lauren Choi, JD, Senior Advisor, Office of the National Coordinator for Health Information Technology **(Confirmed)** **HIPAA and OCR** Marissa Gordon-Nguyen, JD, MPH, Health Information Privacy Policy Specialist, Office for Civil Rights, U.S. Department of Health and Human Services **(Confirmed)** **Precision Medicine** Stephanie Devaney, Project Manager, Precision Medicine Initiative, White House Office of Science and Technology Policy **(Confirmed)** Note: Audience Q&A will follow remarks
10:15 – 11:00 am	**On the Horizon: Overview of MACRA, MIPS and the Future of Alternative Payment Models** *Facilitated by Mark Segal, PhD, Vice President, GE Healthcare IT; Chair Emeritus, eHI Policy Steering Committee **(Confirmed)** • Rob Anthony, Health Insurance Specialist, Centers for Medicare and Medicaid Services Note: Audience Q&A will follow remarks.
11:00 – 11:15 am	**Action Plan for eHI Policy Priorities** *Facilitated by: Laura McCrary, Erin Mackay, Ticia Gerber In light of the remarks from the Congressional and the Administration speakers, we will review potential eHI policy action items for 2016. Participants will submit structured feedback about their ideas which can be in the areas of: • Legislative • Regulatory • Education/Communications • Other
11:15 – 11:30 am	**Wrap-up and Conclusion**

Potential Policy Intersections: *eHI's 2020 Roadmap*

February 2, 2016

A Framework to Transform Patient Care



eHEALTH INITIATIVE

PROGRESS ON THE ROAD TO TRANSFORMATION

1 LAUNCH

eHI Convenes Hundreds at Executive Summit to Transform Care • Release of 2020 Roadmap Priorities

2 RESEARCH & ANALYSIS

DISCUSSION

Enabling Healthy Populations with HIE • Strategies on New Models of Care Delivery

INFORMATION GATHERING

Interviews on Improving Clinical Efficiency • Value of Interperability Study

INFORMATION SHARING

Industry Technology for Dealing with Super-Utilizers • CMS & ONC overview of Proposed Rules

3 CONVENING & CONSENSUS

TOPICS

Data Use & Access • Clinical & Business Motivators • Cybersecurity • Interoperability • Data Analytics & Value-Based Care • Patient-Specific Tools • Roadmap Priorities • Supporting Caregivers with Technology

EVENTS

Executive Rountables • Congressional Meetings • eHI Annual Meeting • Workgroups • Advisory Boards • eHI Innovation Challenge

4 OUTPUTS & RECOMMENDATIONS

GUIDANCE

ONC's Nationwide Interoperability Roadmap

EDUCATION

Experts Share Tips on How to Assess Security Risks & Protect Healthcare Data • Webinar: How Communities Harness Data to Empower Care Coordinators

REPORTS

New Models of Collaboration to Improve Parient Care • mHealth Best Practices to Transform Care • Advanced Case Management Technology • Provider Tools

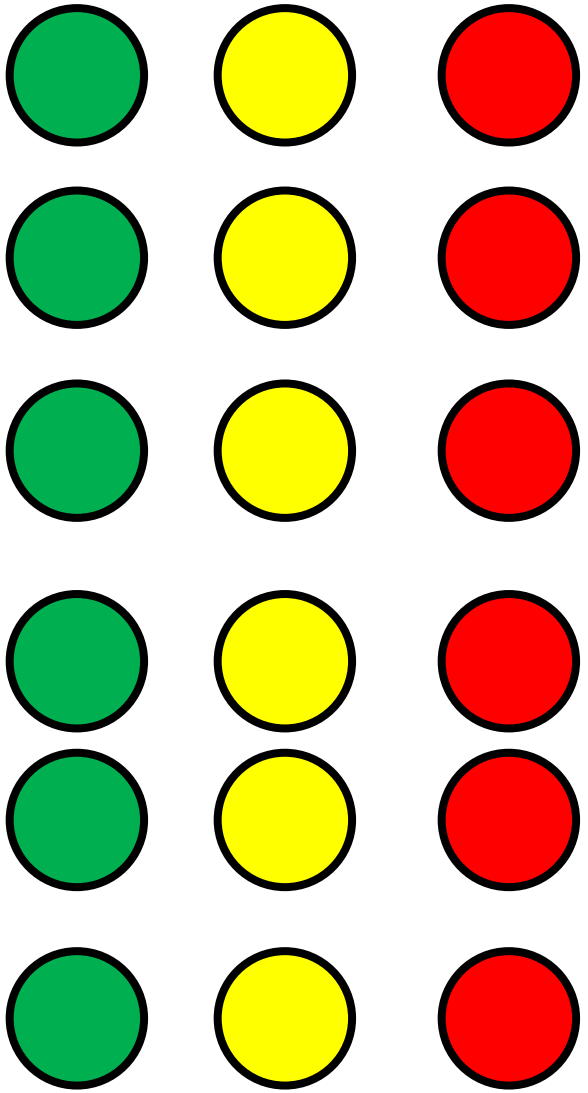
SURVEYS

Interoperability & Impact of ICD-10 Among Providers • How ACOs leverage IT for Cost Savings: Interoperability & Data Use

In October 2014, eHealth Initiative released its **2020 Roadmap**, a result of multi-stakeholder collaboration, consisting of a set of recommendations to implement at the federal level and actions for the private sector to help transform our healthcare system. In the year that followed, eHI continued its collaborative work with leading healthcare associations, organizations and federal agencies to advance the 2020 Roadmap. This timeline outlines the many efforts led by eHI over the past year, successfully moving a plan into progress toward system transformation.

Federal Policy Change

- Focus Federal policy on advancing interoperability
- Identify and promote consistent and efficient methods for electronic reporting
- Lower the burden associated with complex quality measurement programs
- Promote consistency in policy and enforcement
- Provide incentives across the continuum
- Broaden and diversify the incentive programs to leverage innovative market approaches



Focus Federal policy on advancing interoperability

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HIPAA Access Guidance

Marissa Gordon-Nguyen
Office for Civil Rights
February 2, 2016

Components

- Fact Sheet
- Scope FAQs
- Form and Format and Manner of Access FAQs
- Timeliness FAQs
- Other FAQs

General Right

- Access/copy upon request
  - By individual or personal representative
- Designated record set(s)
  - Group of records maintained by or for covered entity

Examples of information subject to access

- EHR and/or paper medical record
- Other medical, billing, payment, enrollment, claims records
- Clinical laboratory test reports
- X-rays, other images
- Wellness and disease management program information
- Clinical case notes
- Old/archived PHI

Examples of excluded information:

- Quality assessment or improvement records
- Patient safety activity records
- Business planning
- Provider performance evaluations
- Psychotherapy notes
- Information compiled for civil, criminal, or administrative action or proceeding

BUT

Included: Underlying PHI relied on in developing such records

Providing Access

- Timeliness
  - No later than within 30 days from when request was received, either by the CE or its BA
  - If unable to meet 30 days, CE may extend to 60 days
    - Must notify individual within initial 30 days
    - Only one extension per access request

Providing Access

- Form and Format and Manner of Access
  - Provide in form and format requested if readily producible
  - Requests for paper copies
    - Provide paper copy
  - Requests for electronic copies
    - If PHI maintained only on paper, provide electronic copy if readily producible. If not, in readable hard copy or other form and format per agreement with individual.
    - If requested PHI maintained electronically, must provide access in electronic form and format requested, if readily producible. If not, in agreed upon alternative electronic format. If individual refuses every offered electronic format, provide paper.

Access and Certified EHR Technology

- If CE uses Certified EHR Technology, electronic PHI is readily producible
- CEs can use View, Download, Transmit mechanisms to fulfill access requests if individual requests or accepts
- Individual always retains right to access PHI in a DRS that is not available through CEHRT

Providing Access, continued

- Fees for copies
  - Reasonable, cost-based
    - Labor for copying PHI
    - Supplies for creating copy
    - Postage, if mailed
    - Preparation of explanation or summary, if individual agrees
  - Does not include*
    - Verification
    - Documentation
    - Search/retrieval
    - Maintaining systems
    - Recouping capital
    - Other costs

* Even if authorized by state law

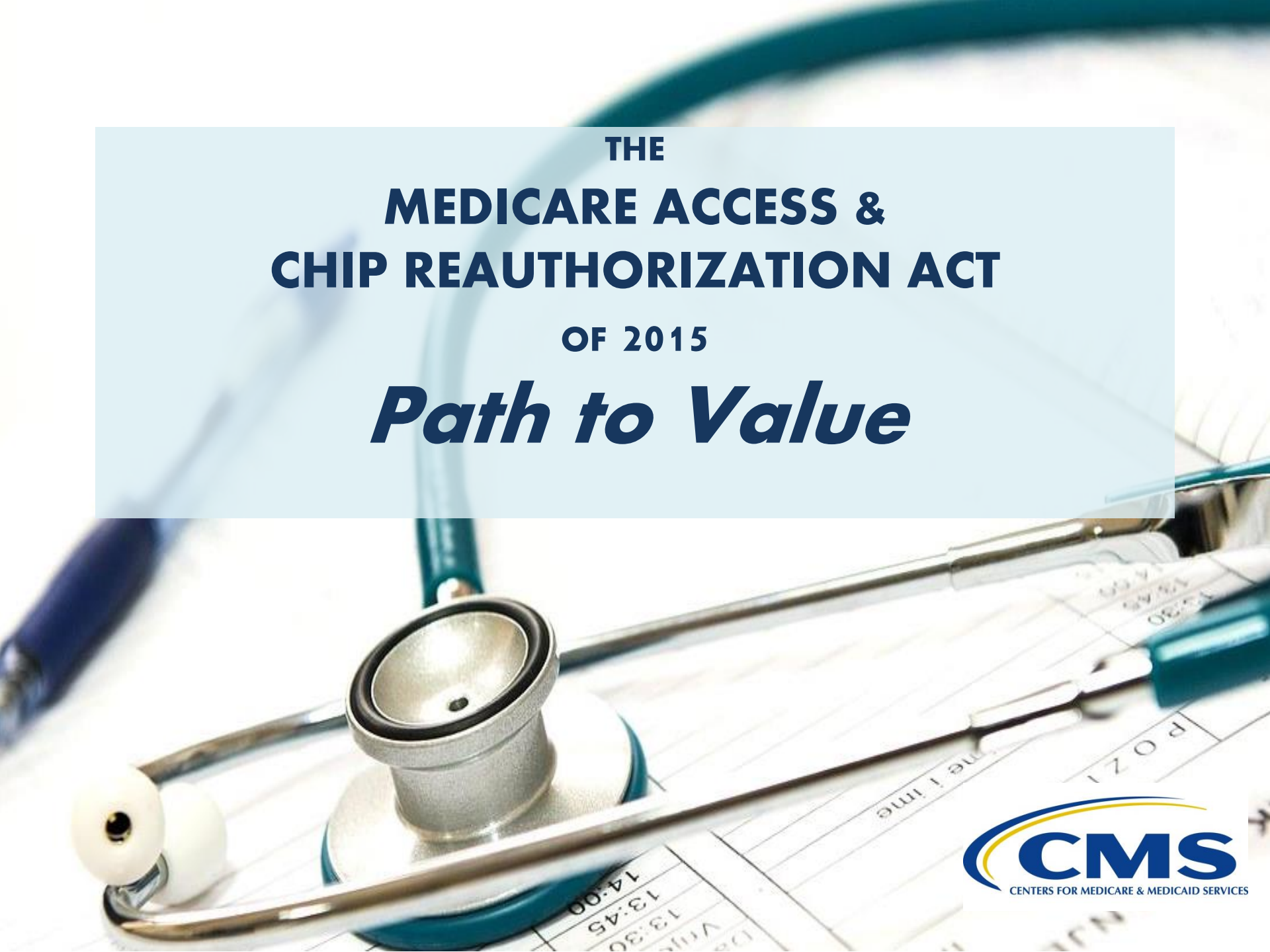
FAQs in development

- Fees
- Directing access to a third party

More Information

Questions?

www.hhs.gov/hipaa



THE MEDICARE ACCESS & CHIP REAUTHORIZATION ACT OF 2015

Path to Value

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Merit-Based Incentive Payment System and Alternative Payment Model Provisions

Centers for Medicare & Medicaid Services

Robert Anthony

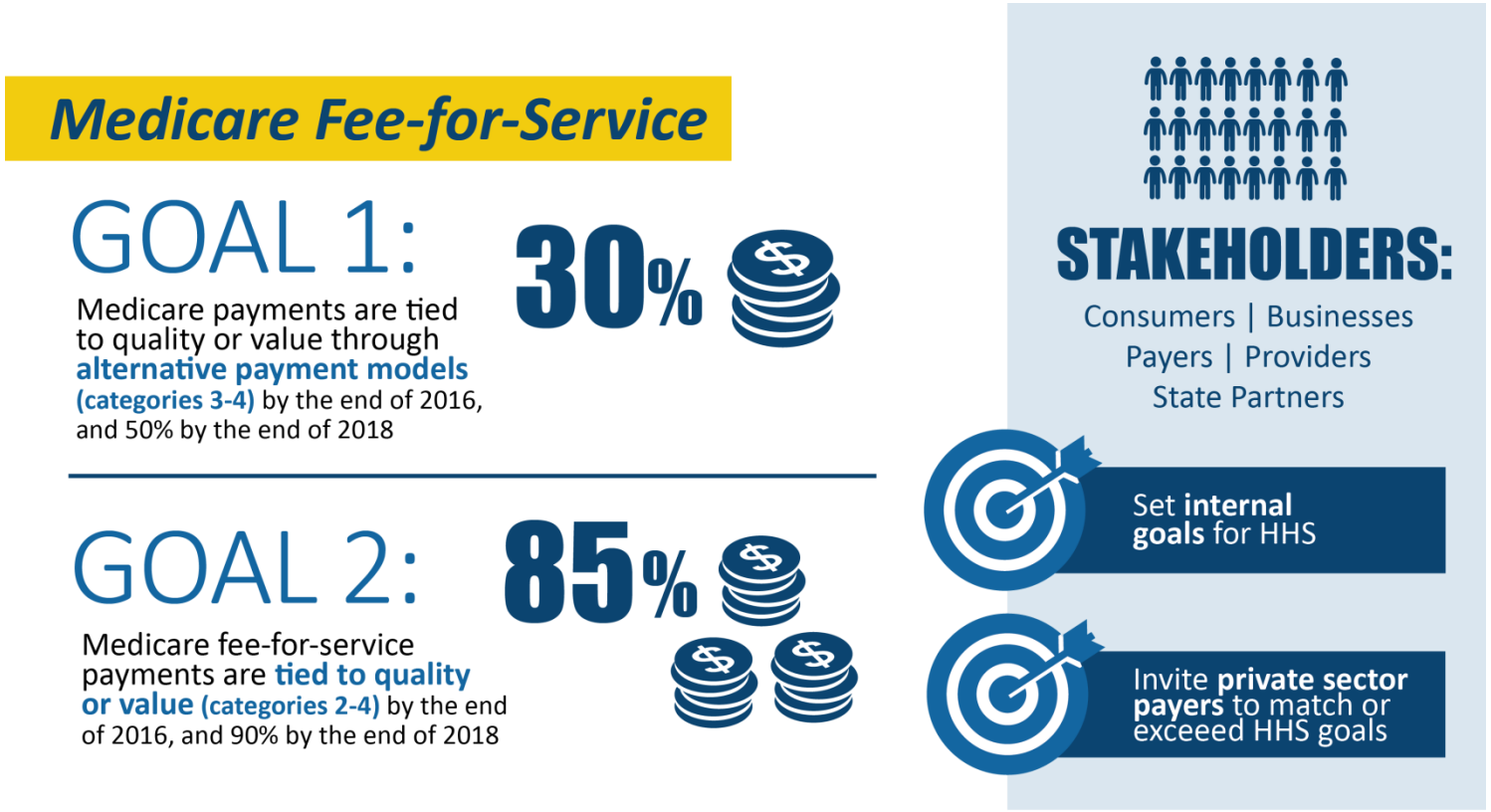
Deputy Director,

Quality Measurement and Value-Based Incentives Group

Center for Center for Clinical Standards & Quality

MACRA is part of a broader push towards value and quality

In January 2015, the Department of Health and Human Services announced **new goals** for **value-based payments** and **APMs in Medicare**

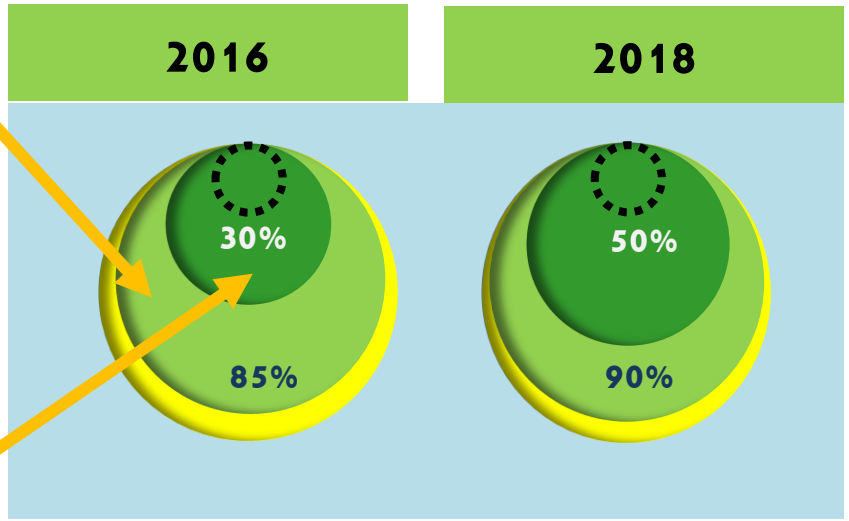


MACRA moves us closer to meeting these goals…

The new Merit-based Incentive Payment System helps to link **fee-for-service payments** to quality and value.

The law also provides incentives for **participation in Alternative Payment Models** in general and bonus payments to those in the most highly advanced APMs

New HHS Goals:



All Medicare fee-for-service (FFS) payments (Categories 1-4)

Medicare **FFS** payments **linked to quality and value** (Categories 2-4)

Medicare payments linked to quality and value **via APMs** (Categories 3-4)

Medicare Payments to those in the most highly advanced APMs under MACRA

...and toward transforming our health care system.

3 goals for our health care system:

BETTER care
SMARTER spending
HEALTHIER people

Via a focus on **3 areas**

Incentives

Care Delivery

Information Sharing

What is "MACRA"?

The **Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)** is a bipartisan legislation signed into law on April 16, 2015.

What does Title I of MACRA do?

- **Repeals** the Sustainable Growth Rate (SGR) Formula
- **Changes the way that Medicare** rewards clinicians for **value** over volume
- **Streamlines** multiple quality programs under the new **Merit-Based Incentive Payments System (MIPS)**
- Provides **bonus payments** for participation in **eligible alternative payment models (APMs)**

MACRA Goals

Through MACRA, HHS aims to:

- Offer **multiple pathways** with varying levels of risk and reward for providers to tie more of their payments to value.
- Over time, **expand the opportunities** for a broad range of providers to participate in APMs.
- **Minimize additional reporting burdens** for APM participants.
- **Promote understanding** of each physician's or practitioner's status with respect to MIPS and/or APMs.
- Support **multi-payer initiatives** and the development of APMs in Medicaid, Medicare Advantage, and other payer arrangements.

MIPS changes how Medicare links performance to payment

There are currently multiple individual **quality and value** programs for Medicare physicians and practitioners:

Physician Quality Reporting Program **(PQRS)**	Value-Based Payment Modifier	Medicare EHR Incentive Program

MACRA streamlines those programs into **MIPS**:

Merit-Based Incentive Payment System **(MIPS)**

MIPS Eligible Professionals (EPs):

- Applies to individual EPs, groups of EPs or virtual groups
- 2019 & 2020 (First two years)
  - Physicians, PAs
  - Certified Registered Nurse Anesthetists
  - NPs, Clinical Nurse Specialists
  - Groups that include such professionals
- 2021 onward
  - Secretary can add EPs (described in 1848(k)(3)(B)) to MIPS
- Excluded EPs
  - Qualifying APM participants
  - Partial Qualifying APM Participants
  - Low volume threshold exclusions

More on MIPS

- Beginning **Jan 1, 2019**
  - CMS must assess performance based on performance standards during a performance period for measures and activities in the following 4 performance categories.
  - A composite or total performance score will be developed using a scoring scale of 0 to 100.
  - The weights for each category are indicated below.

  <u>Performance Categories</u>

  - Quality measures (**30%** of Score)
  - Resource Use measures (**30%** of Score)
    - Counts for not more than 10% in 2019 and 15% in 2020; a*dditional weight of at least 20% and 15%, respectively, are added to the Quality score in those years*
  - Clinical Practice Improvement Activities (**15%** of Score)
    - *Sub-Categories- Include~~s~~ Better Off-Hours Access, Care Coordination*
    - *Patient Safety, Beneficiary Engagement*
    - *Others as Determined by Secretary*
  - Meaningful Use of EHRs (**25%** of Score)

How will physicians and practitioners be scored under MIPS?

A single MIPS **composite performance score** will factor in performance in **4 weighted performance categories**:

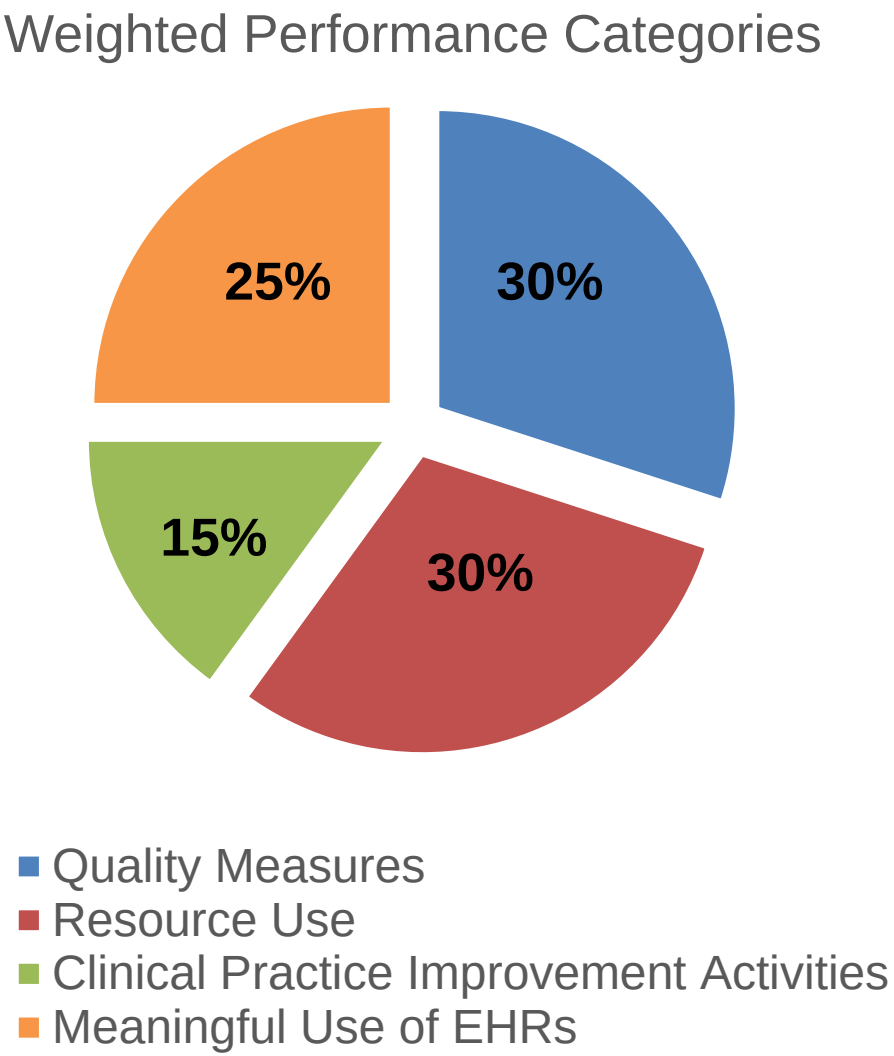
MIPS- Clinical Practice Improvement Activities:

The Secretary is required to specify clinical practice improvement activities. Subcategories of activities are also specified in the statute, some of which are:

Expanded Practice Access	Population Management	Care Coordination	Beneficiary Engagement	Patient Safety Practice Assessment	Alternative Payment Models
•Same day appointments for urgent needs •After hours clinician advice	•Monitoring health conditions & providing timely intervention •Participation in a qualified clinical data registry	•Timely communication of test results •Timely exchange of clinical information with patients AND providers •Use of remote monitoring •Use of telehealth	•Establishing care plans for complex patients •Beneficiary self-management assessment & training •Employing shared decision making	•Use of clinical checklists •Use of surgical checklists •Assessments related to maintaining of certification	•Participation in an APM will also count for CPIA

Secretary shall solicit suggestions from stakeholders to identify activities. Sec. retains discretion. Secretary shall give consideration to practices <15 EPs, rural practices, & EPs in under served areas.

MIPS Performance Categories

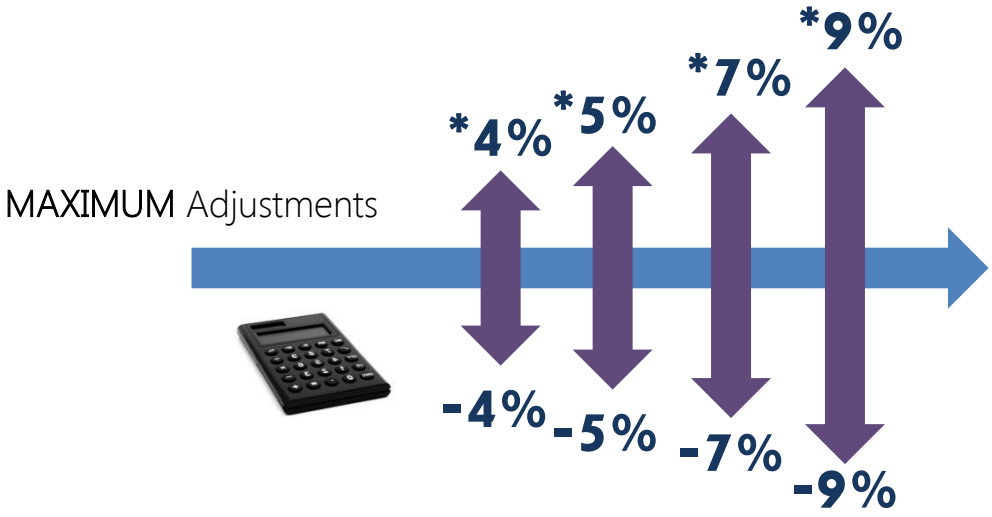


MIPS Composite Performance Score:

- Performance assessment in four categories using weights established in the statute
- Weights may be adjusted if there are not sufficient measures and activities applicable for each type of EP, including assigning a scoring weight of 0 for a performance category.
- EHR weighting can be decreased and shifted to other categories if Secretary estimates the proportion of physicians who are meaningful EHR users is 75% or greater (statutory floor for EHR weight is 15%)
- **Performance threshold** will be established based on the mean or median of the composite performance scores during a prior period
- The composite performance score will range from 0 – 100
- The score will assess achievement & improvement (when data available)

How much can MIPS adjust payments?

- Based on the MIPS **composite performance score**, physicians and practitioners will receive positive, negative, or neutral adjustments up to the percentages below.
- MIPS adjustments are **budget neutral**. A **scaling factor** may be applied to upward adjustments to make total upward and downward adjustments equal.



Adjustment to provider's base rate of Medicare Part B payment

2019 2020 2021 2022 onward

Merit-Based Incentive Payment System **(MIPS)**

***MACRA allows potential 3x upward adjustment BUT unlikely**

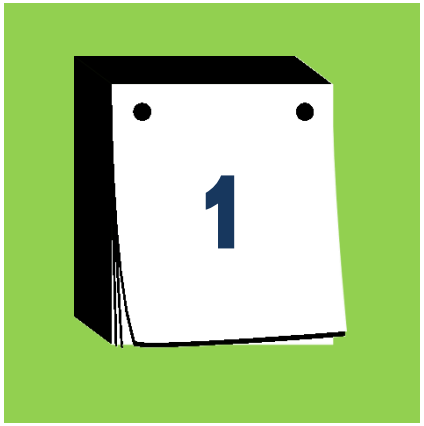
More on MIPS

To implement MIPS, CMS will:

- Make available timely ("such as quarterly") confidential feedback reports to each MIPS EP starting July 1, 2017.
- Provide information about items and services furnished to the EP's patients by other providers and suppliers for which payment is made under Medicare to each MIPS EP, beginning July 1, 2018.
- Make information about the performance of MIPS EPs available on Physician Compare.

Are there any exceptions to MIPS adjustments?

There are **3 groups** of physicians and practitioners who will NOT be subject to MIPS:



FIRST year of Medicare participation

Participants in eligible Alternative Payment Models who qualify for the bonus payment

Below low volume threshold

Note: MIPS **does not** apply to hospitals or facilities

Alternative Payment Models (APMs)

APMs are **new approaches to paying** for medical care through Medicare that **incentivize quality and value.**

According to MACRA law, APMs include:

- ✓ **CMS Innovation Center model** (under section 1115A, other than a Health Care Innovation Award)
- ✓ **MSSP** (Medicare Shared Savings Program)
- ✓ **Demonstration** under the Health Care Quality Demonstration Program
- ✓ **Demonstration** required by Federal Law

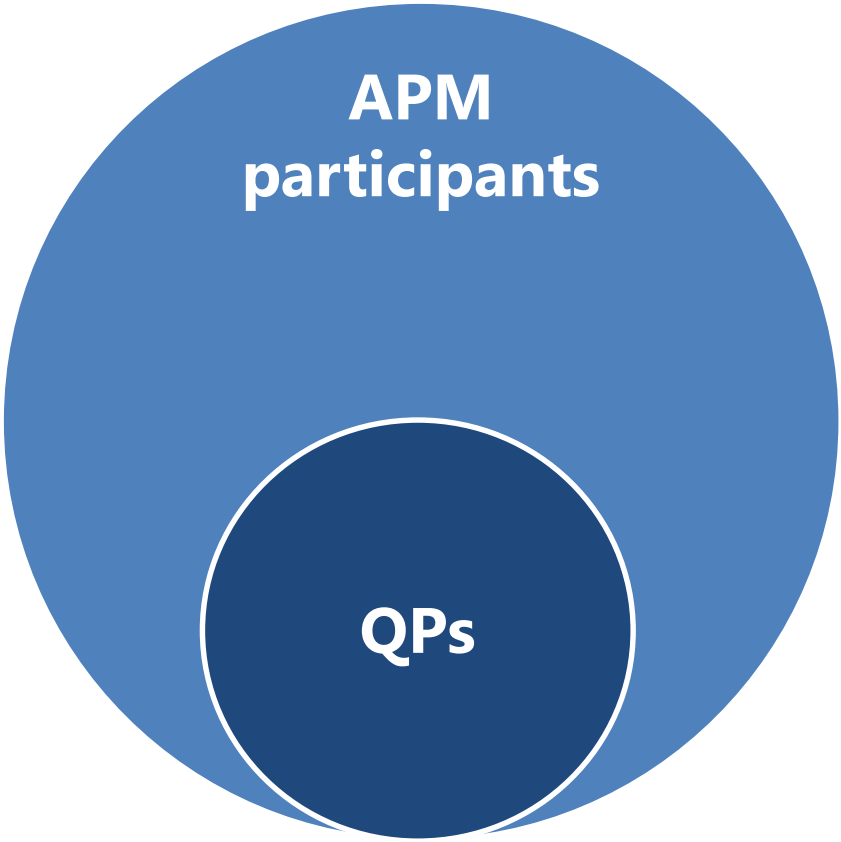
- MACRA **does not change how any particular APM rewards value**.
- APM participants who are not "QPs" will receive **favorable scoring under MIPS**.
- Only **some** of these APMs will be **eligible** APMs.

How does MACRA provide additional rewards for participation in APMs?

Most physicians and practitioners who participate in APMs will be subject to MIPS and will receive **favorable scoring** under the MIPS clinical practice improvement activities performance category.

Those who participate in **the most advanced** APMs may be determined to be **qualifying APM participants ("QPs")**. As a result, QPs:

1. Are **not subject** to MIPS
2. Receive 5% lump sum **bonus payments** for years 2019-2024
3. Receive a **higher fee schedule update** for 2026 and onward



What is an eligible APM?

Eligible APMs are the **most advanced** APMs that meet the following criteria according to the MACRA law:

- ✓ **Base payment on quality** measures comparable to those in MIPS
- ✓ Require use of certified **EHR** technology
- ✓ Either (1) bear more than nominal **financial risk** for monetary losses **OR** (2) be a **medical home model expanded** under CMMI authority

How do I become a qualifying APM participant (QP)?

QPs are physicians and practitioners who have a certain **% of their patients or payments** through an **eligible** APM.

Beginning in 2021, this threshold % may be reached through a **combination** of Medicare and other **non-Medicare payer arrangements**, such as private payers and Medicaid.

QPs:

1. Are **not subject** to MIPS
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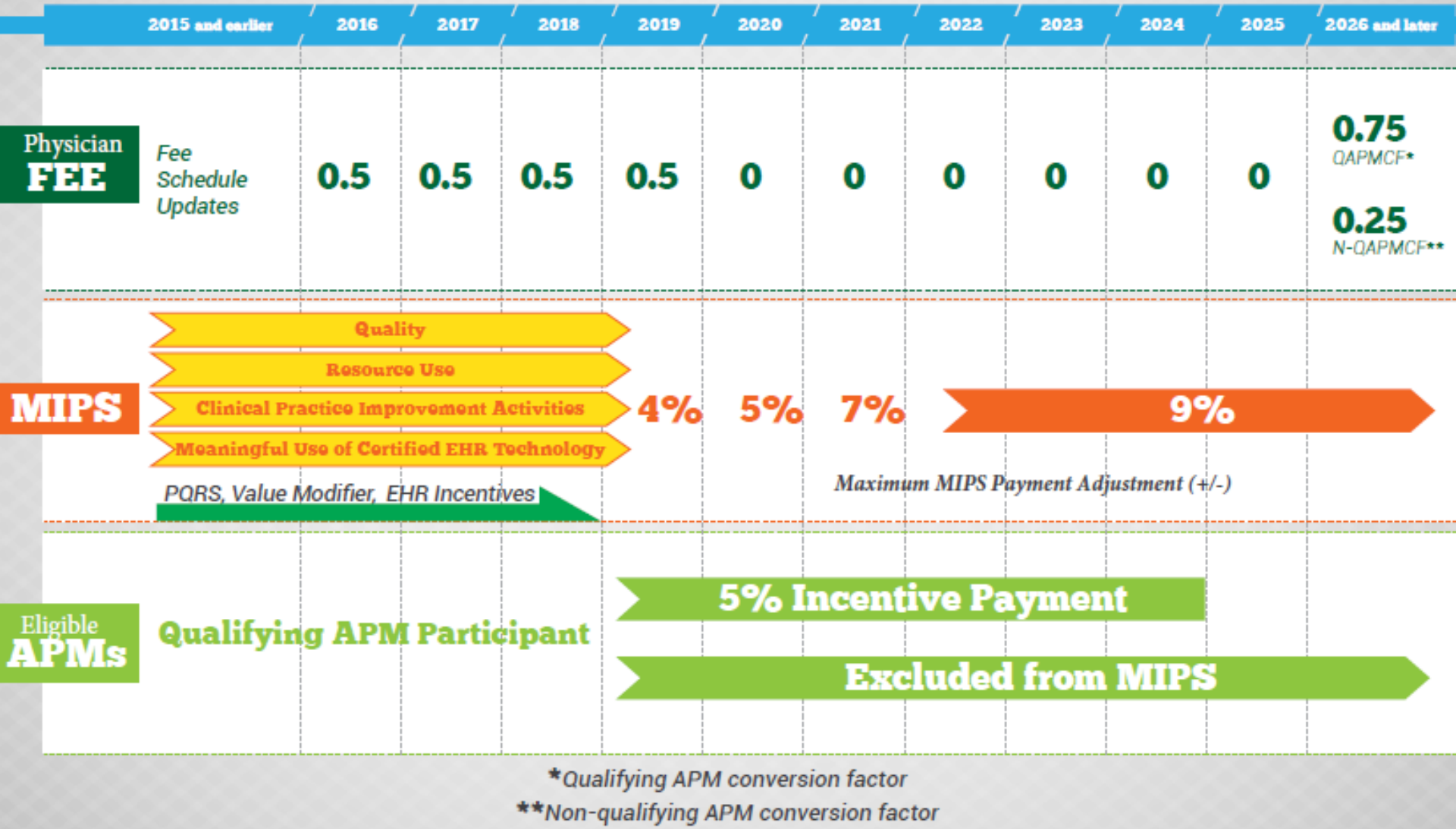
3. Receive a **higher fee schedule update** for 2026 and onward

Potential value-based financial rewards

- APMs—and eligible APMs in particular—offer greater **potential risks and rewards** than MIPS.
- **In addition** to those potential rewards, MACRA provides a bonus payment to providers committed to operating under the most advanced APMs.

MIPS only	APMs	eligible APMs
MIPS adjustments	**APM-specific rewards** + MIPS adjustments	**eligible APM-specific rewards** + 5% lump sum bonus

Timeline



*Qualifying APM conversion factor

**Non-qualifying APM conversion factor

What should I do to prepare for MACRA?

- Look for future educational activities
- Look for a proposed rule in spring 2016 and provide comments on the proposals.
- Final rule targeted for early fall 2016.

Disclaimer

This presentation was prepared as a tool to assist providers and is not intended to grant rights or impose obligations. Although every reasonable effort has been made to assure the accuracy of the information within these pages, the ultimate responsibility for the correct submission of claims and response to any remittance advice lies with the provider of services.

This publication is a general summary that explains certain aspects of the Medicare Program, but is not a legal document. The official Medicare Program provisions are contained in the relevant laws, regulations, and rulings. Medicare policy changes frequently, and links to the source documents have been provided within the document for your reference

The Centers for Medicare & Medicaid Services (CMS) employees, agents, and staff make no representation, warranty, or guarantee that this compilation of Medicare information is error-free and will bear no responsibility or liability for the results or consequences of the use of this guide.

References:

- HR 2- Medicare Access and CHIP Reauthorization Act of 2015
  - https://www.govtrack.us/congress/bills/114/hr2

- CRS Review of HR2
  - https://www.fas.org/sgp/crs/misc/R43962.pdf
  - http://go.cms.gov/valuebasedprogams

Questions ?

Better, Smarter, Healthier:

Delivery System Reform

U.S. Department of Health and Human Services



Better, Smarter, Healthier

Improving the way providers are incentivized, the way care is delivered, and the way information is distributed will help provide better care at lower cost across the health care system.

FOCUS AREAS

- Pay Providers
- Deliver Care
- Distribute Information

Source: Burwell SM. Setting Value-Based Payment Goals – HHS Efforts to Improve U.S. Health Care. NEJM 2015 Jan 26; published online first.

A health system that provides better care, spends dollars more wisely, and has healthier people

Focus Areas	Description
INCENTIVES	▪ Promote value-based payment systems – Test new alternative payment models – Increase linkage of Medicaid, Medicare FFS, and other payments to value ▪ Bring proven payment models to scale ▪ Align quality measures
CARE DELIVERY	▪ Encourage the integration and coordination of clinical care services ▪ Improve individual and population health ▪ Support innovation including for access
INFORMATION	▪ Bring electronic health information to the point of care for meaningful use ▪ Create transparency on cost and quality information ▪ Support consumer and clinician decision making

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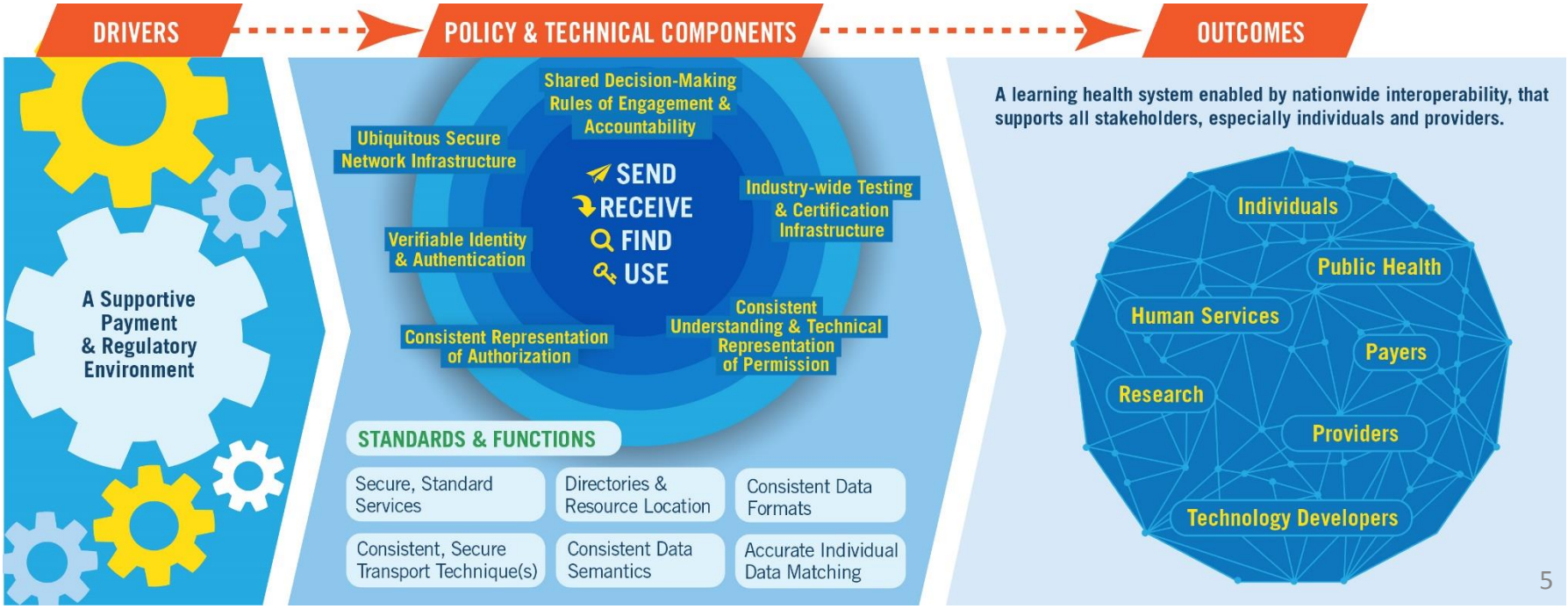
Nationwide Interoperability Roadmap

Goals:

***2015-2017*:** Send, receive, find and use priority data domains to improve health care quality and outcomes.

***2018-2020*:** Expand data sources and users in the interoperable health IT ecosystem to improve health and lower cost.

***2021-2024*:** Achieve nationwide interoperability to enable a learning health system, with the person at the center of a system that can continuously improve care, public health, and science through real-time data access.



Commitments and Call to Action

Consumers easily and securely access their electronic health information, direct it to any desired location.

Share individual's health information for care with other providers and their patients as much as permitted by law and refrain from **blocking** electronic health information.

Implement **federally recognized, national interoperability standards**, policies, guidance, and practices for electronic health information and adopt best practices including those related to privacy and security.

The President's Precision Medicine Initiative

“And that’s why we’re here today. Because something called precision medicine … gives us one of the greatest opportunities for new medical breakthroughs that we have ever seen.”

President Barack Obama

January 30, 2015

The Precision Medicine Initiative (PMI)

Mission Statement

To enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward development of individualized care.

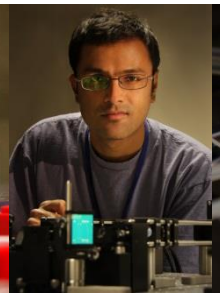
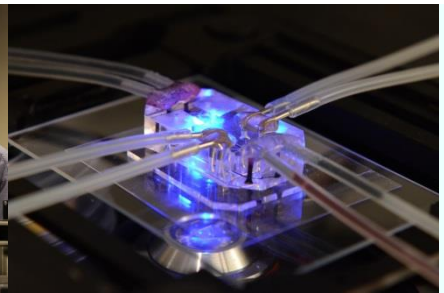
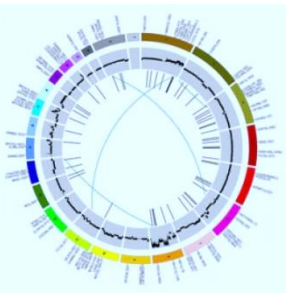
Precision Medicine

Concept is not new

- Consider prescription eyeglasses, blood transfusions…
- Prospects for broader application raised by recent advances in basic research, technology development, genomics, proteomics, metabolomics, EHRs, Big Data, mHealth, etc.
- Reinforced by 2011 National Research Council report

What is needed now

- Development of rigorous research program to provide scientific evidence needed to turn concept into reality
- Recruitment of the best and brightest from multiple disciplines to join the team
- Development of standards and resources for generating and sharing data


Precision Medicine Initiative:
Timing is Everything

Challenges:

- Many diseases lack effective prevention & treatment strategies
- Research findings take too long to be implemented into clinical practice

Now is the time:

- Americans' Growing Desire to Be Partners in Research
- Advances in data science and bioinformatics
- Better technologies for biomedical analysis
- FDA-cleared technologies for genomics are now available
- Human-genome sequencing continues to get cheaper and faster
- Availability of new data – microbiome, diagnostics, and sensor data
- Availability of Existing Research Cohorts

PMI: Priorities

- Reducing disparities and bringing the promise of precision medicine to everyone;
- Engaging participants as partners in research, including returning results to them in dynamic, user-centered ways;
- Opening up data and technology tools to invite citizen participation, unleash new discoveries, and bring together diverse collaborators to share their unique skills;
- Making it easier for patients to access, understand, and share their own digital health data, including donating it for research; and
- Adhering to strong privacy and data security principles.

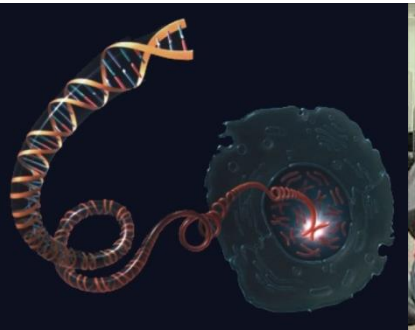
PMI: Building a national research cohort of one million or more participants

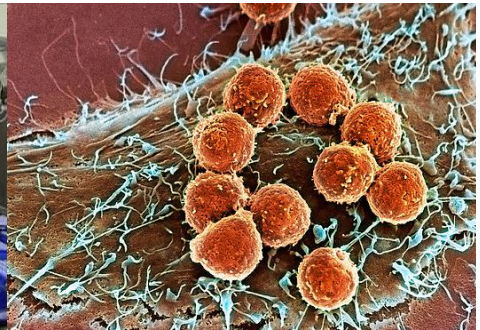
- Longitudinal cohort with continuing interactions
- Will comprise:
  - >1 million U.S. volunteers
  - Two methods of recruitment
    - Direct volunteers
    - Healthcare provider organizations
- Participants will:
  - Be centrally involved in design, implementation
  - Be able to share genomic data, Other "–omics", lifestyle information, biospecimens, data from mobile devices, EHR data
  - Get information back if they desire
- Emphasis on open, responsible data sharing with privacy protections

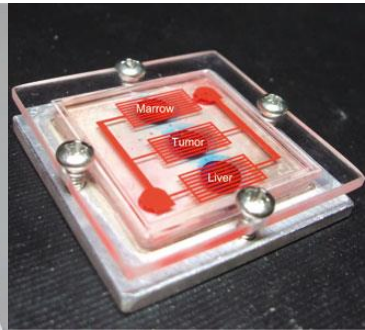
PMI: Accelerating the development of cancer treatment through genomics

Apply tenets of precision medicine to cancer

- Dramatically expand the NCI-MATCH trial
- Increase mechanistic understanding of immunotherapy
- Repository of patient-derived pre-clinical models
- Database integrating genomic information with clinical response and outcomes







PMI: Establishing a regulatory pathway for evaluating genomic technologies

Vision: Implement new regulatory policies to promote research and accelerate the translation of precision medicine into the clinic.

- **Near Term:** Develop standards and shared resources that will assure quality in genomic testing and evidence generation
- **Longer Term:** Develop standards-based regulation of genomics and diagnostic tests that will bring safe and eff

In December 2015, FDA released an open-source, cloud-based platform where labs can validate test data

- To date, more than 300 organizations have raised their hands to beta test

PMI: Developing a privacy and security framework for PMI

"We're going to make sure that protecting patient privacy is built into our efforts from day one."

- President Barack Obama, January 30th 2015

PMI Privacy and Trust Principles:

- Articulate a core set of values and responsible strategies for engendering public trust to serve as a foundation for PMI.
- Principles organized into these categories:
  - Governance
  - Transparency
  - Respecting Participant Preferences
  - Participant Empowerment Through Access to Information
  - Data Sharing, Access, and Use
  - Data Quality and Integrity
- Finalized in November

PMI Data Security Policy; Principles and Framework:

- Consulted with many experts
- Framework will go out for public comment

PMI: Designing a data and technology framework to accelerate PMI

The success of PMI depends on high-quality health and research data that move easily and securely

The White House has been focused on the following for PMI:

- Enabling patients to access their EHR data easily, including to contribute it for research
- Executing the best approaches for data management, storage, security, and usage for PMI.

Close coordination with the Office of the National Coordinator for Health IT and the Office for Civil Rights, among our other Federal partners.

The private sector is critical here!

Precision Medicine Success Stories

William Elder Jr.

Emily Whitehead

Elana Simon

Melanie Nix

Hugh and
Beatrice Rienhoff

Kareem
Abdul-Jabbar

Noah and
Alexis Beery