Can Technology Improve the Value Equation in Healthcare?

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Disclosures

- Uncompensated activities
  - Senior Advisor, Bipartisan Policy Center
  - Visiting Fellow, Duke Margolis Center for Health Policy
  - Co-Chair, Safety Workgroup, Coalition for Health AI
  - Member, Board for Health Services, National Academy of Medicine (NAM)
  - Digital Health Advisory Committee, NAM
- Compensated activities
  - Principal, Rubrum Advising, LLC

Providers must lead the way in making value the overarching goal

Michael E. Porter and Thomas H. Lee

Harvard Business Review
October 2013

$$\text{Value} = \frac{\text{Medical outcomes + patient experience}}{\text{Direct costs + indirect costs}} = \frac{\text{Quality}}{\text{Cost}}$$


Patients
want better health
Heath systems
want less mortality
Employers
want healthier employees
STOP

Vision: What's to Come Over the Next 10 Years

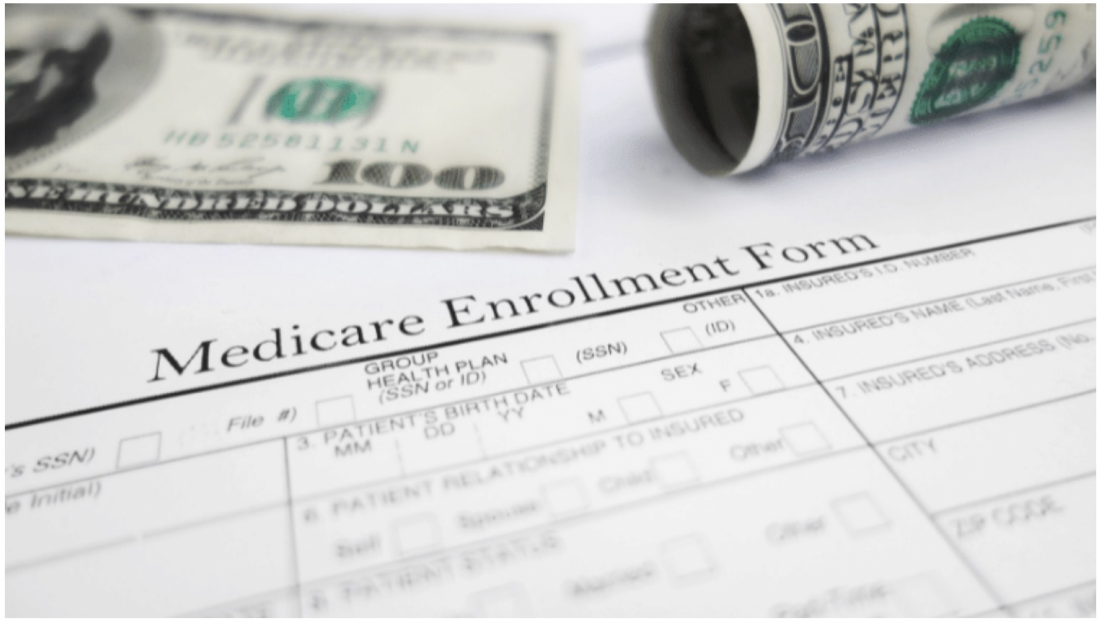
How are we defining value in this strategy?

- Value **for all people with Medicare.**

The Medicare Value-Based Care Strategy: Alignment, Growth, And Equity

Douglas Jacobs, Elizabeth Fowler, Lee Fleisher, Meena Seshamani

JULY 21, 2022 10.1377/forefront.20220719.558038



3 Value-Based Care (VBC) Priorities

- Established goal to have all Traditional Medicare beneficiaries as part of an accountable care relationship by 2030.
- Growth of accountable care relationships can improve quality, increase savings for Medicare, and promote innovative delivery of services that meet patients' needs.

- From the provider's perspective, multi-payer alignment is critical and even aligning across CMS can help set the stage for broader alignment in our health care system.
- If value-based arrangements are not aligned, providers face challenges focusing attention on the right quality metrics and making the investments necessary to improve care.

- For too long profound inequities have existed across our health care system. The design of value-based arrangements can be a key way to advance equity.
- Quality care for all is not possible without care that is also equitable.

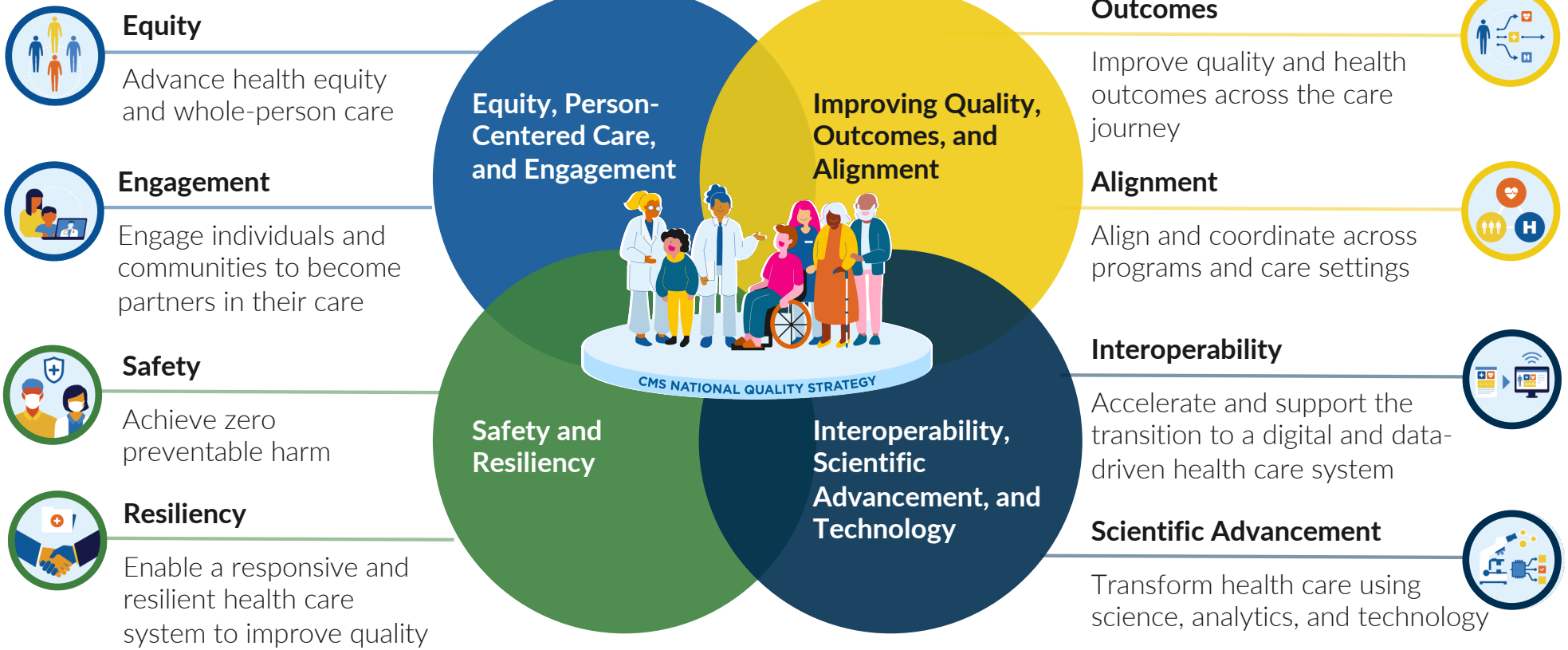
Available from: Jacobs, Douglas, Elizabeth Fowler, Lee Fleisher, and Meena Seshamani. The Medicare Value-Based Care Strategy: Alignment, Growth, and Equity. Health Affairs Forefront. July 21, 2022. 10.1377/forefront.20220719.558038

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

CMS Quality Incentive Programs

Hospital IQR – Inpatient Quality	MIPS - Clinician	Post Acute Care – SNF QRP
Hospital – Readmissions Reduction	MSSP Clinician Reporting	Expanded SNF VBP
Hospital Value Based Purchasing	Advance Payment Models	Hospice Quality Reporting
Hospital Acquired Conditions	Support Act – eRX of Opioids	Home Care Quality Reporting
Hospital Promoting Interoperability	Medicare C& D Stars Rating	Inpatient Rehabilitation Facility
Cancer Exempt Hospital	Hospital Stars	Long Term Care Hospital
Inpatient Psychiatric Hospital	Nursing Home Stars	Medicaid Adult Core Set
Hospital Outpatient	Home Health VBP	Medicaid Child Core Set
Ambulatory Surgery Program	Rural Emergency Hospitals	
ESRD QIP	Marketplace Quality Reporting	

CMS National Quality Strategy Goals



Equity

Advance health equity and whole-person care

Engagement

Engage individuals and communities to become partners in their care

Safety

Achieve zero preventable harm

Resiliency

Enable a responsive and resilient health care system to improve quality

Outcomes

Improve quality and health outcomes across the care journey

Alignment

Align and coordinate across programs and care settings

Interoperability

Accelerate and support the transition to a digital and data-driven health care system

Scientific Advancement

Transform health care using science, analytics, and technology

Safety and Resiliency

Goal: Achieve Zero Preventable Harm

Target: Improve safety metrics with a goal to return to pre-pandemic levels by 2025 and reduce harm by an additional 25% by 2030 through expanded safety metrics, targeted quality improvement, and Conditions of Participation.

Objective: Improve performance on key safety metrics through application of CMS levers such as quality measurement, payment mechanisms, and health and safety standards.

CMS National Quality Strategy Priority Areas

Goal: Enable a responsive and resilient health care system to improve quality

Target: Ensure support for health care workforce and systems, as well as address workforce issues to reduce burnout and shortages to safeguard vital health care needs.

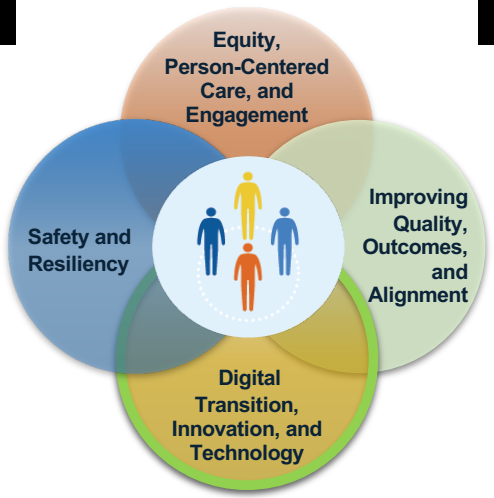
Objective: Foster a more resilient health care system that is better prepared to respond to future emergencies by addressing workforce challenges such as burnout and shortages.

Digital Transition, Innovation, and Technology

Goal: Accelerate and support the transition to a digital and data-driven health care system

Target: Transition to all digital quality measures and achieve all-payer quality data collection by 2030 to reduce burden and make quality data rapidly available.

Objective: Support data standardization and interoperability by developing and expanding requirements for sharing, receipt and use of digital data, including digital quality performance measures, across CMS quality and value-based programs.



CMS National Quality Strategy Priority Areas

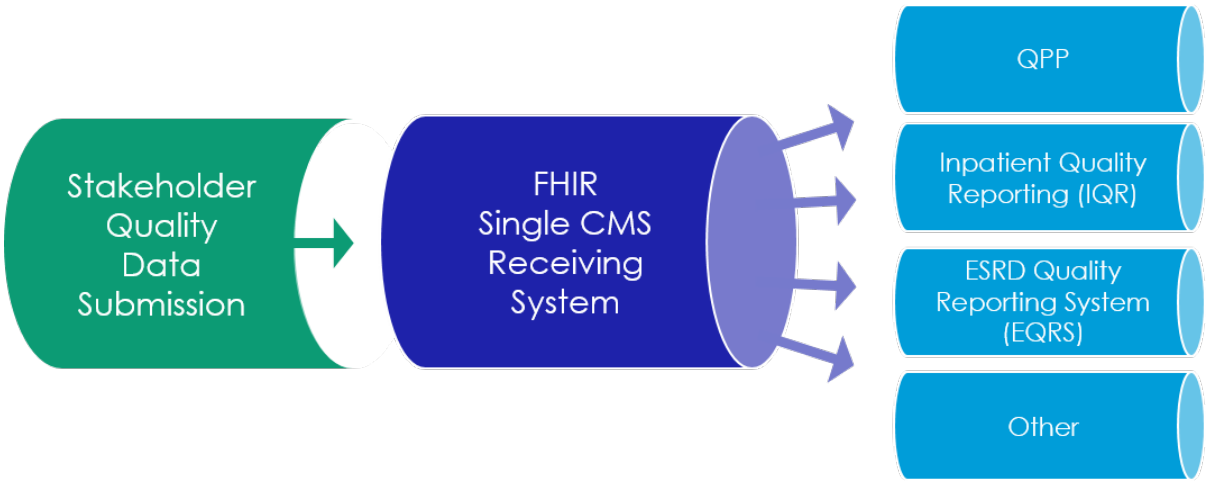
Goal: Promote Innovation in science, analytics, and technology

Target: Utilize advanced data analytic models to support data-driven policy decisions for quality care.

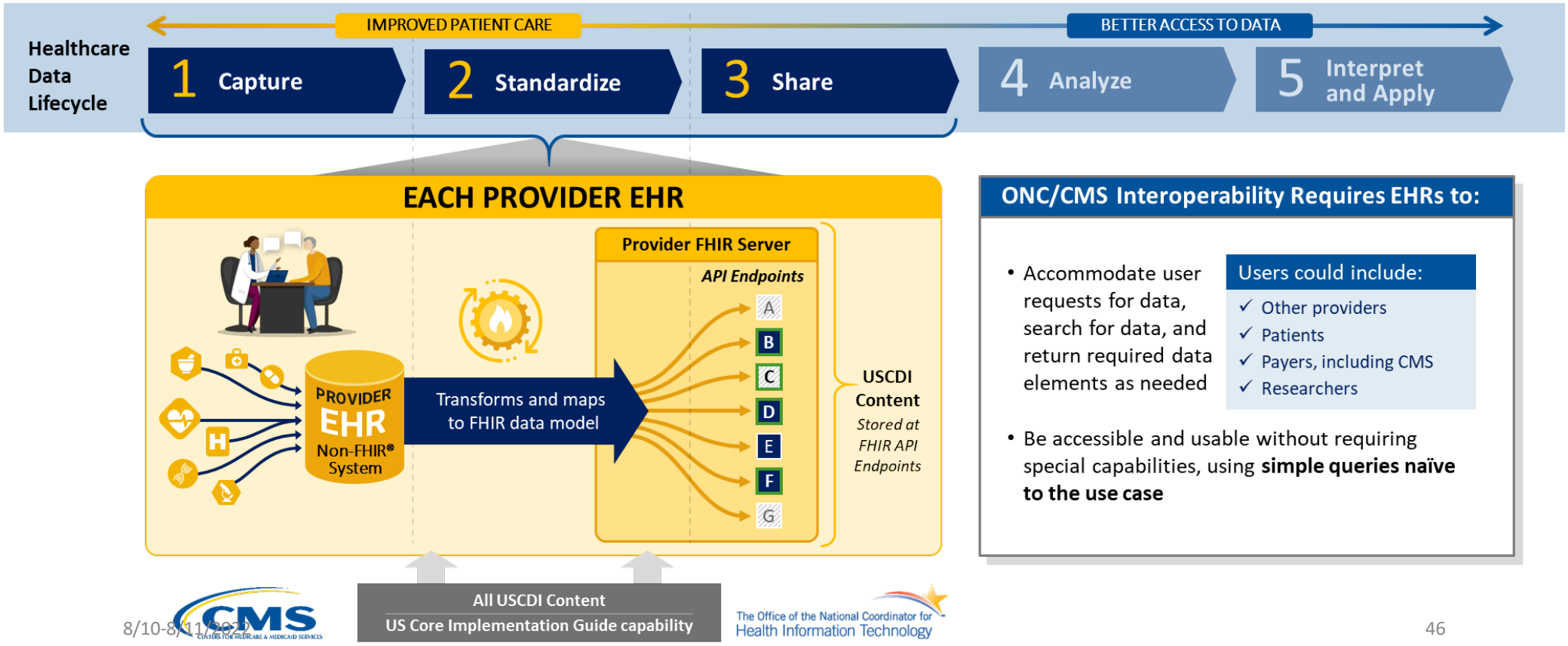
Objective: Support and drive innovation and access through streamlined, evidence-based reviews of novel technologies and devices for coverage decisions, and advanced data analytics.

FHIR Pilot: Future State Submissions

A successful FHIR pilot leads the way for stakeholders to submit to a centralized submission solution for quality reporting. The receiving system can then do the measure calculations and exchange data and results with applicable quality programs, removing the burden from the submitter.



Many providers already have to implement FHIR APIs that **perform transformation functions** for data interoperability



ONC/CMS Interoperability Requires EHRs to:

- Accommodate user requests for data, search for data, and return required data elements as needed

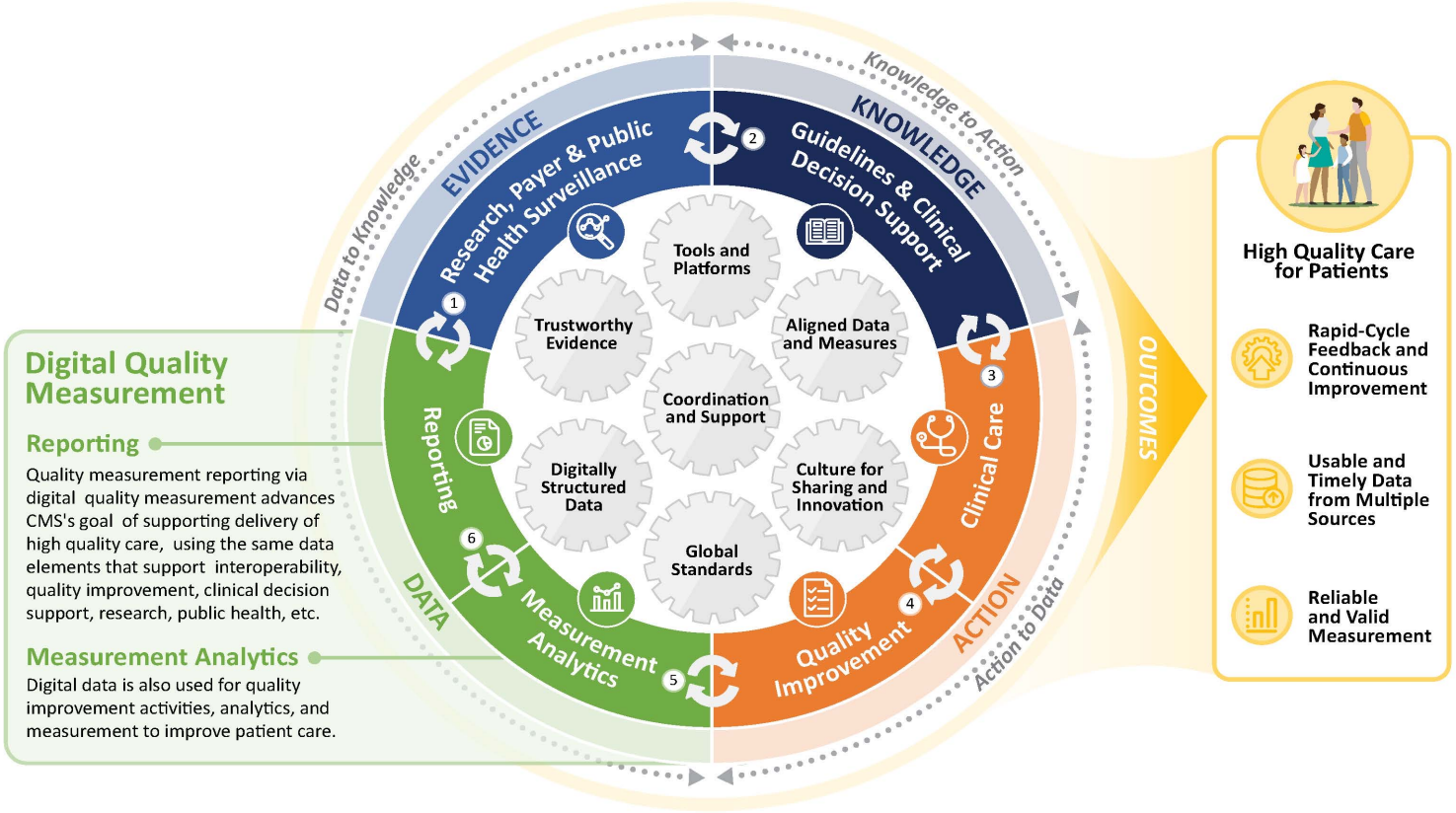
Users could include:

- ✓ Other providers
- ✓ Patients
- ✓ Payers, including CMS
- ✓ Researchers

- Be accessible and usable without requiring special capabilities, using **simple queries naïve to the use case**

The Office of the National Coordinator for Health Information Technology

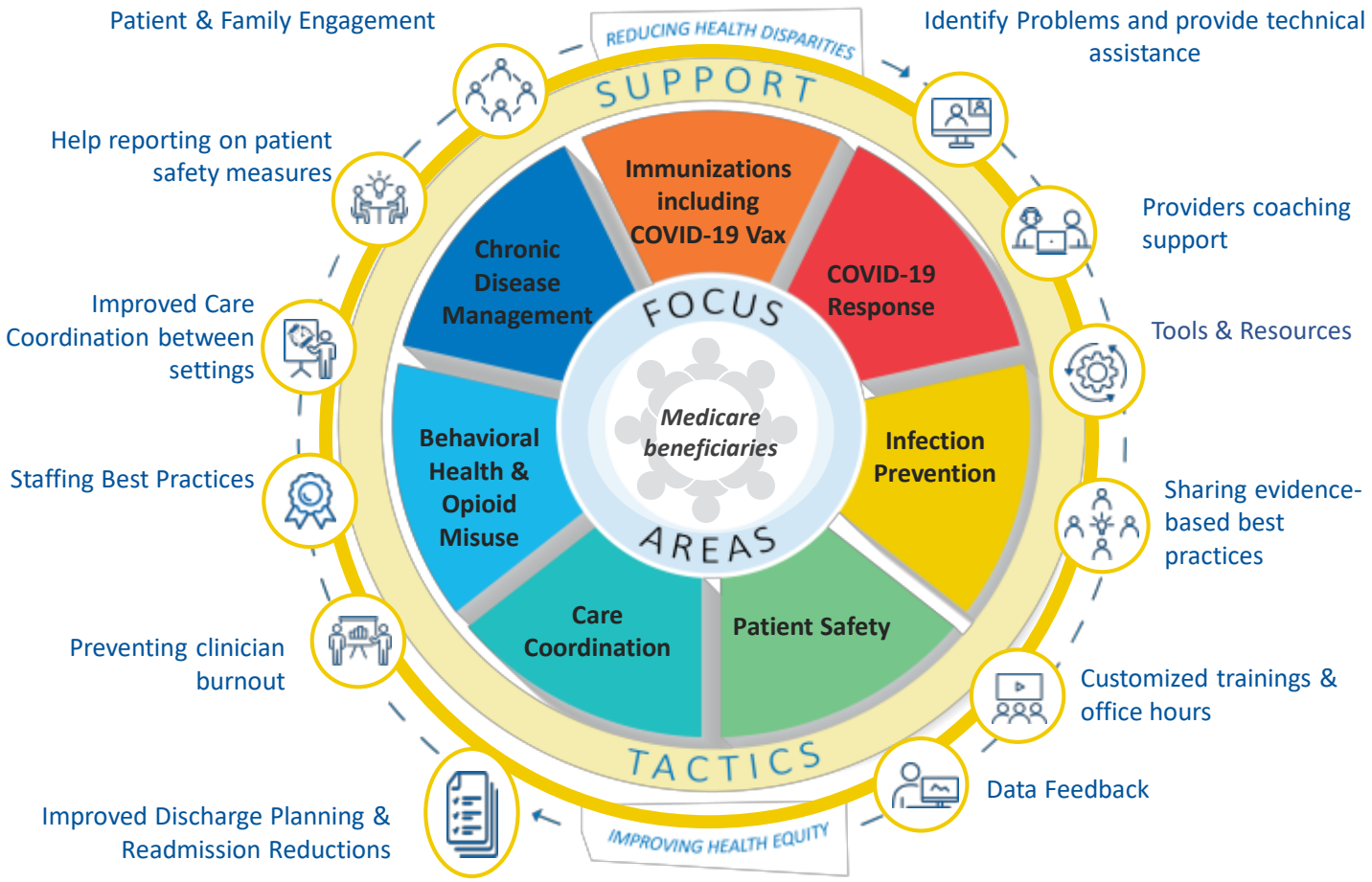
A learning health system uses standardized data to drive health care



Sponsoring HL7 Workgroups: Clinical Decision Support (CDS) | Clinical Quality Information (CQI) | Public Health (PH)

Adapted from HL7 Clinical Quality Information (CQI) Workgroup by Maria Michaels, Centers for Disease Control and Prevention

National Quality Improvement Program



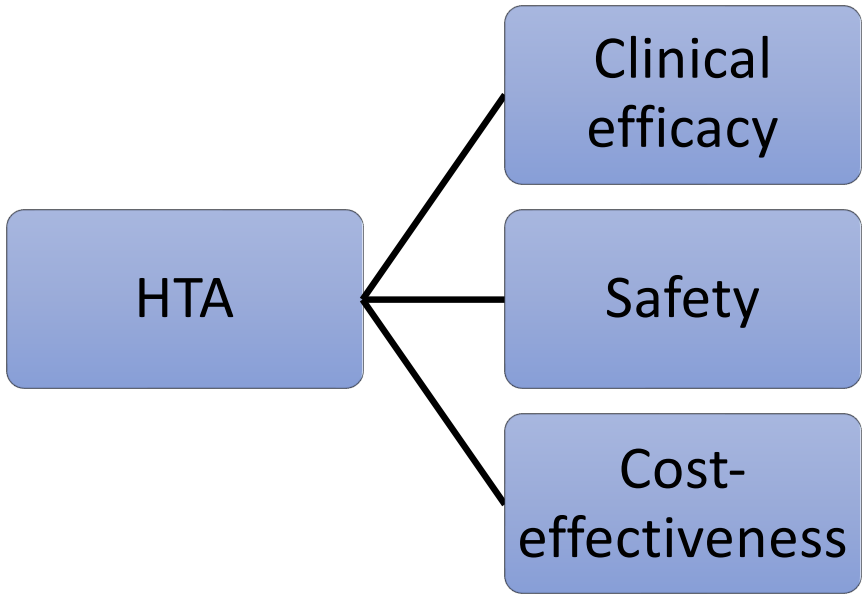
Health Technology Assessments

- Many definitions

> "Technology assessment in health care is a multidisciplinary field of policy analysis. It studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology."
>
> *– International Association of HTA (INAHTA)*

> "A form of policy research that examines short- and long-term consequences of technology. . . safety, efficacy, patient-reported outcomes, real-world effectiveness, cost, and cost-effectiveness as well as social, legal, the application of a health-care ethical, and political impacts."
>
> *– International Society for Pharmacoeconomics and Outcomes Research (ISPOR)*

Regardless of the technology assessed, HTAs include similar elements



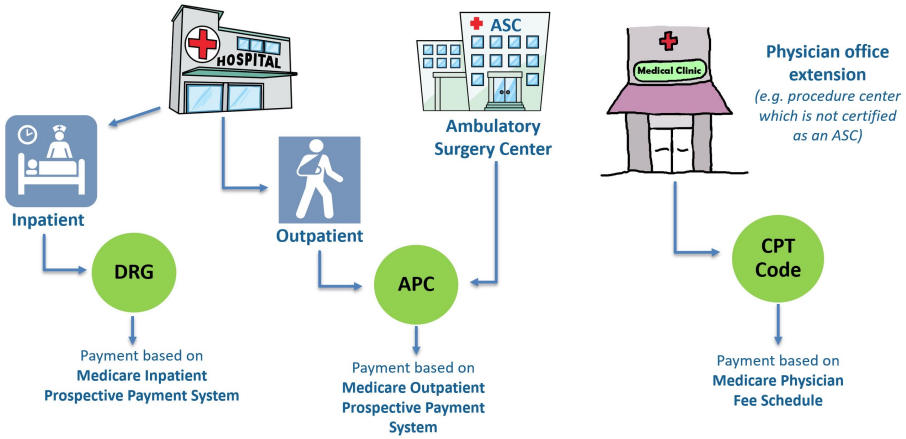
HTAs are used to support many health care decisions

Clinicians and patients	Public and private payers	Hospitals
• Prescribing decisions • Practice guidelines	• Drug plan formularies • Level of coverage	• Technology acquisition • Hospital formularies

Who pays for innovative technologies?

Direct payment

Payment as part of DRG/APC/CPT



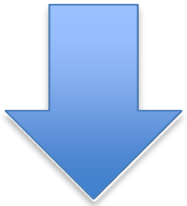
Direct payment

FDA and CMS Authorities

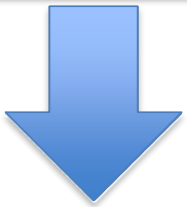
"Responsible for protecting the public health by ensuring the **safety, efficacy, and security** of … drugs, biological products, and medical devices."[1]

Authority to determine whether a particular medical item or service is "**reasonable and necessary**"[2] **for the treatment of an illness or injury**.

Device Risk



Class



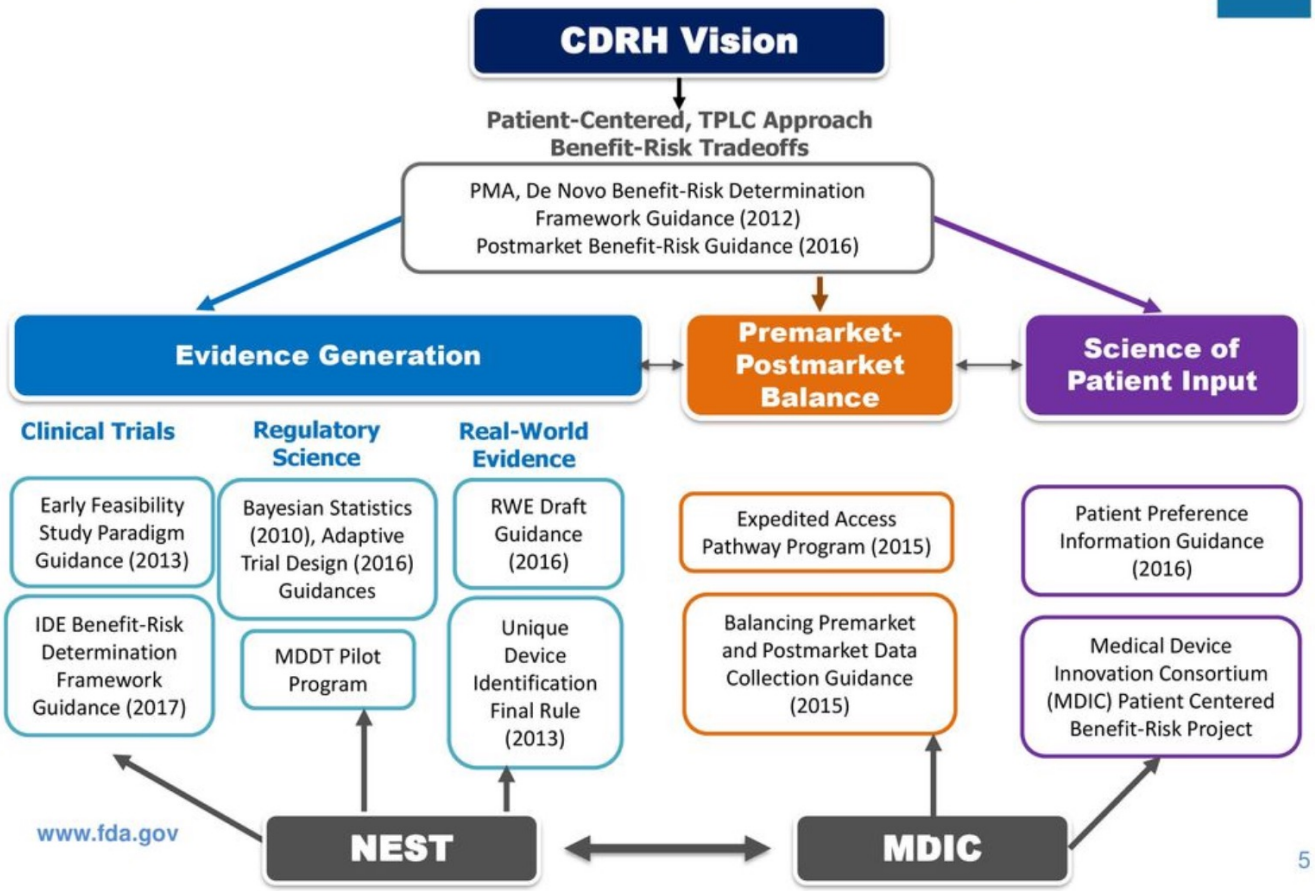
Extent of Regulatory Controls

Classes of Medical Devices

Class	Risk	Potential Harm	Regulatory Controls	Submission Type or Exemption	Percent Devices in Class*
I	Lowest	Present minimal potential for harm	General	510(k) 510(k) Exempt *93% are exempt from 510(k)	35%
II	Moderate	Higher risk than Class I devices	General and Special (if available)	510(k) 510(k) Exempt	53%
III	Highest	Sustain or support life, are implanted, or present potential unreasonable risk of illness or injury	General and PMA	PMA	9%

***3% of devices are Unclassified**

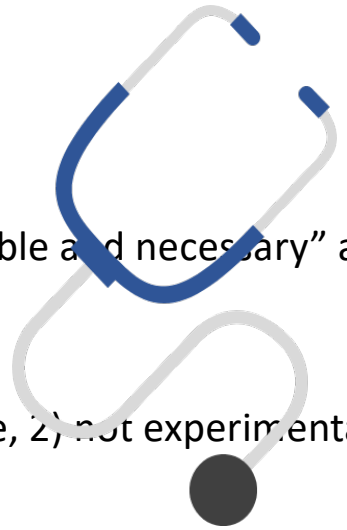
Flexible Regulatory Paradigms Applied Across the Total Product Life Cycle



www.fda.gov

CMS Mission: Promoting Evidence-based Care

- Evidence-based coverage underpins the HHS / CMS value mission
- CMS is uniquely positioned to establish evidence-based care standards
- CMS may extend coverage to an item or service that is considered "reasonable and necessary" as defined under the Social Security Act
- CMS is evaluating items and services to ensure they are 1) safe and effective, 2) not experimental or investigational, and 3) appropriate for Medicare beneficiaries



Current State: Coverage Challenges with Technologies

- National Coverage Determinations establish conditions of coverage for emerging, high impact technologies. Anyone can ask to open an NCD
- Benefit Categories
  - Medicare is a defined benefit program (BCD)
  - Coding
- With respect to coverage decisions
  - Evidence of Benefit
    - Strength of evidence
  - Risk of Harm
    - Low risk
    - High risk
    - Adequate evidence to define risk including patient, provider, facility characteristicS

CMS Coverage Options for both Routine and Emerging (Breakthrough) Technologies

National Level

National Coverage Determination (NCDs)
+/- Coverage with Evidence Development

- 3 - 4 completed annually, on average
- Timing driven by available resources, priorities, and external factors
- Finalized 9 months after opening
- Current waitlist

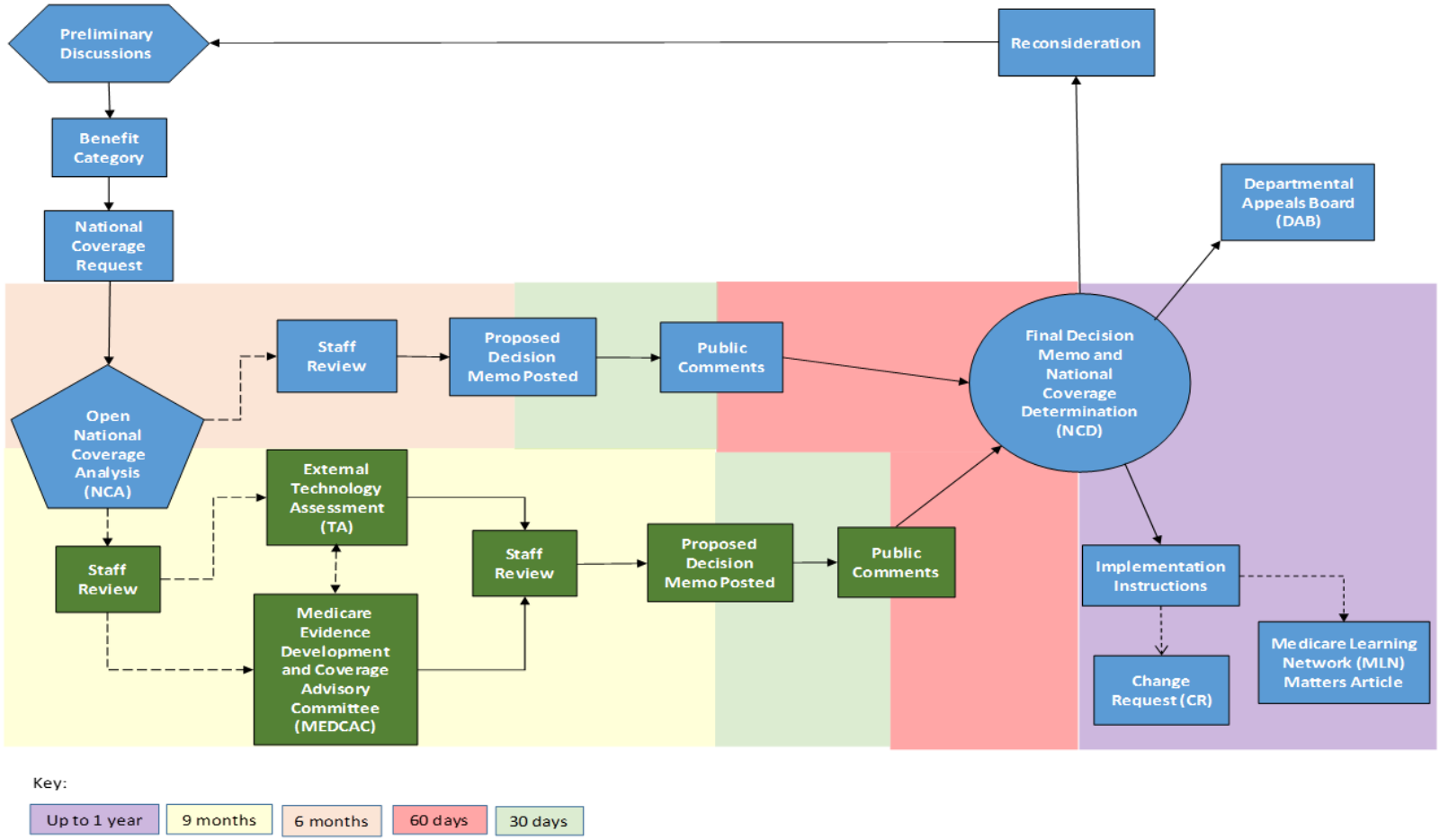
Local (MAC) Level

Local Coverage Determination (LCDs)

- 37 unique LCDs annually, on average
- May vary by jurisdiction, less so for lab tests and durable medical equipment
- Effective ~ 9 months after opening

Individual Claim Determination

- No NCD or LCD
- Coverage based on individualized MAC assessment


Preliminary Discussions
Benefit Category
National Coverage Request
Open National Coverage Analysis (NCA)
Staff Review
Proposed Decision Memo Posted
Public Comments
External Technology Assessment (TA)
Staff Review
Medicare Evidence Development and Coverage Advisory Committee (MEDCAC)
Staff Review
Proposed Decision Memo Posted
Public Comments
Final Decision Memo and National Coverage Determination (NCD)
Reconsideration
Departmental Appeals Board (DAB)
Implementation Instructions
Change Request (CR)
Medicare Learning Network (MLN) Matters Article
Key:
Up to 1 year
9 months
6 months
60 days
30 days

Jun 22, 2023

Transforming Medicare Coverage: A New Medicare Coverage Pathway for Emerging Technologies and Revamped Evidence Development Framework

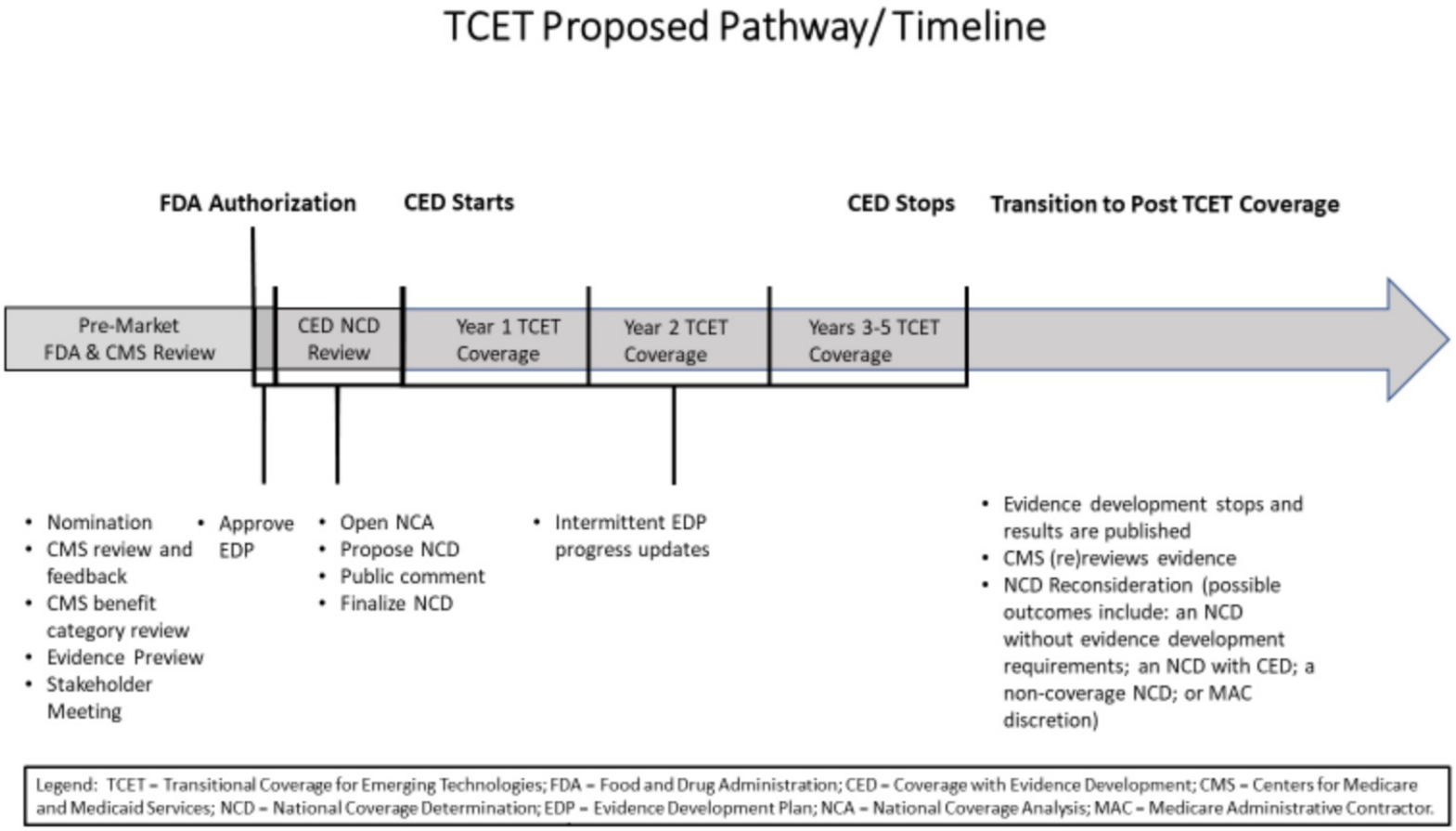
By: Lee Fleisher, MD; Steve Farmer, MD, PhD; Lori Ashby, MA; and Jonathan Blum, MPP, Centers for Medicare & Medicaid Services

Coverage

TCET PRINCIPLES

- TCET applies to certain FDA-designated Breakthrough Devices that fall within a Medicare benefit category.
- Manufacturer participation in the TCET pathway is voluntary.
- CMS may conduct an early evidence review (Evidence Preview) before FDA decides on marketing authorization for the device and discuss with the manufacturer the best available coverage pathways depending on the strength of the evidence.
- Before FDA marketing authorization, CMS may initiate discussions with manufacturers about any evidence gaps for coverage purposes and the types of study designs that could address them. The manufacturer may then propose an Evidence Development Plan (EDP). As part of the EDP development process, CMS will work with manufacturers to efficiently meet both CMS evidence development and FDA post-market requirements.
- For Breakthrough Devices in the TCET pathway, CMS' goal is to finalize a TCET NCD within six months after FDA market authorization. We intend to have coverage under the TCET NCD continue only as long as is needed to facilitate the timely generation of evidence that can inform patient and clinician decision making and lead to a predictable, long-term Medicare coverage determination.

TCET Pathway at a Glance



Outside the box

Why we should expand hospital-at-home during the COVID-19 pandemic

Hospital-at-home programmes can save resources and lives, during the pandemic and long term. Image: REUTERS/Flavio Lo Scalzo

NEJM Catalyst

COMMENTARY

Acute Hospital Care at Home: The CMS Waiver Experience

Douglas V. Clarke, MD, MBA, Jillian Newsam, MPH, Douglas P. Olson, MD, Danielle Adams, MS, BSN, RN, Ashby J. Wolfe, MD, MPP, MPH, Lee A. Fleisher, MD

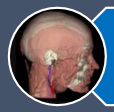
Digital Health Technology

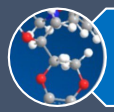
Healthy living | Prevention | Diagnosis | Treatment Recovery | Home care | Management

Convergence of computing power, connectivity, sensors, and software used in healthcare.


Used as a medical product


Incorporated into a medical product (include a pharmacologic product)

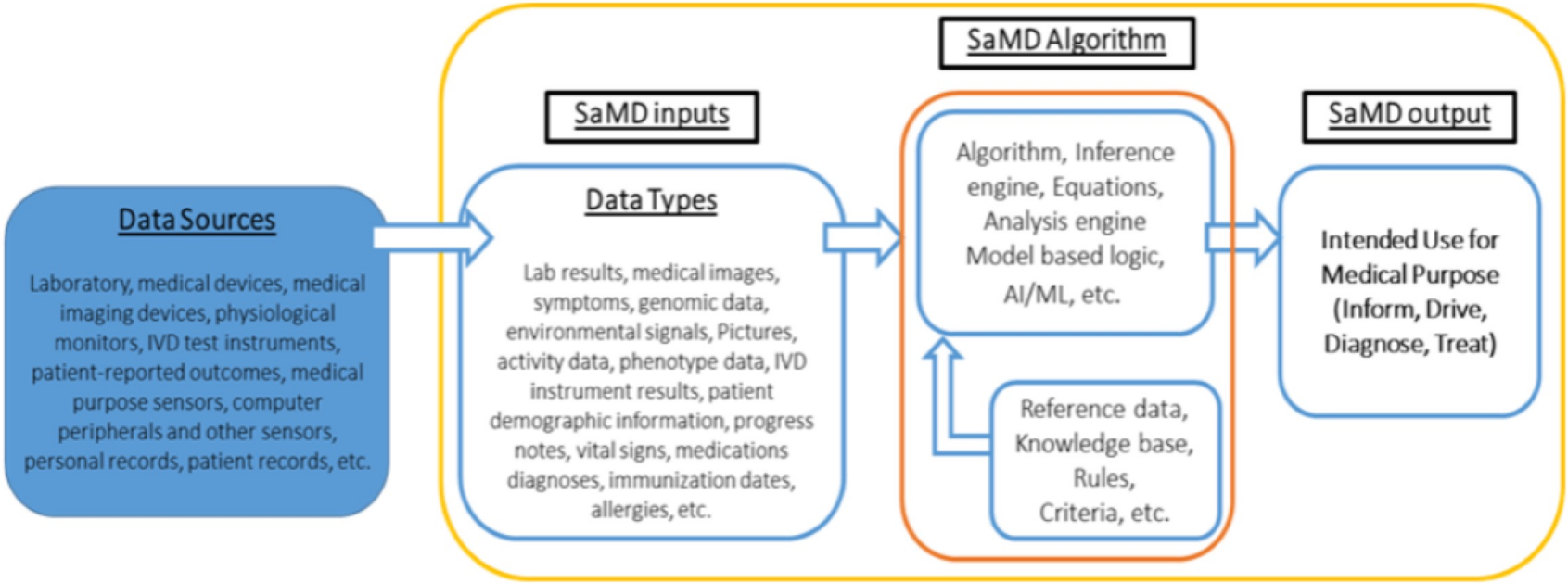

Used to develop a medical product


Used to study a medical product


Used as a companion or adjunct to a medical product, including diagnostics and therapeutics.

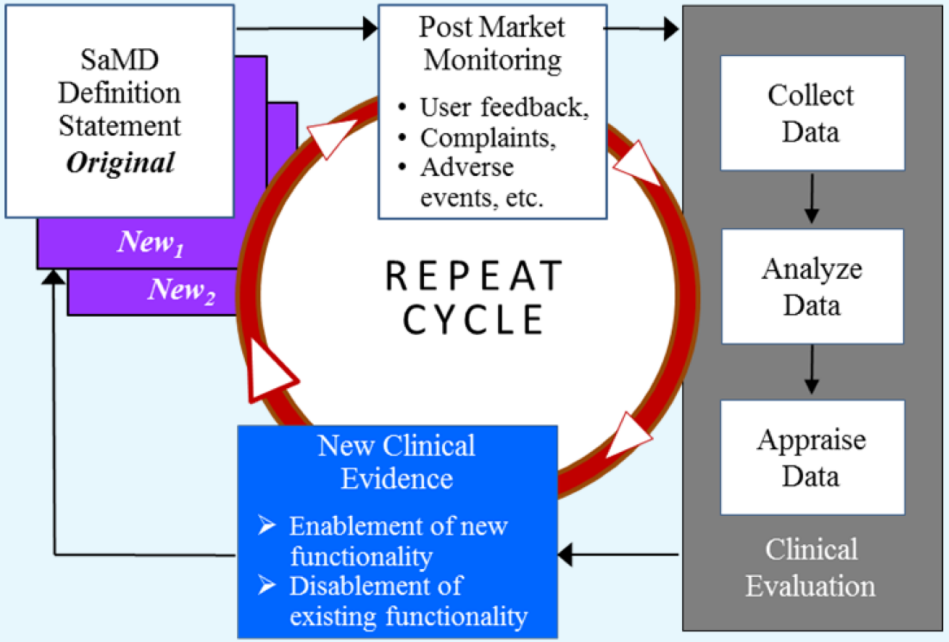
What is a SaMD?

"Software as a Medical Device" (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.[5]

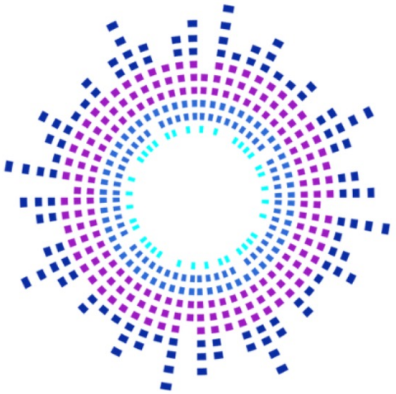


Pathway for Continuous Learning Leveraging Real World Performance Data

SaMD manufacturers are encouraged to leverage SaMD's technology capability to capture real world performance data to understand user interactions with the SaMD, and conduct ongoing monitoring of analytical and technical performance to support future intended uses.



1. Additional clinical data is gathered.
2. The data may create and support new intended use(s).
3. The SaMD manufacturer will update the clinical evaluation and generate a new definition statement.
4. Then the cycle repeats.



Health Care Artificial Intelligence Code of Conduct

Toward a Code of Conduct for Artificial Intelligence Used in Health, Medical Care, and Health Research

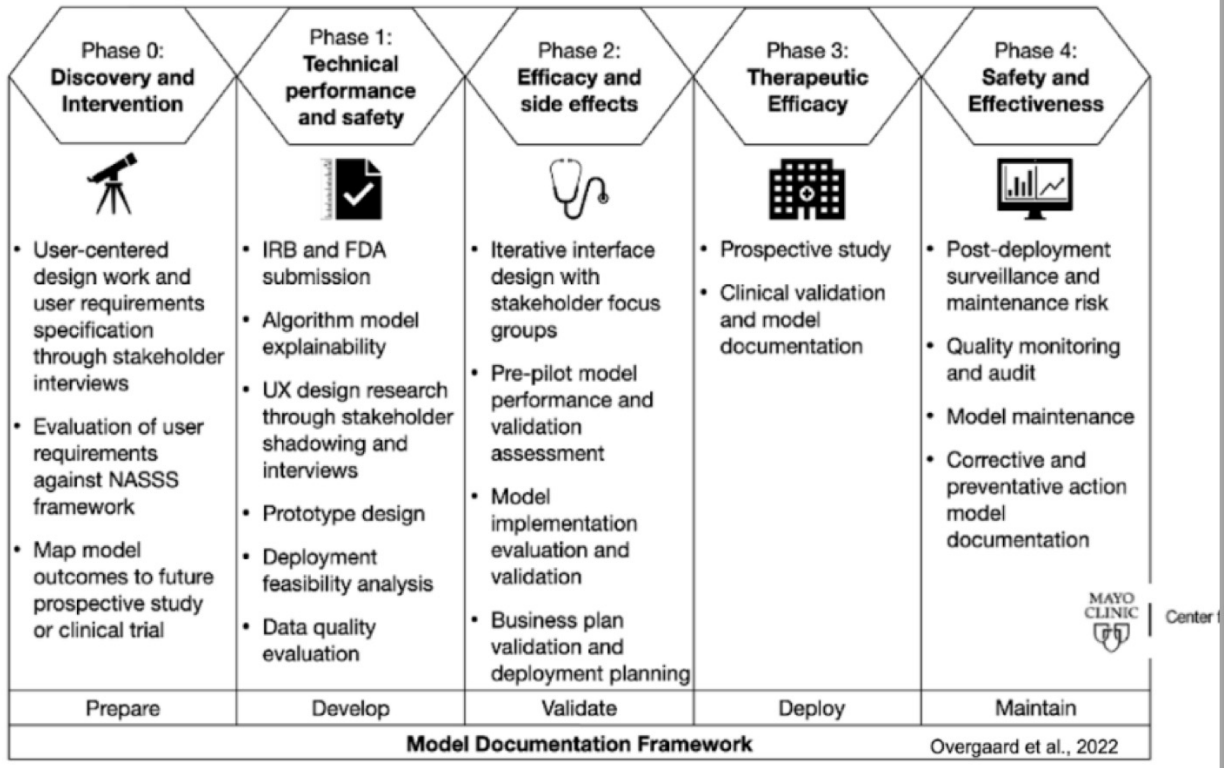
The Artificial Intelligence Code of Conduct (AICC) project is a pivotal initiative of the National Academy of Medicine (NAM), aimed at providing a guiding framework to ensure that AI algorithms and their application in health, medical care, and health research perform accurately, safely, reliably, and ethically in the service of better health for all. Stewarded by the NAM Leadership Consortium, the project will yield a pioneering AI Code of Conduct framework reflecting best practices to serve as a starting point of reference for follow-on testing, validation, monitoring, and continuous improvement. This project represents a unique opportunity for national leaders across disciplines to work together to advance trustworthy artificial intelligence in health, medical care, and health research.

Register for Updates

Steering Committee Biographies

Read the Project Announcement

Phased Research Framework and Model Documentation for Evaluation of AI models



Thank you

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