American College of Radiology®

FDA Patient Advisory Committee
Open Public Hearing

Advancing Health Equity In Medical Devices: Artificial Intelligence Applications In Healthcare

September 6, 2023

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No Commercial Conflicts Of Interest

Neither I nor my immediate family have a financial relationship with a commercial organization that may have a direct or indirect interest in the content of this presentation

Other Disclosures

- Chief Medical Officer American College of Radiology Data Science Institute

- Former ACR Board Chair and ACR President

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MEDICAL SPECIALTY SOCIETIES HAVE THE OPPORTUNITY TO BE THE HONEST BROKERS FOR ENSURING SAFE AND EFFECTIVE CARE FOR OUR PATIENTS

REGULATORS

PHYSICIANS

INDUSTRY

Trusted Relationships
Public Private Partnerships

Medical Specialty Societies Have The Opportunity To Be The Honest Brokers For Ensuring Safe And Effective Care For Our Patients

Pursuant to Executive Order 13985 (January 20, 2021) on "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government"

REGULATORS

Equity Action Plan Summary

U.S. Department of Health and Human Services

The mission of the U.S. Department of Health and Human Services (HHS) is to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

Delivering equity through HHS
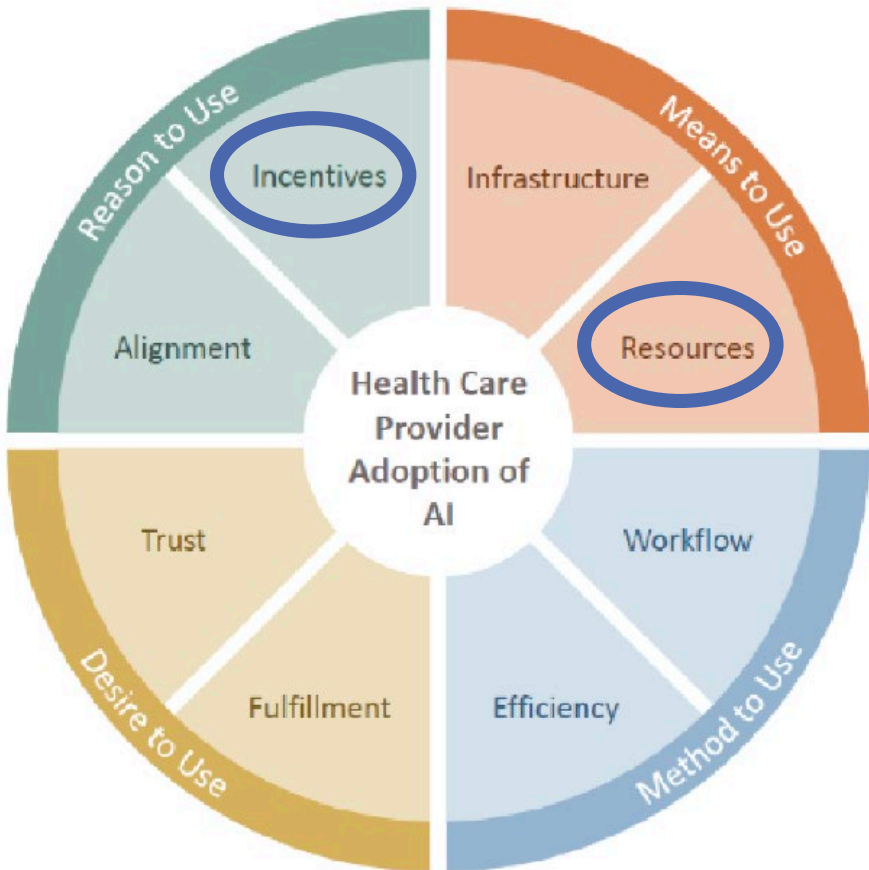
TECHNOLOGY ASSESSMENT

ARTIFICIAL INTELLIGENCE IN HEALTH CARE

Benefits and Challenges of Machine Learning Technologies for Medical Diagnostics

CHALLENGES TO THE WIDESPREAD ADOPTION OF AI

GAO
Jointly published with
NATIONAL ACADEMY of MEDICINE
September 2022

United States Government Accountability Office
Report to Congressional Requesters

TECHNOLOGY ASSESSMENT

Artificial Intelligence in Health Care

NATIONAL ACADEMY OF MEDICINE

"Many health care systems operate on **razor-thin financial margins** (Kaufman Hall & Associates, 2022). Moving forward, **robust insurance reimbursement programs** for the purchase and use of AI-DDS tools will be critical to promoting greater adoption by providers and health systems (Chen et al., 2021)."

How Will We Pay For AI?

IPPS – New Tech

HOPPS – Technical Payments

CMS
SaaS

RESEARCH ARTICLE | ARTICLES IN PRESS

PDF [877 KB]

Current Reimbursement Landscape of AI

George Wu, DO • Colin S. Segovis, MD PhD MRMD (MRSC) • Lauren Nicola, MD •
Melissa M. Chen, MD

Published: August 19, 2023 • DOI: https://doi.org/10.1016/j.jacr.2023.07.018

Fee For Service

MPFS – Physician Payments

MPFS – Technical Payments

Alternate Payment Models

CMS Vision For Reimbursement Of Emerging Technology

HEALTH CARE POLICY AND LAW

VIEWPOINT

A Vision of Medicare Coverage for New and Emerging Technologies—A Consistent Process to Foster Innovation and Promote Value

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Therapeutic advances enable new treatments and cures for disease. The Centers for Medicare & Medicaid Services (CMS) is committed to ensuring access to emerging technologies that benefit Medicare beneficiaries. For individuals covered by Medicare Part A or Part B, Congress has charged CMS with determining whether items and services are reasonable and necessary to diagnose or treat an illness or injury, or "to improve the functioning of a malformed body member."[1] The US Food and Drug Administration (FDA) determines that the item or service (eg, drug, biologic, medical device) is safe and effective for the intended population.

In January 2021, a federal regulation known as "The

dence development for FDA premarket review decisions and the reasonable and necessary coverage criteria of CMS. Early feedback can assist manufacturers in designing pivotal trials and collect evidence that can answer evidentiary questions from both agencies. If there are insufficient data that are relevant to the statutory requirements of CMS, it is difficult for the agency to make a favorable evidence-based decision regarding whether a drug, device, or other medical product meets the legal criteria to be reasonable and necessary. The CMS is also considering releasing a series of "Medicare Evidence Development and Coverage Advisories" that would provide more guidance to manufacturers about

October 12, 2022

CMS Vision For Reimbursement Of Emerging Technology

"One example is the parallel review program, in which both agencies collaboratively engage with manufacturers regarding evidence development for FDA premarket review decisions and the reasonable and necessary coverage criteria of CMS"

- Does the software add value for patients / beneficiaries?
- Will the software be widely generalizable to diverse populations?
- Determining the appropriate reimbursement?

CMS VISION FOR REIMBURSEMENT OF EMERGING TECHNOLOGY PROPOSED RULE 2023 HOPPS

CMS proposes to instead **establish HCPCS codes, specifically, C-codes, to describe the add-on codes as standalone services that would be billed with the associated imaging service**. CMS believes the payment for the proposed C-codes describing the SaaS procedures with add-on CPT codes…

FDA Clearance → C-Code → Payment

- Concern for the large number of individual codes and how the services add value
- ACR and other stakeholders commented that we should establish more general CPT codes based on function of the AI models
- CMS did not finalize this proposal

AI EQUITY: TRANSPARENCY AND REIMBURSEMENT

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office for Civil Rights

FEDERAL REGISTER
The Daily Journal of the United States Government
NATIONAL ARCHIVES

(PR) Proposed Rule

Nondiscrimination in Health Programs and Activities

A Proposed Rule by the Centers for Medicare & Medicaid Services on 08/04/2022

"A covered entity must not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs and activities through the use of clinical algorithms in its decision-making." (§92.210; 87 FR 47824)

"providers **may be held liable under this provision** *for their decisions made in reliance on clinical algorithms."*

ACR COMMENTS:

- SHARING AMONG AGENCIES
- TRANSPARENCY IN TESTING AND TRAINING DATA
- DEMONSTRATE GENERALIZABILITY IN VALIDATION

OPPORTUNITIES:

- IMPROVE TRANSPARENCY FOR END-USERS
- LEVEL PLAYING FIELD FOR AI USE REQUIRES EQUITABLE PAYMENT POLICY TO PREVENT A TWO-TIER SYSTEM

Conclusions

- Lack of reimbursement options for AI applications is limiting adoption of AI
- Many academic and well funded institutions will likely be early adopters even without reimbursement
- Small and rural facilities and institutions in under-resourced areas may not be financially able to adopt leading to two-tier systems which disadvantages those who may benefit the most
- A reimbursement pathway that parallels FDA clearance is a welcomed solution but has challenges both for both payment policy development and the regulatory process

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THANK YOU