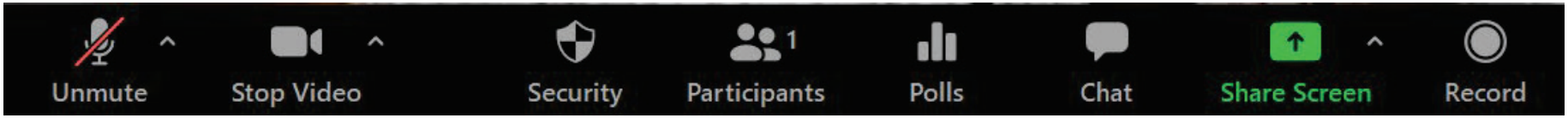
Healthcare AI, Rapidly Evolving Regulatory & Payment Environment: What Every Clinician Should Know

Cybil Roehrenbeck, Partner Hogan Lovells LLC | David Vidal, Vice Chair Center for Digital Health Data & Analytics Mayo Clinic

January 16th, 2023

Zoom Tips



Muted on Entry

You are muted on entry. If you wish to comment or ask a question, you can unmute yourself.

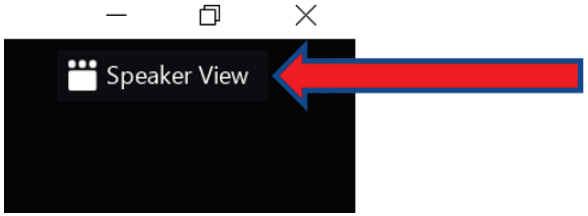
Open the Chat & Q&A

Please open the chat and use it liberally; we want to hear from you!

Send comments and feedback to **"Everyone"**

Session Recording

We are recording today's session to capture LIVE responses. The recording will be made public. By attending you consent to be included



Speaker View vs Gallery View

At the top right of your screen you can change the video panel to just show the main speaker, or to gallery view to see the speaker and other participants, depending on your preference.

Before We Get Started

Today's session is purely for informational purposes.

CTRC does not provide legal advice. CTRC has no relevant financial interest, arrangement, or affiliation with any organizations related to commercial products or services mentioned in this session.

The California Telehealth Resource Center (CTRC) and all resources and activities produced or supported by the CTRC are made possible by grant number U1UTH42520-01-01 from the Office for the Advancement of Telehealth, Health Resources and Services Administration, DHHS. CTRC also appreciates the support of the California Department of Health Care Access and Information's (HCAI) State Office of Rural Health (CalSORH). This information or content and conclusions are those of the CTRC and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS, the U.S. Government, HCAI or CalSORH.

Meet the Presenters

Cybil Roehrenbeck, JD, is a partner with Hogan Lovells where she provides counsel on federal legislative and regulatory opportunities, often focusing on healthcare reimbursement and emerging sectors such as digital health, artificial intelligence (AI), and value-based care. Cybil also serves as Executive Director of the AI Healthcare Coalition, which advocates on behalf of healthcare AI innovators. Cybil serves on the American Bar Association (ABA) Standing Committee on Governmental Affairs, and as Chair of the ABA Health Law and Policy Committee. Cybil is an Adjunct Associate Professor at American University Washington College of Law, where she teaches health law and policy, and a frequent speaker at national health law conferences.

David Vidal, JD, is an attorney and FDA quality/regulatory expert focused on Software as a Medical Device (SaMD). As Vice Chair of SaMD Regulation in Mayo Clinic Center for Digital Health, he is leading the development of enterprise-wide infrastructure to enable safe, effective, and ethical realization of FDA-regulated software. David is also part of the leadership council for the Health AI Partnership, a multi-stakeholder collaborative with the mission to empower healthcare organizations to use AI safely, effectively, and equitably. David previously held the position of General Counsel and Senior VP of Quality Assurance & Regulatory Affairs at IDx Technologies Inc., where he played an instrumental role in the clearance and deployment of IDx-DR, the first autonomous AI diagnostic authorized by the FDA.

Clinician Check List of Questions
Intervention/Digital Modality/Tool

Is it effective?

Is it safe?

Is it covered by health programs and health insurers?

What are the compliance requirements and liability risk?

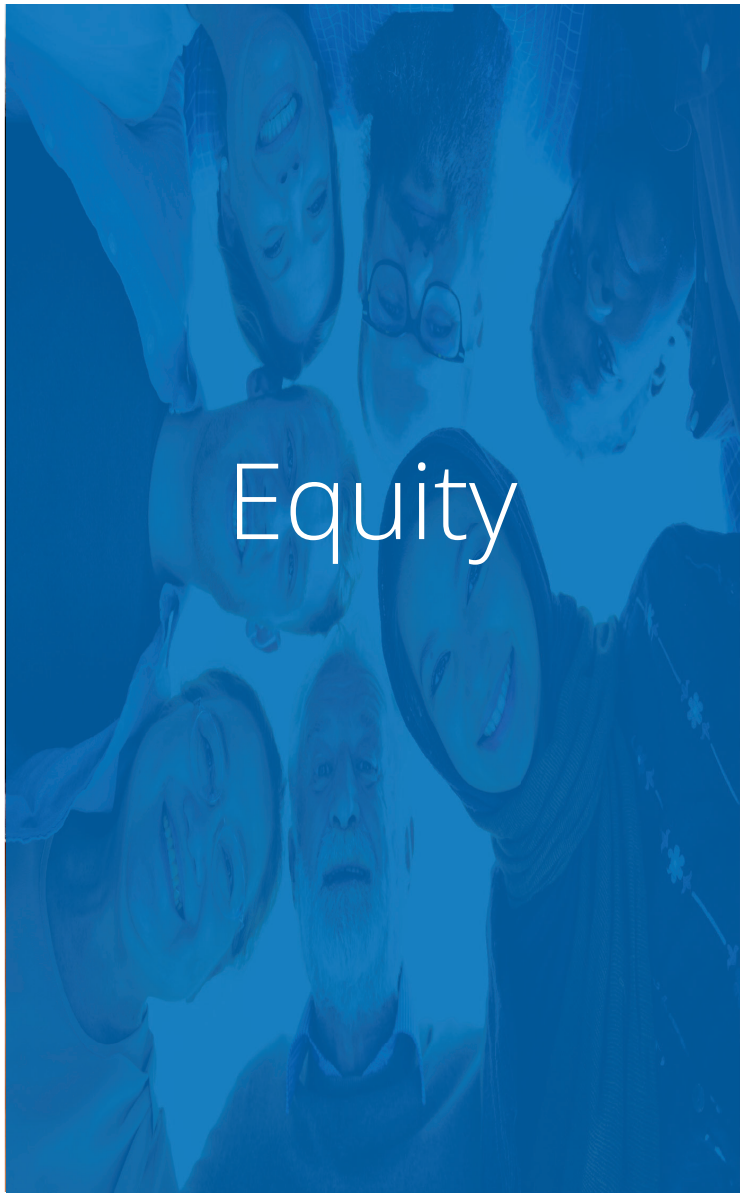
What **infrastructure** is needed to support the digital modality for my practice and patients?

Will it work in my practice as part of workflow, EHR integration, and staffing?

*Derived from 2016 AMA Study of Key Questions Clinicians Ask (and repeated in 2019 and 2022)

Safety

Effectiveness



Sustainability

Scalability

AI-Enabled Digital Health Tools
Existing Regulatory and Payment Ecosystem

CALIFORNIA TELEHEALTH RESOURCE CENTER
Part of OCHIN

Deep Dive Into FDA Regulation

Detail of FDA-Regulated AI Systems Along the Continuum of Regulatory Activities

Broad Overview

Review of Various Levers Federal Agencies are using to Regulate AI-Enabled Digital Health Tools

MAYO CLINIC | School of Continuous Professional Development

California Telehealth Resource Center

EMPOWERING AI USERS

David Vidal, JD
Vice Chair, SaMD Regulation
Mayo Clinic

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIP(S) WITH INELIGIBLE COMPANIES

- Nothing to disclose

REFERENCES TO OFF-LABEL USAGE(S) OF PHARMACEUTICALS OR INSTRUMENTS

- Nothing to disclose

All relevant financial relationships have been mitigated.

THIS IS NOT LEGAL ADVICE

The content of this presentation constitutes the opinion and interpretations of the presenters and should not be misconstrued as legal advice

REVIEW YOUR INSTITUTIONAL POLICIES & LOCAL REGULATIONS/LAWS

REVIEW YOUR IRB/HUMAN SUBJECT PROTECTION REQUIREMENTS

TODAY

Objective: Empower physicians and patients with an understanding of the regulatory obligations on digital health & AI developers in healthcare

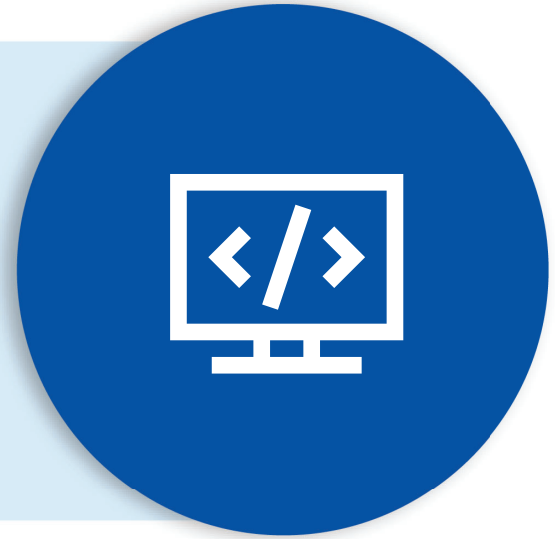
Purpose: In choosing or being subject to a digital technology, know what the developers should be doing so you know what to ask and expect from them.

Software as a Medical Device (SaMD)

SaMD

...software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.

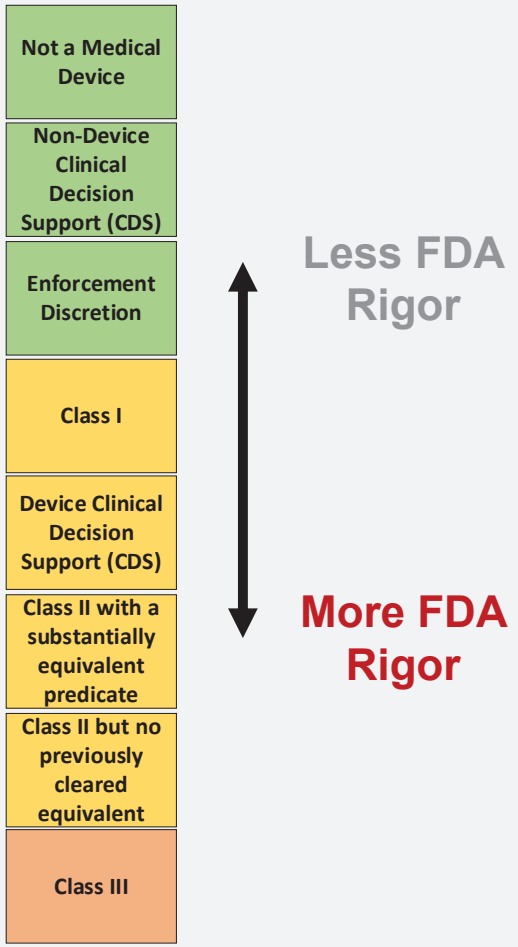
A medical device is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.



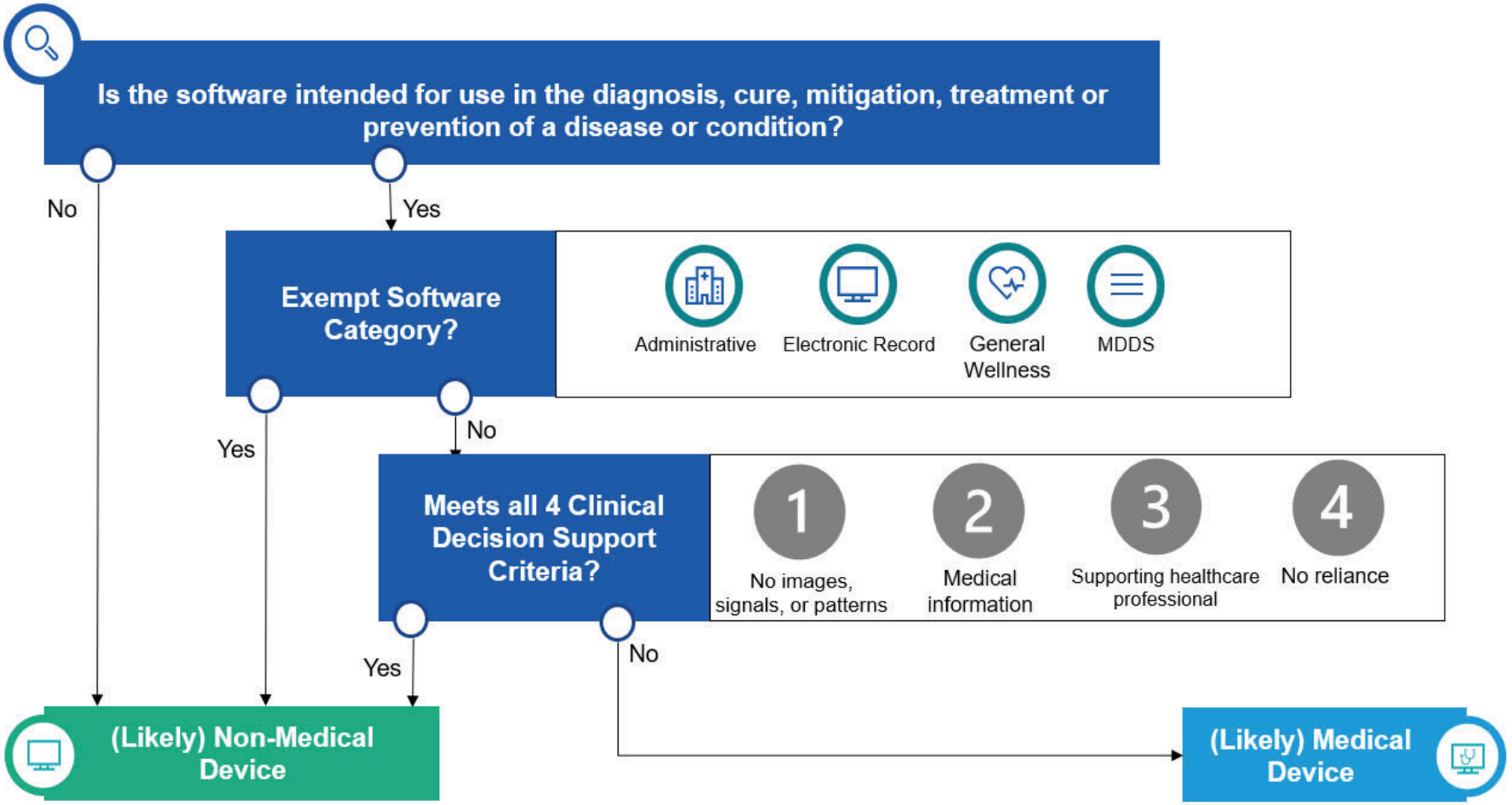
e.g., software that screens for melanoma in an image of a mole, software that detects abnormalities in an EKG, etc...

FDA's Risk-Based Approach

What can I expect from products subject to FDA regulation?



WHEN IS SOFTWARE REGULATED BY THE FDA?



SOFTWARE FUNCTIONALITY & REGULATORY POLICY

Digital Health Technologies (DHTs)

Medical Devices

- Class I
- Class II
- Class III

FDA Regulations, Oversight, and Enforcement Apply

Non-Medical Devices

- Administrative
- Electronic Health Record
- General Wellness
- Medical Device Data Systems
- Clinical Decision Support

FDA Regulations, Oversight, and Enforcement DO NOT Apply

Non-Medical Devices

Administrative	Electronic Health Record	General Wellness	Medical Device Data Systems	Clinical Decision Support

1

Not intended to acquire, process, or analyze a medical image or signal from an in vitro diagnostic or a pattern or signal from an acquisition system

2

Intended for the purpose of displaying, analyzing, or printing medical **information about a patient** or other medical information

3

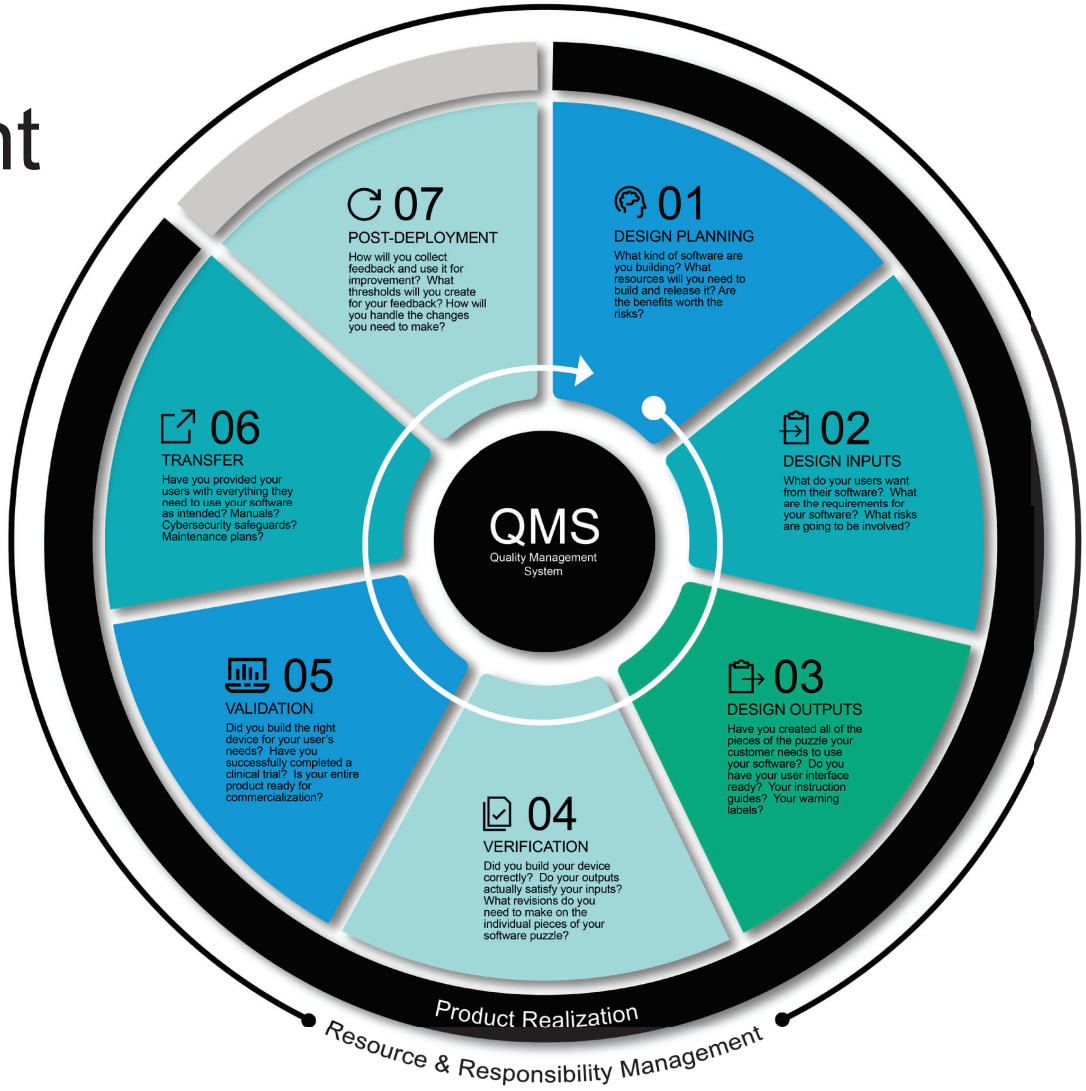
Intended for the purpose of **supporting or providing recommendations** to a health care professional about prevention, diagnosis, or treatment of a disease or condition

4

Intended to enable an HCP to independently review the recommendations so as **not to rely primarily on the recommendations** to make a clinical diagnosis / treatment for an individual patient

Regulated Development

What can I expect from products subject to FDA regulation?



Non-Regulated Digital Health & AI

White House Blueprint

Establishes a framework addressing privacy, transparency, discrimination, and accountability in the development & deployment of AI technologies.

White House Executive Order on AI

Advances the responsible use of AI by promoting federal agency collaboration, prioritizing R&D, and establishing principles for performance, transparency, & accountability.

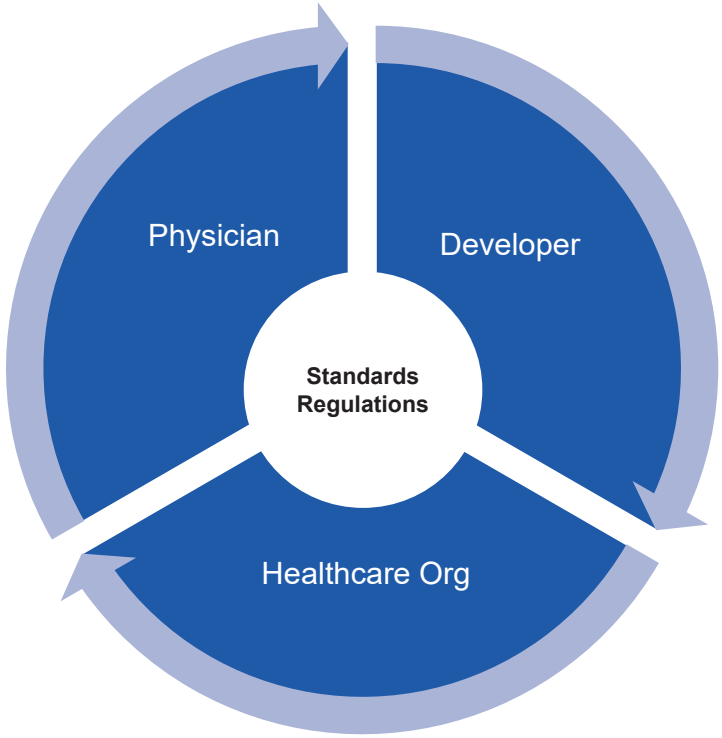
Non-Regulated Digital Health & AI

FTC enforcement to ensure AI claims are substantiated

FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

Distributed Liability/Accountability

What party is best positioned to take accountability for software & AI risk?



Example – responsibility for “transparency”

- FDA final clinical decision support (CDS) guidance criteria 4 – **Manufacturer**
- Office of the National Coordinator (ONC) for Health IT proposed rule transparency – **Health IT Certification**
- Office of Civil Rights (OCR) proposed rule to mitigate bias in clinical algorithms – **Covered Entity**

Example – responsibility for “transparency”

- FDA final clinical decision support (CDS) guidance criteria 4 – **Manufacturer**

In order to qualify as “non-device CDS,” manufacturers must enable healthcare professionals to independently review the basis for the recommendation by including information about model logic, data relied upon, and clinical validation results.

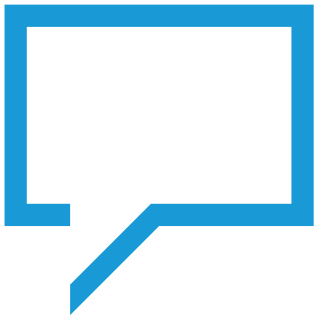
- Office of the National Coordinator (ONC) for Health IT proposed rule transparency – **Health IT Certification**

In order to be certified under the proposed rule, Health IT would need to provide users information about training data, intended use, performance, and maintenance to determine quality and whether to use.

- Office of Civil Rights (OCR) proposed rule to mitigate bias in clinical algorithms – **Covered Entity**

Under the proposed rule, covered entities are liability for decisions made in reliance on AI, even if they did not design the algorithm or have knowledge of how it works.

QUESTIONS & DISCUSSION



Health Care AI Rapidly Evolving Regulatory and Payment Environment

What Every Clinician Should Know

Cybil Roehrenbeck, JD
Executive Director, AI Healthcare Coalition
Partner, Hogan Lovells LLP

January 16, 2024

New AI Rules for Certified HIT

What is the new ONC AI rule for certified HIT?

- Last month the HHS Office of the National Coordinator (ONC) released its final rule on *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing*.
- The HTI-1 final rule updated functionality, configuration, and transparency requirements for the decision support intervention (DSI) criterion and clarified that health IT developers are responsible for only the Predictive DSIs that they supply as part of their certified health IT.
- Among other requirements, health IT developers will need to comply with certain ongoing maintenance requirements to keep their DSI "source attribute" information complete and up to date as well as implement risk management practices for Predictive DSIs they supply to address risk analysis, risk mitigation, and governance.

New AI Rules for Certified HIT

What is the scope of the ONC HIT rule? Do I have to report?

- ONC changed "enabled or interfaced with" in the proposed rule to "supplied by" in the final rule to reflect its intent to "only apply additional Predictive DSI related stewardship responsibilities to health IT developers who supply Predictive DSIs as part of their Health IT Module" and narrow the focus of these requirements, reducing the overall scope of technologies subject to these specific requirements.
- According to the HTI-1 Preamble, ONC interprets "supplied by" to include "interventions authored or developed by the health IT developer as well as interventions authored or developed by another party that the health IT developer includes as part of its Health IT Module, such as stated in the comments, 'when entities have contracts specifically covering the enablement and use of such technologies.'"
- (Note: another party means any party that develops a DSI, a model, or an algorithm that is used by a DSI and is not the developer of certified health IT or a subsidiary of the developer of certified health IT.)

New AI Rules for Certified HIT

I have an FDA-authorized AI system – is it exempt from ONC's new DSI rule?

- No. ONC declined to exclude FDA-regulated SaMD from the definition of "predictive DSI"—and associated disclosure and reporting requirements for Certified HIT developers.
- Specifically, ONC noted in the final rule preamble:
  - *Comment. Several commenters expressed concern about consistency, duplication, and redundant requirements across various federal programs. Commenters recommended that ONC tailor the scope of the proposed term Predictive DSI, and the proposed definition at § 170.102, to exclude FDA-authorized AI and machine learning medical devices to mitigate their concerns mentioned above….*
  - *Response. …We appreciate the suggestions to exclude from our definition for Predictive DSI software that are regulated medical devices and to exclude third-party software that qualify as non-device software functions per the statutory exemption for CDS software. However, we decline to include any exclusionary criteria in our definition for Predictive DSI…*

AI in Certified HIT

How can I learn more about the new requirements?

- Key Dates:
  - By **December 31, 2024**:
    - Health IT developers will need to update health IT currently certified to the CDS criterion to meet the DSI criterion's requirements and provide the updated certified health IT to customers by December 31, 2024.
  - Starting **January 1, 2025**:
    - Developers with health IT certified to the DSI criterion must comply with the associated maintenance of certification requirement
    - The DSI criterion will become the criterion required for health care providers to have health IT that continues to meet the Base EHR definition and thus be in a position to have "Certified EHR Technology" for the purposes of certain CMS programs (for example, MIPS reporting compliance).
- ONC is holding an informational session on Wednesday, January 17 at 1 pm ET on the "Decision Support Intervention" component of the final rule. You may register here: https://kauffmaninc.zoom.us/webinar/register/WN_ewsPYfXQTy262r3R2xUv_w#/registration

AI Payment & Coverage

Do payers cover and reimburse for health AI systems?

- In some instances, Medicare reimburses and pays for AI applications as medical services.
- Payment structure and rates vary by care setting:
  - Inpatient hospital services
    - New Technology Add-on Payment (NTAP) pathway
    - As part of a Diagnosis-Related Group (DRG)
  - Outpatient hospital services
    - New Technology Ambulatory Payment Classification (New Tech APC) pathway
    - Clinical APC
  - Physician office / clinic
    - Medicare Physician Fee Schedule fee-for-service payment

AI Payment – Inpatient Setting

- In the inpatient hospital setting, the Centers for Medicare & Medicaid Services (CMS) has developed a New Technology Add on Payment (NTAP) pathway to reimburse for AI medical services.
- To be eligible for an NTAP payment:
  - the medical service or technology must be new;
  - the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; *and*
  - the service or technology must demonstrate a substantial clinical improvement over existing services or technologies.

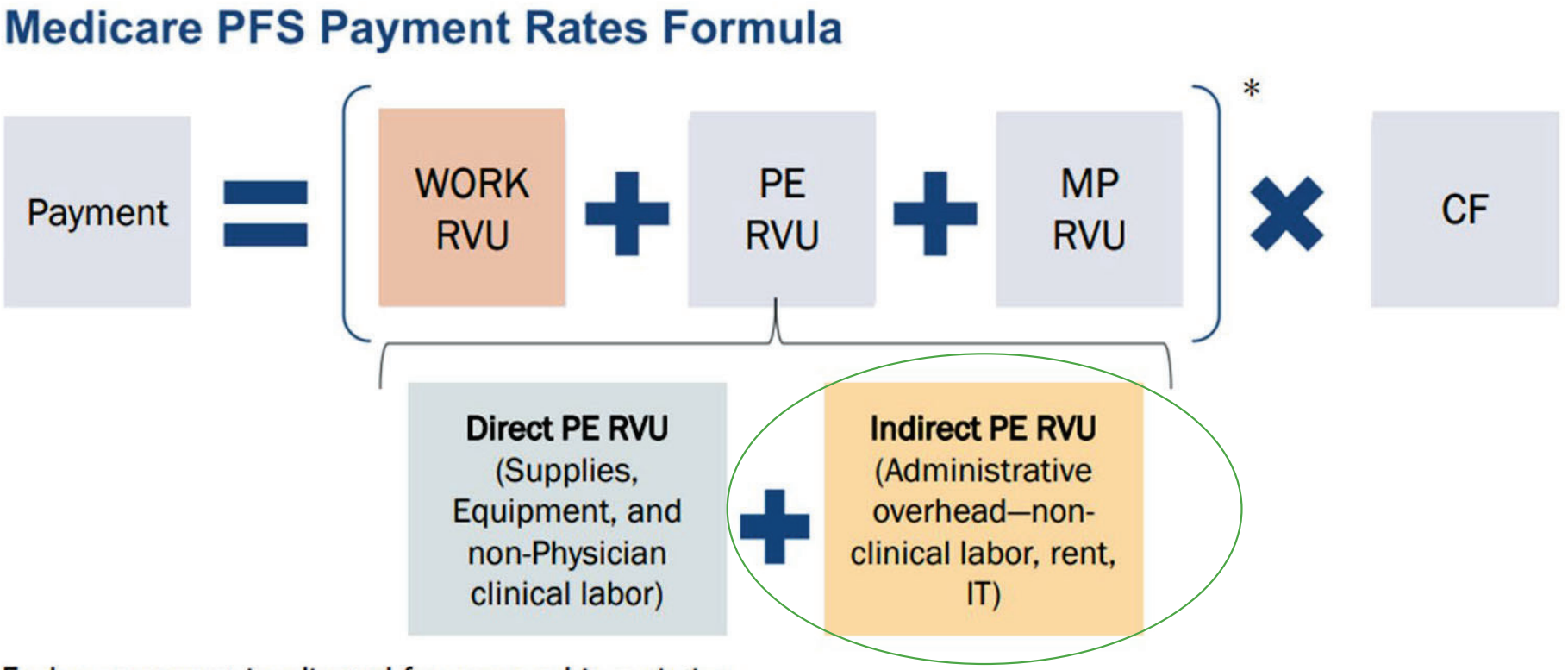
AI Payment – Inpatient Setting

- Since FY 2021, a medical device designated under FDA's Breakthrough Devices Program that has received marketing authorization as a Breakthrough Device, for the indication covered by the Breakthrough Device designation, may qualify for the NTAP under an alternative pathway.
- Under the alternative pathway:
  - a technology will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS and
  - will not need to meet the requirement that it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- These technologies must still be within the 2- to-3-year newness period to be considered ‘‘new,’’ and must also still meet the cost criterion.

AI Payment – Outpatient Setting

- Some new technologies result in the creation of a new procedure that has a distinct beginning, middle, and end, and which is not described by a current procedure code.
- For these new procedures, manufacturers can request assignment of the procedure to a New Technology APC.
- Unlike clinical APCs, where procedures are grouped based on cost and clinical similarity, New Technology APCs are based solely on cost bands.
- Thus, a new service can be assigned to a New Technology APC based on reported costs of the procedure and without regard to whether it is clinically similar to other procedures assigned to that APC.
- Benefits:
  - Tends to result in payment, at least for a limited time, that is closer to the actual costs of the service than if the service were to be assigned to a clinical APC.
  - Can result in CMS creating a code for the procedure sooner than a code could be created through the CPT application process.

AI Payment – Physician Office or Clinic Setting



* Each component is adjusted for geographic variation

Graphic adapted from Medicare Learning Network Booklet, MLN901344, March 2021

AI Payment: Value & Quality Considerations

- MIPS / QPP / Advanced Alternative Payment Model Measures
  - The Medicare Access & CHIP Act (MACRA) created pathways for value-based care incentive payments, namely:
    - the Merit-Based Incentive Payment System (MIPS) (+/-9 percent of Part B revenue)
    - Advanced Alternative Payment Models (AAPMs) (+3.5 percent of Part B revenue)
  - CMS staff oversees
  - Part B providers and ACOs
- HEDIS measurement
  - The Healthcare Effectiveness Data and Information Set (HEDIS) is a tool used by more than 90 percent of U.S. health plans to measure performance on dimensions of care and service.
  - More than 190 million people are enrolled in health plans that report quality results using HEDIS.
  - Administered by the National Committee on Quality Assurance (NCQA).

Example: MIPS & HEDIS Measurement of CPT 92229

CPT 92229:

"Imaging of retina for detection or monitoring of disease; point of care autonomous analysis and report, unilateral or bilateral"

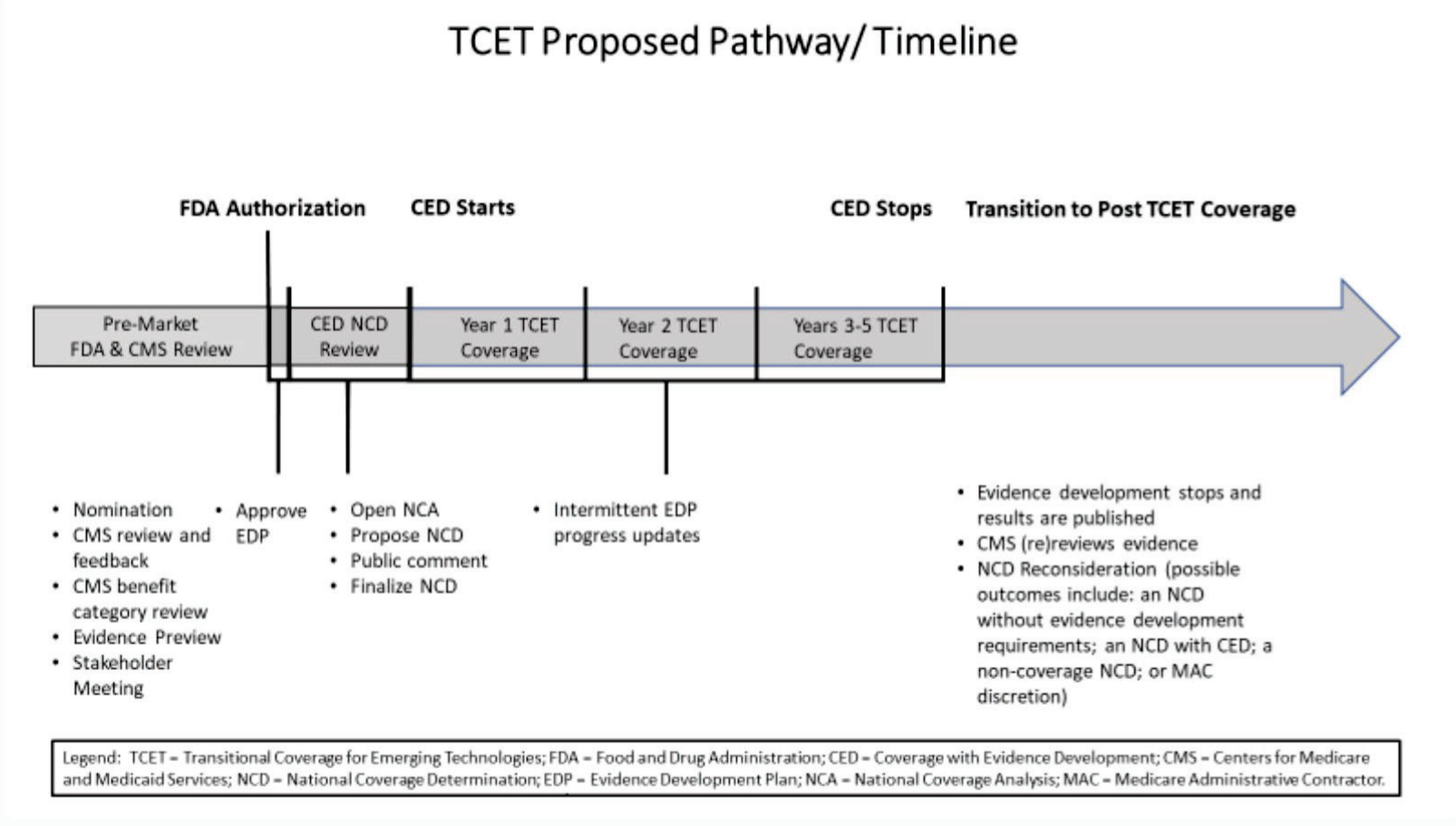
D.14 Diabetes: Eye Exam

Category	Description
CBE # / eCQM CBE #:	0055 / N/A
Quality #:	117
CMS eCQM ID:	CMS131v12
Current Collection Type:	eCQM Specifications | MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy in any part of the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.
Substantive Change:	**Updated denominator exclusion: For the** MIPS CQMs Specifications collection type**: Added:** Dementia combinations: Donepezil-memantine **to** list of dementia exclusion medications. **Updated numerator note: For the MIPS CQMs Specifications collection type: Added:** reporting of CPT 92229 meets the intent of the quality action for performance met.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the denominator exclusion for the MIPS CQMs Specifications collection type to include Donepezil-memantine in the list of dementia medication list, as this is an applicable medication for the purposes of the denominator exclusion. This medication is used for patients with dementia and therefore aligns with intent of the measure to exclude patients with this condition from the measure. Additionally for the MIPS CQMs Specifications collection type, we proposed to update the numerator note to indicate that denominator eligible patients who receive services under CPT code 92229 will meet the intent of the measure and should be included in the appropriate performance met numerator option, based on retinopathy findings.
Comment: A couple of commenters indicated that clinicians who participate in MIPS have been required to make manual updates to EHR systems to document measure performance, which could prevent access to this vision saving technology for people with diabetes. An update to the CQMs file to include CPT 92229 will ensure consistency with the CY 2022 PFS and the technical specifications published by the measure steward for the Diabetes: Eye Exam measure (NCQA, HEDIS MY 2023 Vol 2 Value Set). The commenters supported the substantive change proposed to measure Q117: Diabetes: Eye Exam to add the following numerator note: "For the MIPS CQMs Specifications collection type: reporting of CPT 92229 meets the intent of the quality action for performance met." Another commenter also supported the update to include CPT 92229 and CMS' support in including the use of artificial intelligence in this measure. *Response:* The inclusion of CPT 92229 within the denominator of the measure will bias the measure analytic and prevent it from performing as intended since the code is a direct correlation to numerator compliance. However, after discussion with the measure steward, NCQA, we have provided clarification within the numerator of the measure that allows clinicians to achieve numerator compliance if this code is documented within the medical record. After consideration of public comments, and for the reasons stated above and in the proposed rule (88 FR 53094), we are finalizing the changes to measure Q117 as proposed for the CY 2024 performance period/2026 MIPS payment year and future years.	

Example: MIPS & HEDIS Measurement of CPT 92229

Diabetes		
Measure	**Best Practice**	**Codes**
Hemoglobin A1c Control for Patients With DM (HBD) (Age 18-75)	Last Hemoglobin A1c in MY Compliant HbA1c control= Less than 8.0%	3044F: <7.0 3051F: 7-7.9 3052F: 8-9 3046F: >9
Eye Exam for Patients with DM (EED) (Age 18-75)	Dilated Retinal Eye Exam (DRE) – Yearly	Negative Screen: 2023F, 2025F, Positive Screen: 2022F, 2024F Negative Screen Prior Year: 3072F Automated Eye Exam: 92229. S0620, S0621, S3000 Diabetic Retinal Screening S0620, S0621, S3000
Kidney Health Evaluation for Patients With DM (KED) (Age 18-85)	Estimated glomerular filtration rate (eGFR) AND a urine albumin-creatinine ratio (uACR) yearly	eGFR: 80047, 80048, 80050, 80053, 80069, 82565 Urine Quantitative Albumin Test: 82043 Urine Creatinine Test: 82570
Blood Pressure Control for Patients With DM (BPD) (Age 18-75)	Most recent BP in MY Compliant BP=Less than 140/90	3074F: SBP <130, 3075F: SBP 130-139 3077F: SBP equal to or > 140 3078F: DBP <80, 3079F: DBP 80-89 3080F: DBP equal to or > 90

AI Coverage – TCET Pathway



AI Coding – CPT Taxonomy for AI Services

Appendix S

Artificial Intelligence Taxonomy for Medical Services and Procedures

This taxonomy provides guidance for classifying various artificial intelligence (AI) applications (eg, expert systems, machine learning, algorithm-based services) for medical services and procedures into one of these three categories: assistive, augmentative, and autonomous. AI as applied to health care may differ from AI in other public and private sectors (eg, banking, energy, transportation). Note that there is no single product, procedure, or service for which the term "AI" is sufficient or necessary to describe its intended clinical use or utility; therefore, the term "AI" is not defined in the code set. In addition, the term "AI" is not intended to encompass or constrain the full scope of innovations that are characterized as "work done by machines." Classification of AI medical services and procedures as assistive, augmentative, and autonomous is based on the clinical procedure or service provided to the patient and the work performed by the machine on behalf of the physician or other qualified health care professional (QHP).

Assistive: The work performed by the machine for the physician or other QHP is assistive when the machine **detects** clinically relevant data without analysis or generated conclusions. Requires physician or other QHP interpretation and report.

►***Augmentative:*** The work performed by the machine for the physician or other QHP is augmentative when the machine **analyzes** and/or **quantifies** data to yield clinically meaningful output. Requires physician or other QHP interpretation and report.

Autonomous: The work performed by the machine for the physician or other QHP is autonomous when the machine automatically **interprets** data and independently generates clinically meaningful conclusions without concurrent physician or other QHP involvement. Autonomous medical services and procedures include interrogating and analyzing data. The work of the algorithm may or may not include acquisition, preparation, and/or transmission of data. The clinically meaningful conclusion may be a characterization of data (eg, likelihood of pathophysiology) to be used to establish a diagnosis or to implement a therapeutic intervention. There are three levels of autonomous AI medical services and procedures with varying physician or other QHP professional involvement:

Level I. The autonomous AI draws conclusions and offers diagnosis and/or management options, which are contestable and require physician or other QHP action to implement.

Level II. The autonomous AI draws conclusions and initiates diagnosis and/or management options with alert/opportunity for override, which may require physician or other QHP action to implement.

Level III. The autonomous AI draws conclusions and initiates management, which requires physician or other QHP initiative to contest.◄

AI Coding – CPT Taxonomy for AI Services

►Service Components	AI Category: Assistive	AI Category: Augmentative	AI Category: Autonomous
Primary objective	Detects clinically relevant data	Analyzes and/or quantifies data to yield clinically meaningful output	Interprets data and independently generates clinically meaningful conclusions
Provides independent diagnosis and/or management decision	No	No	Yes
Analyzes data	No	Yes	Yes
Requires physician or other QHP interpretation and report	Yes	Yes	No
Examples in CPT code set	Algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (0764T, 0765T)	Noninvasive estimate of coronary fractional flow reserve (FFR) (75580)	Retinal imaging (92229)◄

Cybil Roehrenbeck, JD
Executive Director, AI Healthcare Coalition
Partner, Hogan Lovells LLP
202-701-4261
cybil.roehrenbeck@ai-coalition.org
www.ai-coalition.org

If you missed the inaugural presentation by Michael Abramoff, MD, PhD, watch it on demand here: https://www.youtube.com/@CaliforniaTRC

CTRC Presents:

DIGITAL HEALTH

IN-PERSON WORKSHOPS

SACRAMENTO, CA
JANUARY 25, 2024

FRESNO, CA
MARCH 21, 2024

LOS ANGELES CA,
DATE - TBD

FREE & IN-PERSON

Thank **You**

CALIFORNIA TELEHEALTH RESOURCE CENTER

Part of OCHIN

www.caltrc.org