Coalition for Health AI

CHAI is setting the best practice frameworks for AI safety and reliability in Health

CHAI, the Coalition for Health AI, is committed to setting the best practice frameworks for the trustworthy and responsible implementation of AI in health.

By bringing together a coalition of patient-community advocates, technology companies start-ups, public sector organizations, medical device manufacturers, payors and healthcare organizations, we will develop a consensus set of frameworks for Responsible Health AI.

CHAI

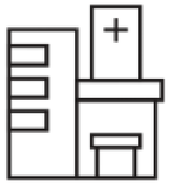
CHAI is bringing together a diverse community of creators, users and beneficiaries to develop consensus-driven products

2500+ members of CHAI

Creators of AI

Health Systems
Medical Device manufacturers
Pharmaceutical Companies
Software Creators for health
Hardware Creators for health
& more

+



Users of AI

Health Systems
Life Science
Companies
Physicians
Payors
CMS

+

Patient Consumers of AI

Patient Advocacy Groups

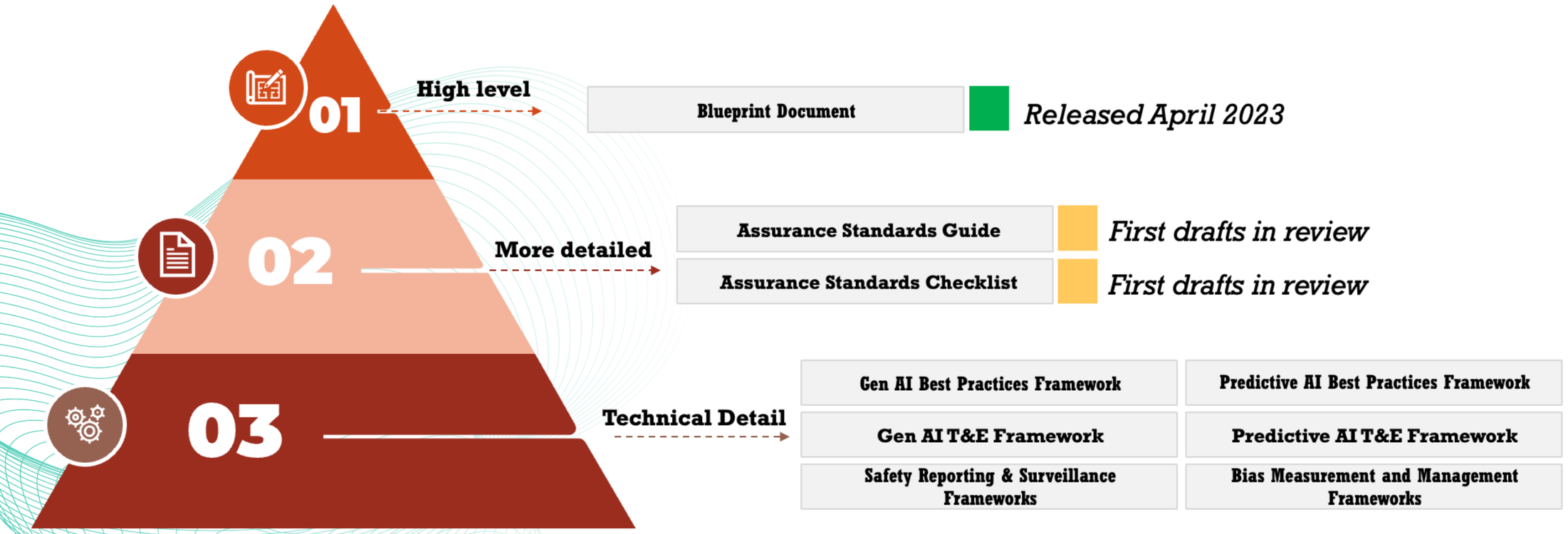
CHAI

We are using consensus to develop the gold-standard for trustworthy and Responsible Health AI that serves all

Need	CHAI's Proposed Solution
1 Adherence to **FAVES principles**	The development of **Technical Standards**, including Bias, Safety and Surveillance frameworks, and **Implementation Guides**, including Testing and Evaluation and Best Practices frameworks 1
2 Current regulation **does not apply** to all Health AI	A **nationwide network of CHAI-certified Quality Assurance Labs**, responsible for assuring all AI for use in health, with supportive Assurance Standards 2
3 Lack of **transparency**	A **National Registry Platform**, featuring model report cards, for algorithms that have been through Assurance Labs 3
4 **Workforce upskilling and engagement**	Registry publications, **educational materials** and Assurance certification processes 4

CHAI

Alongside Assurance Lab certification and development of the registry, we are also focusing on developing frameworks



THE AI LIFECYCLE

The AI lifecycle is central to understanding and implementing CHAI's Assurance Standards in healthcare. The six-step lifecycle outlines the essential stages and processes involved in developing, deploying, and maintaining AI systems.

By systematically addressing each phase of the lifecycle the framework ensures that AI systems adhere to the highest standards of safety, efficacy, fairness, transparency, and security. This structured approach supports risk mitigation, managing biases, and promotes accountability and trustworthiness in AI applications.

CHAI

1

- Engage stakeholders to define the problem & perform root-cause analysis
- Identify solution & plan future state
- Gather business requirements
- Assess feasibility, potential for impact, & prioritization
- Make procure/build/ partner decision

2

- Select/understand model task & architecture
- Capture design & technical requirements or determine best solution to meet business requirements
- Design solution application & system workflow according to human-centered design principles
- Design deployment strategy with end users
- Design risk management, monitoring & reporting plan

3

- Access data
- Prepare data
- Develop data management plan
- Train & tune model

4

- Conduct installation qualification (when applicable)
- Validate local system performance (when applicable)
- Execute prospective, silent evaluation
- Establish risk management plan
- Train end users
- Test usefulness
- Ensure compliance with applicable healthcare regulations & standards

5

- Implement small-scale pilot to assess real-world impact
- Execute and update risk management plan
- Educate & train users on AI application reporting

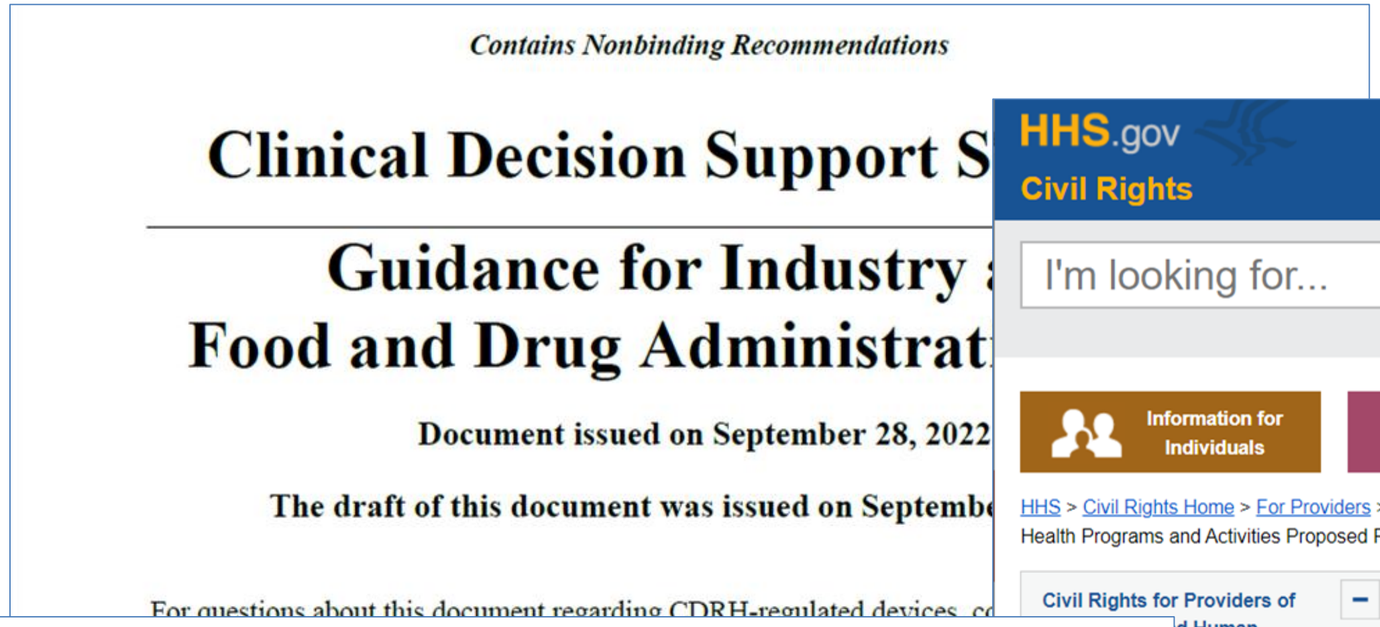
6

- Deploy at a larger scale on a general population
- Audit AI system to inform whether to maintain, refine or sunset
- Conduct ongoing risk management

CHAI is supporting the development of a nationwide network of Assurance Labs with its certification framework

A Federated Network of Labs - All Models are Local

Regulatory Landscape Changing Rapidly



Contains Nonbinding Recommendations

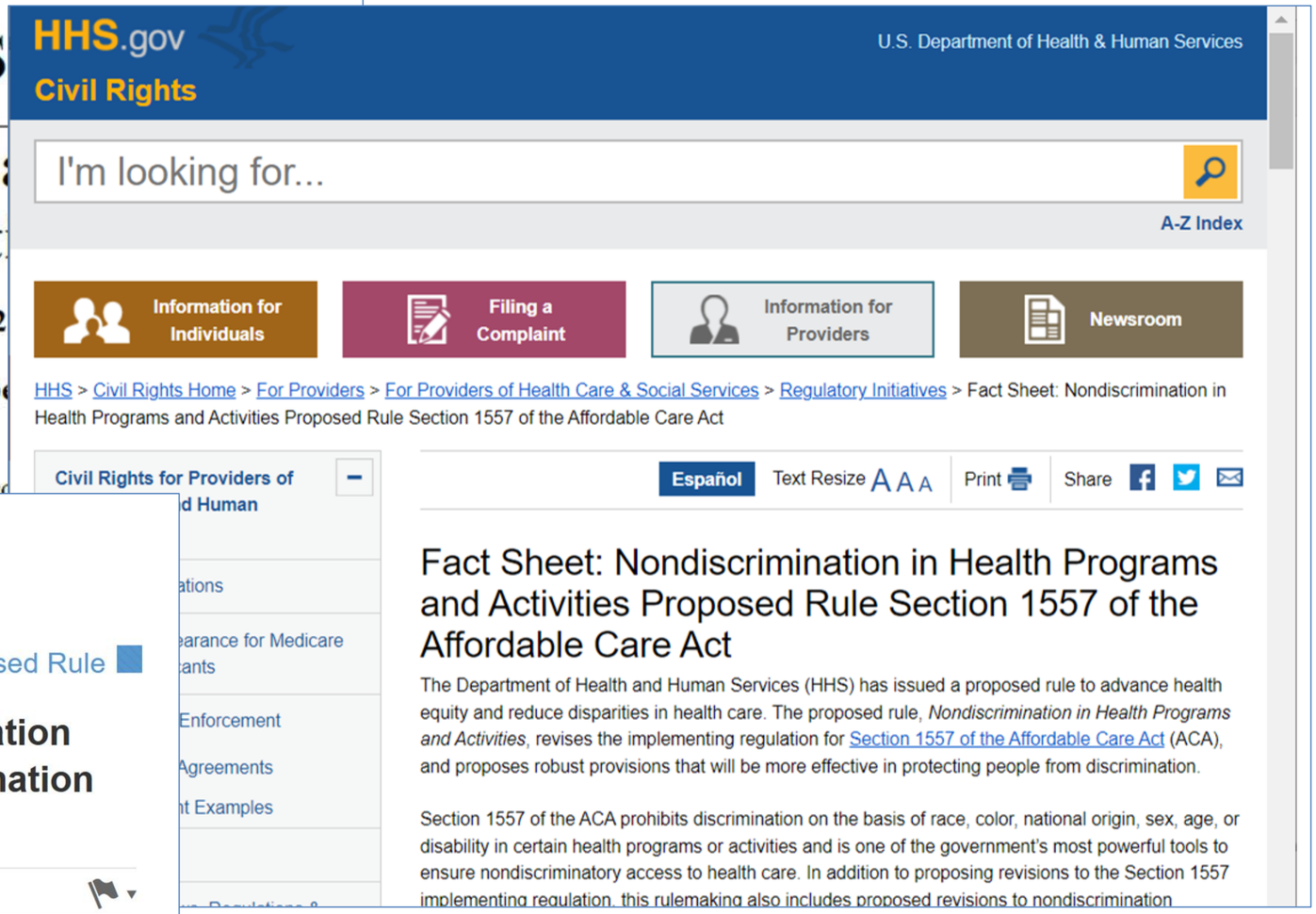
Clinical Decision Support S

Guidance for Industry
Food and Drug Administrat

Document issued on September 28, 2022

The draft of this document was issued on Septembe

For questions about this document regarding CDRH-regulated devices, co



HHS.gov
Civil Rights

U.S. Department of Health & Human Services

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Information for Individuals | Filing a Complaint | Information for Providers | Newsroom

HHS > Civil Rights Home > For Providers > For Providers of Health Care & Social Services > Regulatory Initiatives > Fact Sheet: Nondiscrimination in Health Programs and Activities Proposed Rule Section 1557 of the Affordable Care Act

Civil Rights for Providers of
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Fact Sheet: Nondiscrimination in Health Programs and Activities Proposed Rule Section 1557 of the Affordable Care Act

The Department of Health and Human Services (HHS) has issued a proposed rule to advance health equity and reduce disparities in health care. The proposed rule, *Nondiscrimination in Health Programs and Activities*, revises the implementing regulation for Section 1557 of the Affordable Care Act (ACA), and proposes robust provisions that will be more effective in protecting people from discrimination.

Section 1557 of the ACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs or activities and is one of the government's most powerful tools to ensure nondiscriminatory access to health care. In addition to proposing revisions to the Section 1557 implementing regulation, this rulemaking also includes proposed revisions to nondiscrimination

NATIONAL ARCHIVES

FEDERAL REGISTER

The Daily Journal of the United States Government

PR Proposed Rule

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

A Proposed Rule by the Health and Human Services Department on 04/18/2023

Model Cards

Model Card - Title

Model Details
- Developers
- Model Date, Version & Type
- Training algorithms
- Resources, Citation, License

Evaluation Data
- Details on data used for quantitative analysis
- Datasets, Motivation, Preprocessing

Training Data
- Same detail as evaluation data if possible (privacy constraints)
- Details of distribution over factors

Intended Use
- Primary intended uses & users
- Out of scope use cases

Quantitative Analysis
Unitary & intersectional results

Factors
- Groups, Environments, Instrumentation
- Relevant factors & evaluation factors

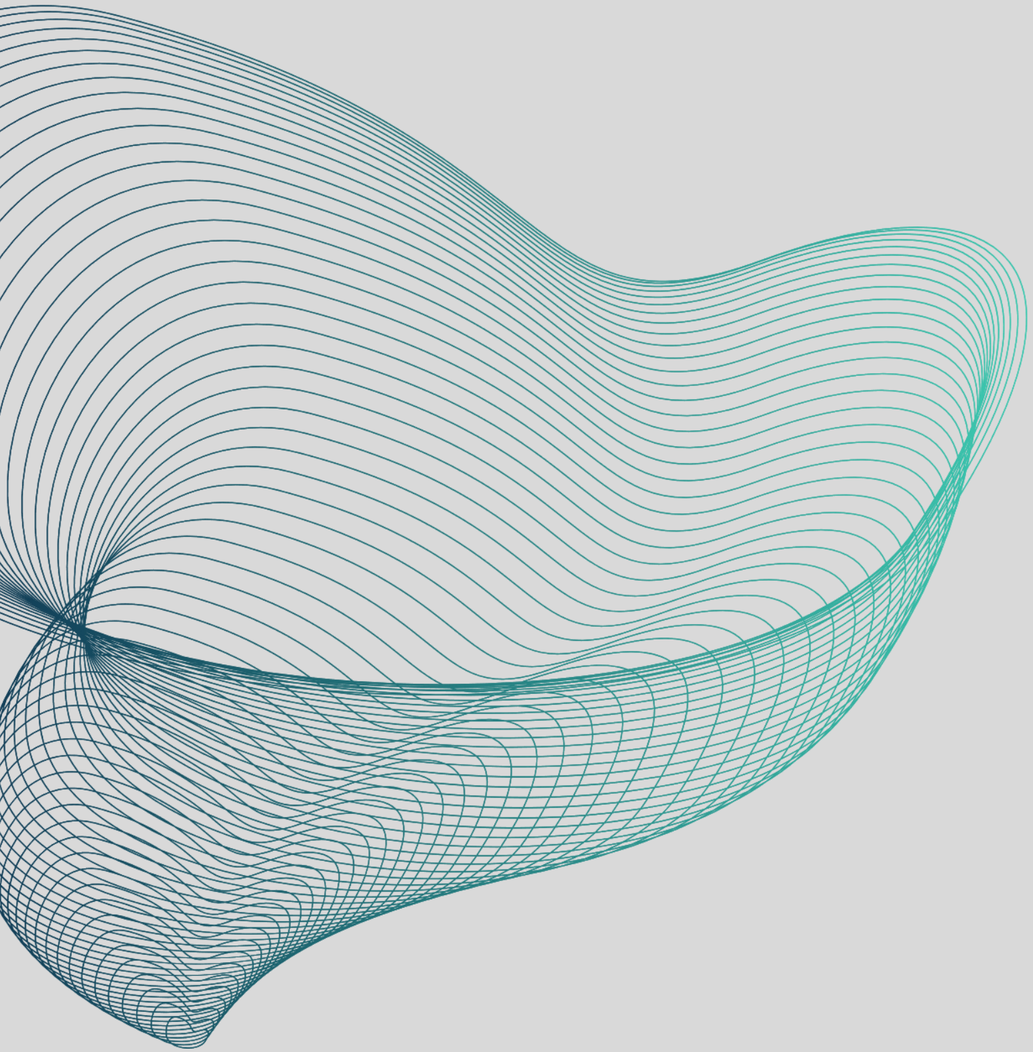
Metrics
- Model performance measures
- Decision thresholds
- Variation approaches

Ethical Considerations
- Bias, fairness, ethical considerations
- Mitigation efforts

Caveats, Recommendations
- Concerns not already covered
- Usage information
- Limitations, risks, trade-offs

An Urgent Need to Develop Consensus Guidelines for GenAI

The Road Ahead



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www.chai.org