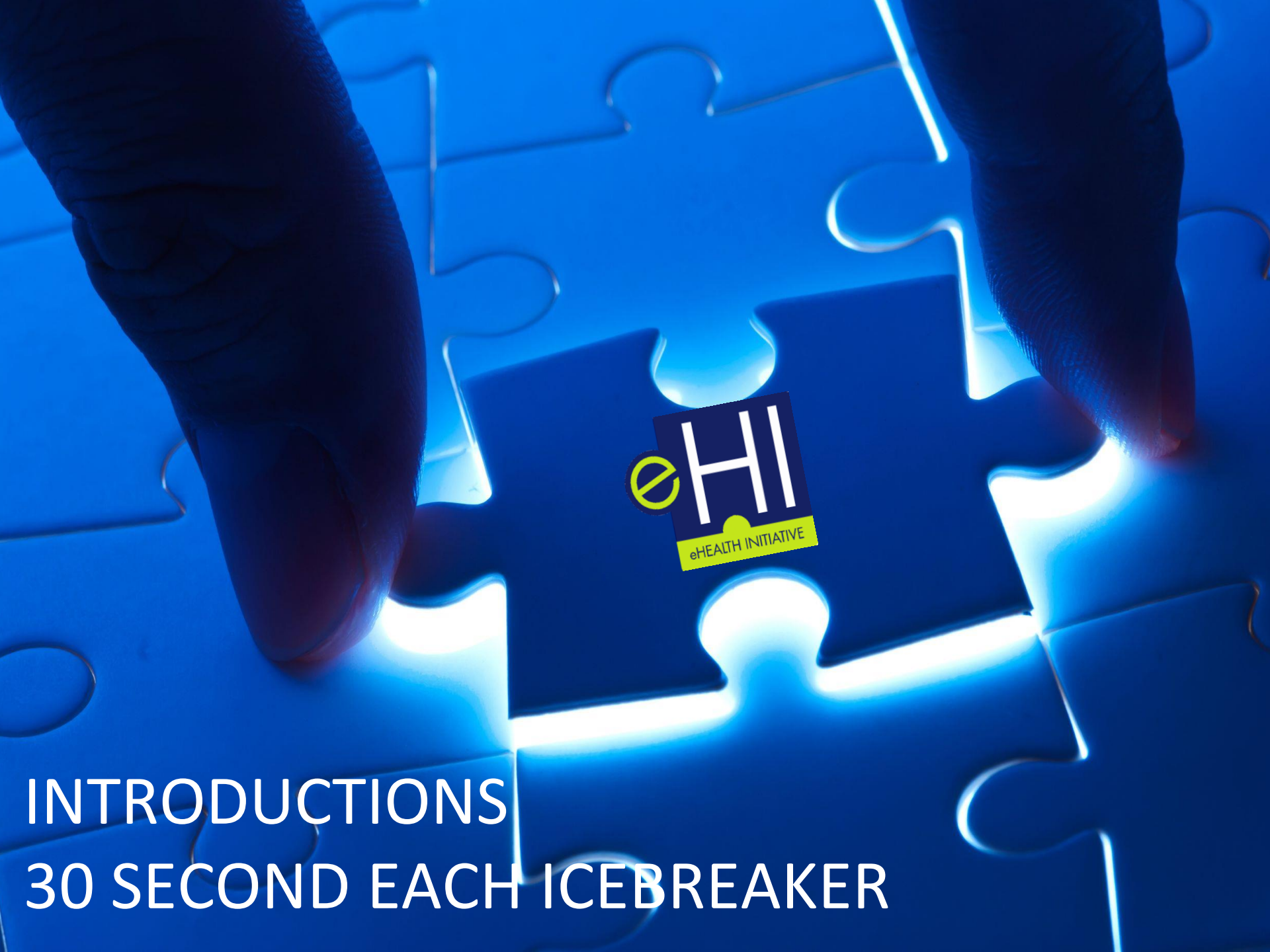
Framing Our Work in 2019

PRIVACY



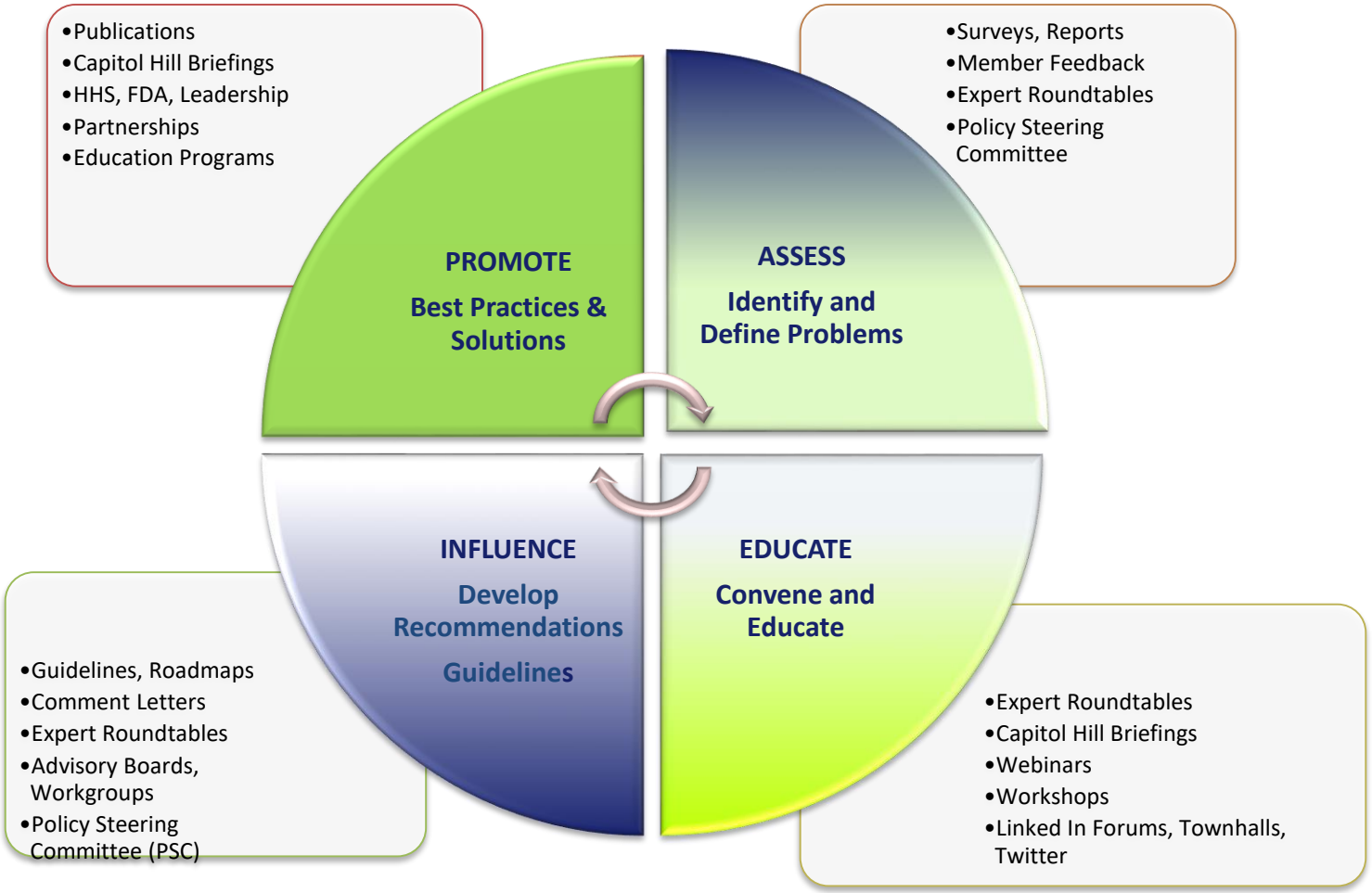
INTRODUCTIONS
30 SECOND EACH ICEBREAKER

Panelists

- **Robert D. Belfort**, Partner, Manatt Health

- **Steve Kastin, MD**, Senior Executive Advisor and Chief Medical Information Officer (CMIO), Booz Allen Hamilton

Our Work


•Publications
•Capitol Hill Briefings
•HHS, FDA, Leadership
•Partnerships
•Education Programs
PROMOTE
Best Practices & Solutions
•Surveys, Reports
•Member Feedback
•Expert Roundtables
•Policy Steering Committee
ASSESS
Identify and Define Problems
INFLUENCE
Develop Recommendations
Guidelines
•Guidelines, Roadmaps
•Comment Letters
•Expert Roundtables
•Advisory Boards, Workgroups
•Policy Steering Committee (PSC)
EDUCATE
Convene and Educate
•Expert Roundtables
•Capitol Hill Briefings
•Webinars
•Workshops
•Linked In Forums, Townhalls, Twitter

Current Areas of Focus

(**Green** Addressed at Roundtables Today)

Value Based Care

- Cost Transparency
- Prior Authorization

Interoperability

- Understanding FHIR/ APIs/DaVinci
- Policy Issues/Burden, Workflow, Info Blocking

Privacy/Security

- Protection Vs Access
- HIPAA Part 2
- Cybersecurity Med Devices

Analytics/SDOH

- Non-Traditional Sources of Data for Health (SDOH, PGHD)
- EHR data for clinical trials (Doublejump)

Privacy and Security: Protection vs Access

- This initiative will develop policy recommendations regarding healthcare privacy state and federal laws that are negatively impacting consumer access to their healthcare data.
- Problem: The rise of consumer-facing health care websites, mHealth apps, and connected medical devices has raised new privacy and security challenges regarding the collection and sharing health data. The existing health information privacy regulatory framework, which is built around HIPAA and state privacy laws, was not designed for the rapidly changing digital landscape driving State and Federal agencies to develop regulations. Although the laws are designed to protect all involved, they can create barriers to exchange and access data. For example, the California Consumer Privacy Act introduces burdensome obligations, most of which were previously unseen by American companies and several of which present questions about implementation.
- Solution: eHI will identify the current regulations and determine how they both support consumer privacy and, at the same time, negatively impact access for consumers and other key stakeholders. eHI will propose policy recommendations and develop guidelines regarding current regulations for payers, providers, and vendors.

manatt

Key Data Sharing Issues Driving Regulatory Change

Robert Belfort

Manatt, Phelps & Phillips, LLP

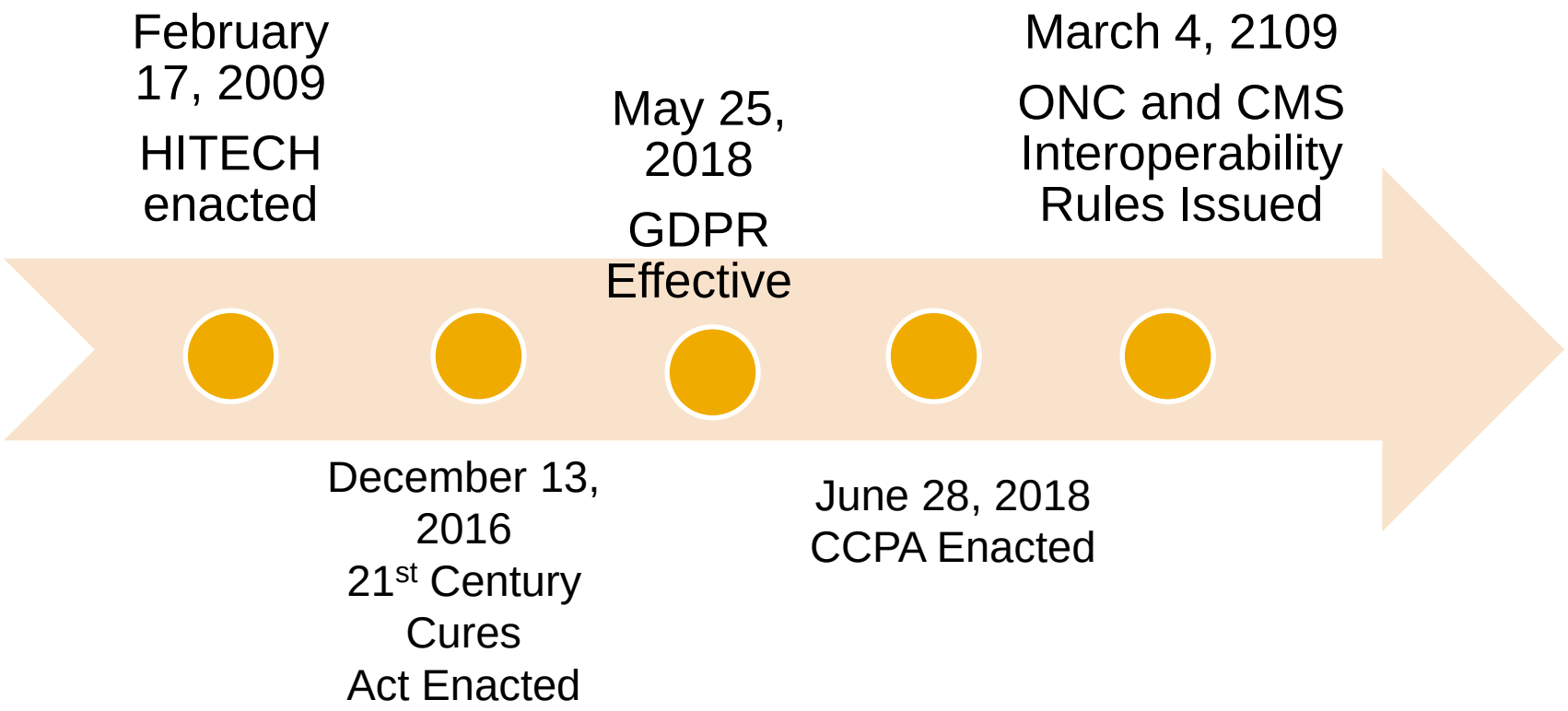
Key Health Data Sharing Issues

Increasing patients' access to their own health information

Eliminating barriers to data sharing within the health care system for treatment and care coordination

Managing the rapid expansion of health data collection by technology companies outside the traditional health care system

Recent Legislative and Regulatory Activity



Historical Obstacles to Patient Access

Accessibility

- Data must be aggregated from multiple providers
- No standardized electronic format to create user-friendly integrated data set

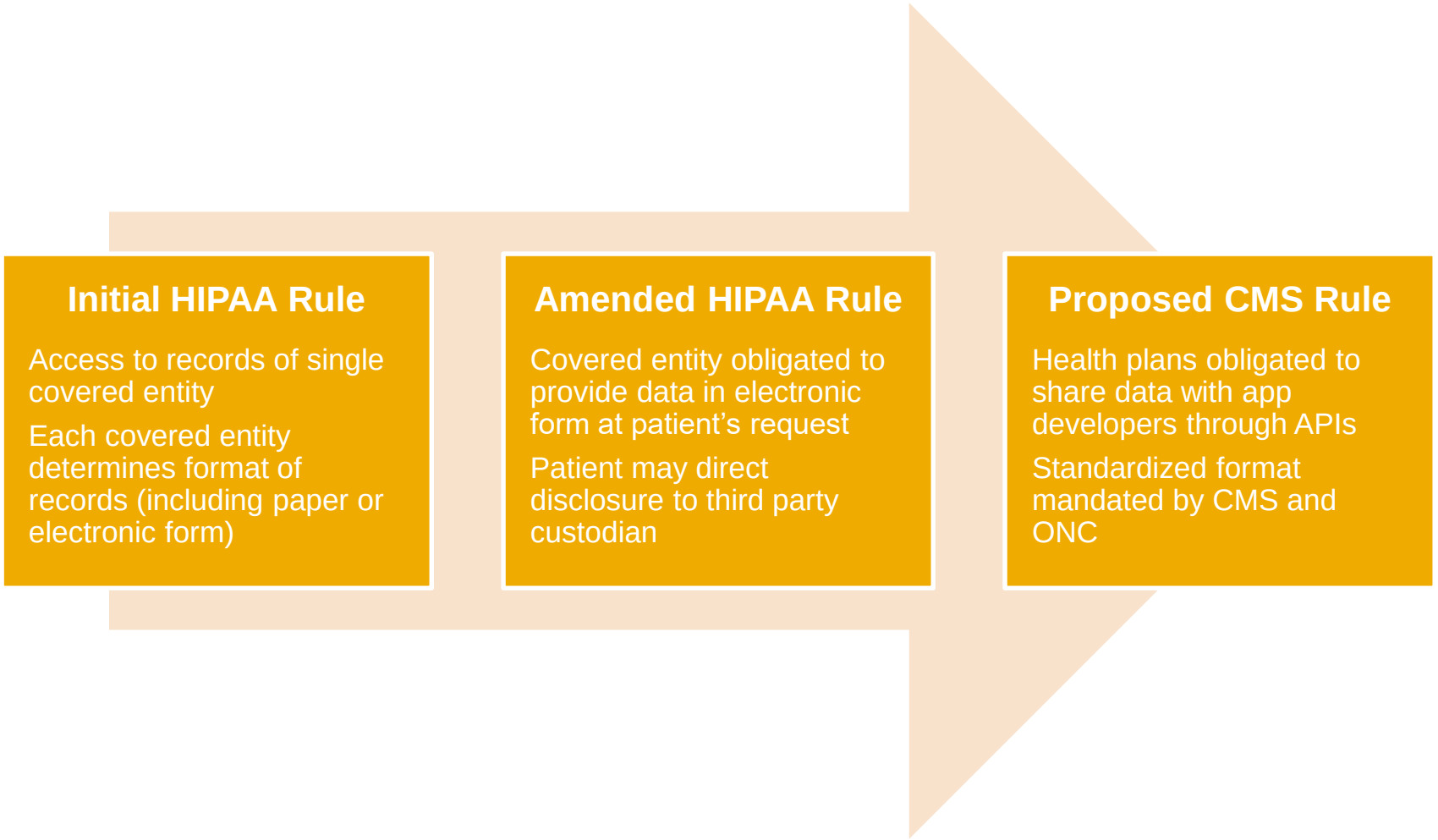
Timeliness

- Long time period to provide copies impedes use of data for time-sensitive medical care
- No simple mechanism for refreshing/updating data

Cost

- Fees can become substantial for large record sets
- New fees payable for each updated data request

Evolution of Regulatory Framework to Promote Patient Access to Data



Potential Benefits and Risks of Reliance on Proposed App Model

Potential Benefits

- Opportunity for patients to aggregate data from multiple sources in single format to get alerts and see complete picture of their health
- Improves capacity for timely patient and provider decision-making
- May minimize duplication of services and reduce health care costs

Potential Risks

- Once data in apps they are not protected by HIPAA; FTC Act may not provide sufficient safeguards
- Patient consent may be inadequate in app environment
- Who vets apps for integrity and safety—what is the app business model?
- Mobile phone security becomes critical

Reasons for Data Blocking Within Health Care System

IT Vendors

- Promote acquisition of vendor's EHR through closed community of data sharers
- Encourage use of vendor's preferred ancillary products and services
- Direct resources toward functionality that improves marketplace position (charge high fees for other functionality)

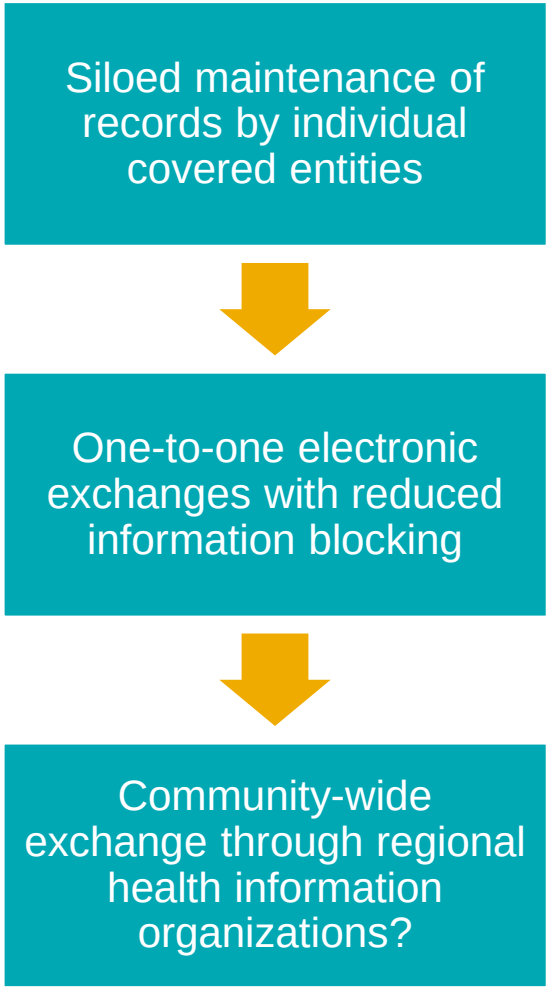
Providers

- Reduce patient referrals outside of provider's system
- Prevent cost or quality of care analyses that can be used for competitive purposes
- Preclude use of data for research by competing academic institutions
- Avoid fallout from data breaches at other entities

ONC Information Blocking Rule: Examples of Interpretive Challenges

- How will sensitive data subject to heightened legal restrictions be filtered?
- How will it be determined when a vendor or provider charges "excessive fees" for interfaces?
- What standards will organizations use to determine if a non-covered entity's privacy policies are adequate?
- When does the refusal to share information promote data security?
- When are licensing terms for interoperability elements non-discriminatory?

Evolution of Marketplace Toward Greater Data Sharing



HIPAA Covered Entities vs. Health App Developers

	Covered Entities	App Developers
Laws regulating use and disclosure of health information	▪ HIPAA—patient authorization required unless exception applies (TPO) ▪ State and federal laws governing sensitive data ▪ FTC Act (see app developers)	▪ FTC Act—liability for "deceptive" and "unfair" practices ▪ CCPA (et al?)
Role of data in business model	Patient data used primarily to deliver the service the patient is requesting; commercialization is secondary	User data commonly commercialized for purposes unrelated to the service obtained through the app—this is central to business model
Core tendencies	Privacy and restricted use	Transparency and sharing

When Is an App Developer a Business Associate?

- Is app offered to consumers "on behalf of" health care provider or health plan?
- Factors likely to include:
  - How app is branded
  - Whether consumer accesses app through covered entity or separate channel
  - Whether app (or enhanced version) is available only through covered entity (i.e., only to provider's patients or plan's members)
  - How data flows between covered entity and app developer
  - Whether app developer provides any related services to covered entity

Challenges When Covered Entities and App Developers Interact

Guidance for Industry	▪ Can regulatory guidance provide greater certainty on when an app developer is a business associate? ▪ Can guidance keep up with rapid change in technology and marketplace?
Clarity for Patients	▪ How can it be made clearer to patients/users when their data is protected by HIPAA and when it is not? ▪ Do benefits of data sharing outweigh a certain amount of consumer confusion?
Regulatory Limits on Certain Behavior	▪ Is user consent ever inadequate as protective measure? ▪ Should government restrict certain data uses even with user consent?

Robert Belfort

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Discussion

- What pending regulations will most impact eHI's membership?

Steve Kastin, MD

Senior Executive Advisor and Chief Medical Information Officer (CMIO), Booz Allen Hamilton

Discussion

- How do current privacy laws unintentionally create barriers to exchange and access data? Consumers? Providers? Payers? Others?

Discussion

- Where do privacy regulations contradict each other?

Discussion

- Where is more guidance on regs needed?

Discussion

- Where can eHI help educate congressional leaders and regulators on industry needs and concerns?

Discussion

- Are there key terms or regulations that are unclear to providers, consumers, others?

Discussion

- Think about the presentation from Maria this morning, what are your greatest concerns about HIPAA 2.0?

Next Steps