Northwestern IAM Health Policy Overview

LEAVITT PARTNERS
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Leavitt Partners Overview

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Federal Insights and Advocacy

The Leavitt Partners team is comprised of experienced policymakers and staffers spanning the executive and legislative branches of government. Our team members have served as congressional staff, and political appointees, and know firsthand the regulatory and legislative processes. Our staff also has deep policy expertise, having helped write significant health care legislation and regulation during their public service. We help health care organizations, from the most sophisticated multi-national organizations to the smallest local providers, navigate a turbulent, and often confusing, Washington, D.C.

We support the most forward-leaning health care entities with legislative support and regulatory insights through:

- *Intel Gathering*
- *Policy Development*
- *Strategy*
- *Advocacy*
- *Meeting Facilitation*
- *Subject Matter Expertise*

BUILDING ALLIANCES

Leavitt Partners' executives have been at the forefront of alliances for over two decades. We have a proven process for achieving results through collaboration, as outlined in *Finding Allies, Building Alliances*, a book co-authored by Leavitt Partners co-founders. We are successful because we bring diverse, multi-sector stakeholders together to build effective alliances focused on solving complex, long-standing policy challenges through development of consensus solutions.

DEVELOPING

We establish alliances that are positioned for success by defining the objective, testing viability, and recruiting cross-sector members, and thought leaders.

CONVENING AND MANAGING

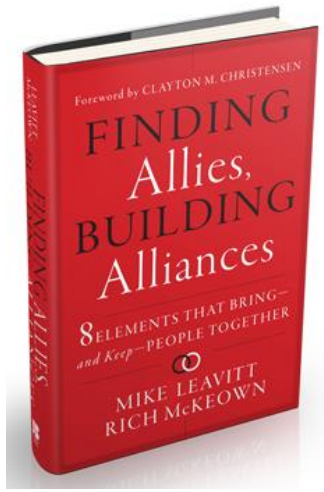
We organize and manage the necessary stakeholders using a suite of tools and processes to keep stakeholders together, focused, and advancing.

ADVISING

We advise alliances on complex policy issues necessary to develop consensus solutions that are viable.

EXECUTING STRATEGY

We develop and execute strategies to successfully implement consensus-driven solutions through industry adoption, regulatory reform, or statutory reform.



ALLIANCES IN ACTION

The following illustrates examples of the types of alliances Leavitt Partners manages and the successes they have experienced.

HEALTHY SAIL ALLIANCE

The Healthy Sail Alliance was a collaborative effort between Royal Caribbean Group and Norwegian Cruise Line Holdings Ltd. to develop new and enhanced cruise health and safety standards informed by the Healthy Sail Panel. The Healthy Sail Panel is comprised of a group of globally recognized experts with diverse backgrounds, including in public health, infectious disease, biosecurity, hospitality, and maritime operations and is co-chaired by Governor Mike Leavitt and Dr. Scott Gottlieb. On September 21, 2020 the Healthy Sail Panel submitted to the U.S. Centers for Disease Control and Prevention its 65-page report including 74 detailed recommendations to protect the public health and safety of guest, crew, and the communities where cruise ships call.

THE PHARMACEUTICAL DISTRIBUTION SECURITY ALLIANCE (PDSA)

The LP-led alliance, PDSA (www.pdsaonline.org), is driving in significant legislative reform and effective agency implementation of the resulting statute. Leavitt Partners organized the legislative drafting and advocacy work that led to the signing of bipartisan legislation without a single recorded vote in opposition, and the bill was signed into law by President Obama in November of 2013 at a time when most bills were held up in bipartisan wrangling and legislative inaction.

CREATING ACCESS TO REAL-TIME INFORMATION NOW THROUGH CONSUMER-DIRECTED EXCHANGE (CARIN)

The LP-led alliance, CARIN (www.carinalliance.com), a multi-sector group of more than sixty healthcare and other stakeholders, is focused on rapidly advancing the ability for consumers and their authorized caregivers to easy get, use, and share their digital health information when, where, and how they want to achieve their goals. Recently, CARIN developed a code of conduct for how entities not covered by the Health Insurance Portability Accountability Act (HIPAA), such as third-party applications, can voluntarily handle healthcare data on behalf of consumers. The CARIN FHIR® Implementation Guide for Blue Button® is now in production in 950+ health plans and state Medicaid agencies in the US. It allows a member or beneficiary to access their claims information on an application of their choice.

General Federal Policy

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Relevant Federal Agencies

ONC

Office of the National Coordinator for Health Information Technology

CMS

CENTERS FOR MEDICARE & MEDICAID SERVICES

FDA U.S. FOOD & DRUG ADMINISTRATION

General Federal Policy Overview

Important federal data and technology statues and regulations that apply to healthcare:

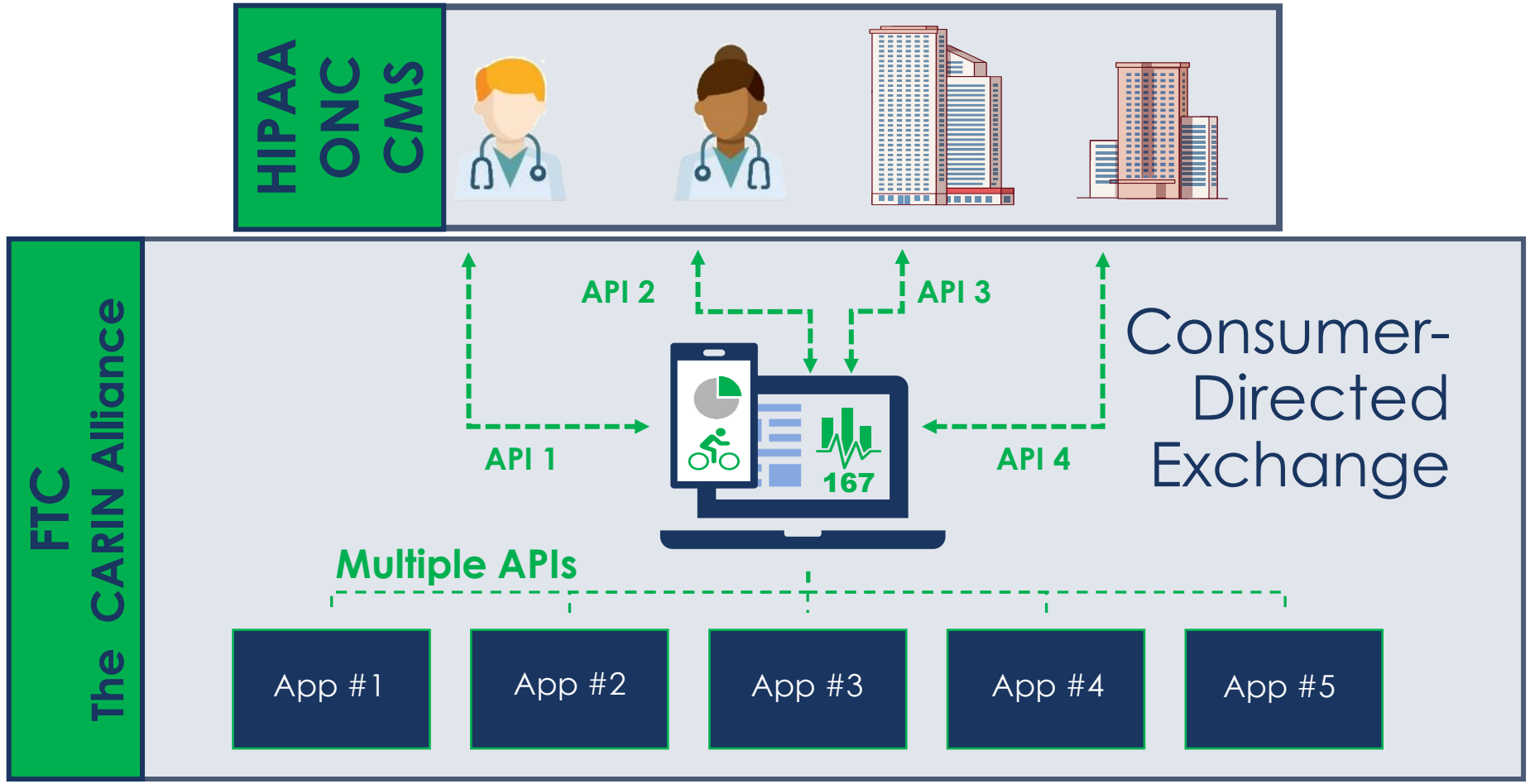
Statutes/Regulations	Summary
Health Insurance Portability and Accountability Act (HIPAA)	National standards to protect sensitive patient health information.
Health Information Technology for Economic and Clinical Health (HITECH) Act	Promote the adoption and meaningful use of health information technology.
STAR HIE Program	Promote greater health information exchanges (HIEs).
21st Century Cures Act	Establishes Conditions of Certification requirements for the ONC Health IT Certification Program.
United States Core Data for Interoperability (USCDI)	Nationally standardized set of health data classes and constituent data elements.
Trusted Exchange Framework and the Common Agreement (TEFCA)	Facilitate data-sharing among health information networks.
Food and Drug Administration	FDA is "responsible for protecting the public health by ensuring the safety, efficacy, and security of drugs, medical devices, etc" under the FD&C Act.

General Federal Policy Overview (continued)

Important federal data and technology regulations that apply to healthcare:

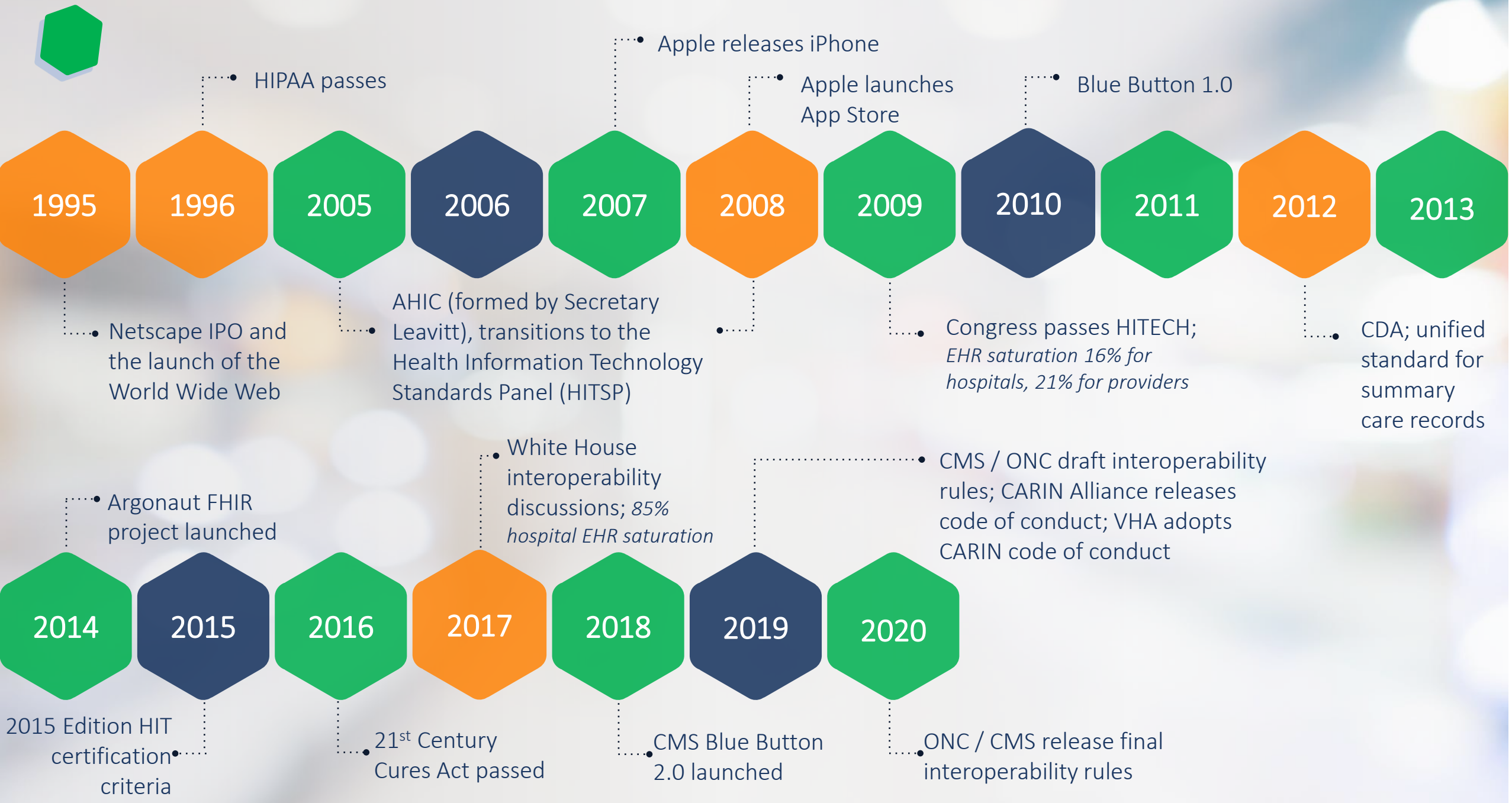
Statutes/Regulations	Summary
Health IT Strategic Planning	Outlines federal health IT goals and objectives.
Strategy on Reducing Burden Relating to the Use of Health IT and EHRs	Strategy to reduce regulatory and administrative burden related to the use of health IT and EHRs.
Interoperability and Patient Access Final Rule	Advance system interoperability and, specifically, patient access to their health plan information.
Transparency in Coverage Final Rule	Require health plans to provide consumers with tools needed to access pricing information.
No Surprises Act	Prohibits patients from receiving surprise medical bills.
Interoperability and Prior Authorization Frozen Rule	Improve health information exchange by adding new provisions.
FDA's Artificial Intelligence/Machine Learning Action Plan	Outlines a multi-pronged approach to promote FDA oversight of AI/ML-based medical software.
FDA's Software Guidance	Recommendations to sponsors regarding premarket documentation for software in medical devices.

How is data shared today and how will it be shared in the future?



HIPAA Applied to Mobile Health (mHealth) Applications

- HIPAA applies to mHealth developers when the app developer creates, maintains, or transmits PHI on behalf of a Covered Entity or Business Associate.
  - When this is the case, mHealth app developers must comply with HIPAA's Privacy, Security, and Breach Notification Rules.
- Direct-to-Consumer (DTC) applications in which consumers provide their own health information are likely not subject to HIPAA.
- HIPAA requires Covered Entities and third-parties to establish a Business Associate Agreement (BAA) that includes:
  - Permitted and required uses of PHI.
  - Agreement that there will be no further disclosure of PHI beyond the permitted and required uses.
  - Safeguards to prevent improper use or disclosure of PHI.
- HIPAA violations are subject to Civil Money Penalties (CMPs) from $50 to $50,000 per violation up to $1.5 million in a given year for the same violations.
  - Impermissible disclosure of PHI that violates the Privacy Rule may lead to a $50,000 criminal penalty and up to one year of imprisonment, with increasing penalties and sentences with false pretenses or intent to use PHI for commercial use or harm.



US Core Data For Interoperability

Allergies and Intolerances *NEW

- Substance (Medication)
- Substance (Drug Class) *NEW
- Reaction *NEW

Assessment and Plan of Treatment

Care Team Members

For more info:

HealthIT.gov/USCDI

Clinical Notes *NEW

- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Goals

Health Concerns

Immunizations

Laboratory

- Tests
- Values/Results

Medications

Patient Demographics

- First Name
- Last Name
- Previous Name
- Middle Name (incl. middle initial)
- Suffix
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Current Address *NEW
- Previous Address *NEW
- Phone Number *NEW
- Phone Number Type *NEW
- Email Address *NEW

Problems

Procedures

Provenance *NEW

- Author Time Stamp
- Author Organization

Smoking Status

Unique Device Identifier(s) for a Patient's Implantable Device(s)

Vital Signs

- Diastolic Blood Pressure
- Systolic Blood Pressure
- Body Height
- Body Weight
- Heart Rate
- Respiratory Rate
- Body Temperature
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2-20 Years) *NEW
- Weight-for-length Percentile (Birth - 36 Months) *NEW
- Occipital-frontal Head Circumference Percentile (Birth - 36 Months) *NEW

TEFCA

On January 18, 2022, the Office of the National Coordinator for Health Information Technology (ONC) and The Sequoia Project released the Trusted Exchange Framework and the Common Agreement (TEFCA).

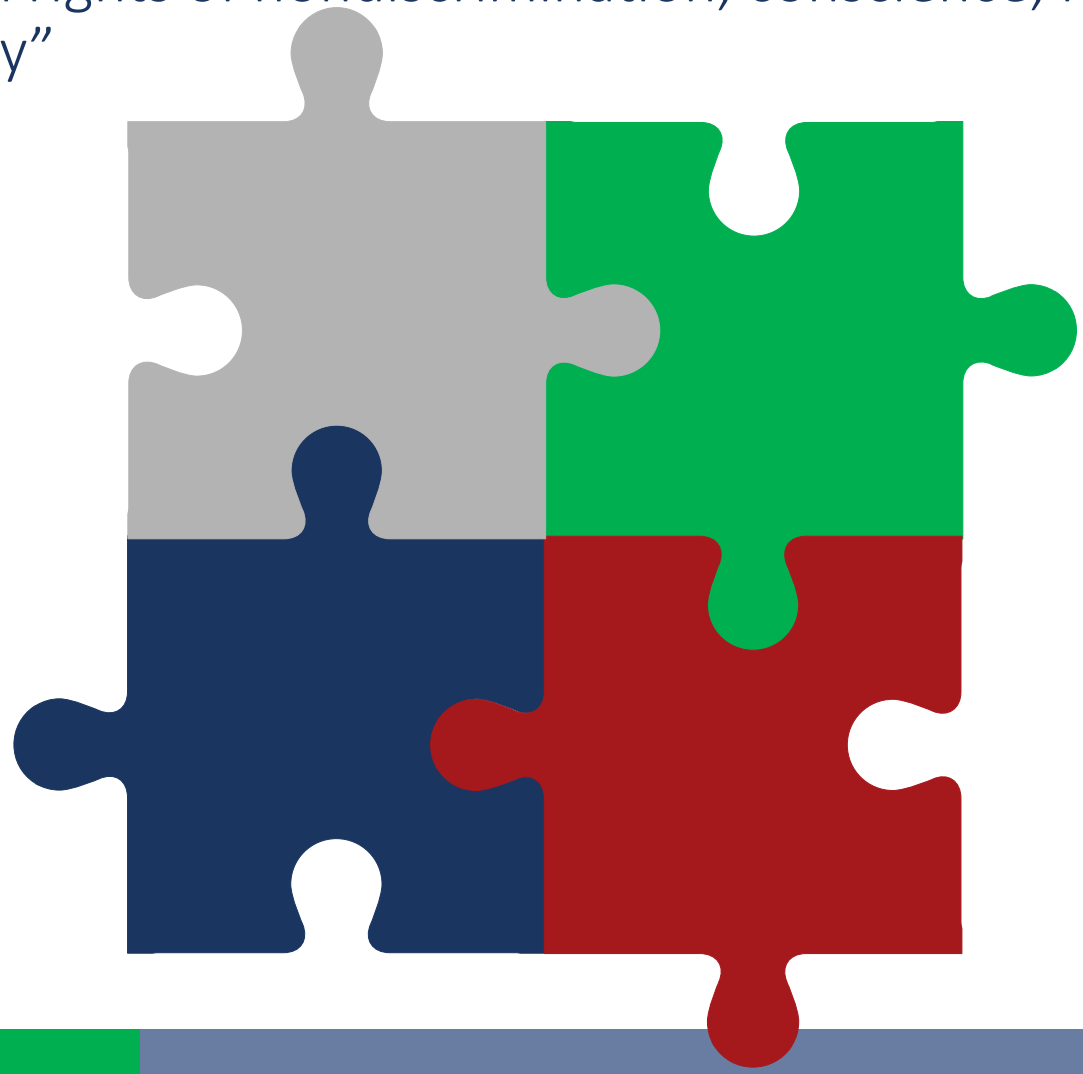
- Required by 21st Century Cures Act
- Aims to facilitate data-sharing among health information networks.
- Goals
  - Establish a universal policy and technical floor for nationwide interoperability.
  - Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value.
  - Enable individuals to gather their health care information.

Office for Civil Rights (OCR)

"Enforces federal civil rights laws, conscience and religious freedom laws, HIPAA Privacy, Security, and Breach Notification Rules, and the Patient Safety Act and Rule, which together protect your fundamental rights of nondiscrimination, conscience, religious freedom, and health information privacy"

Section 1557 of the Patient Protection and Affordable Care Act

Pharmacy Guidance on Reproductive Health Care



HIPAA and Reproductive Health

Gender Affirming Care, Civil Rights, and Privacy

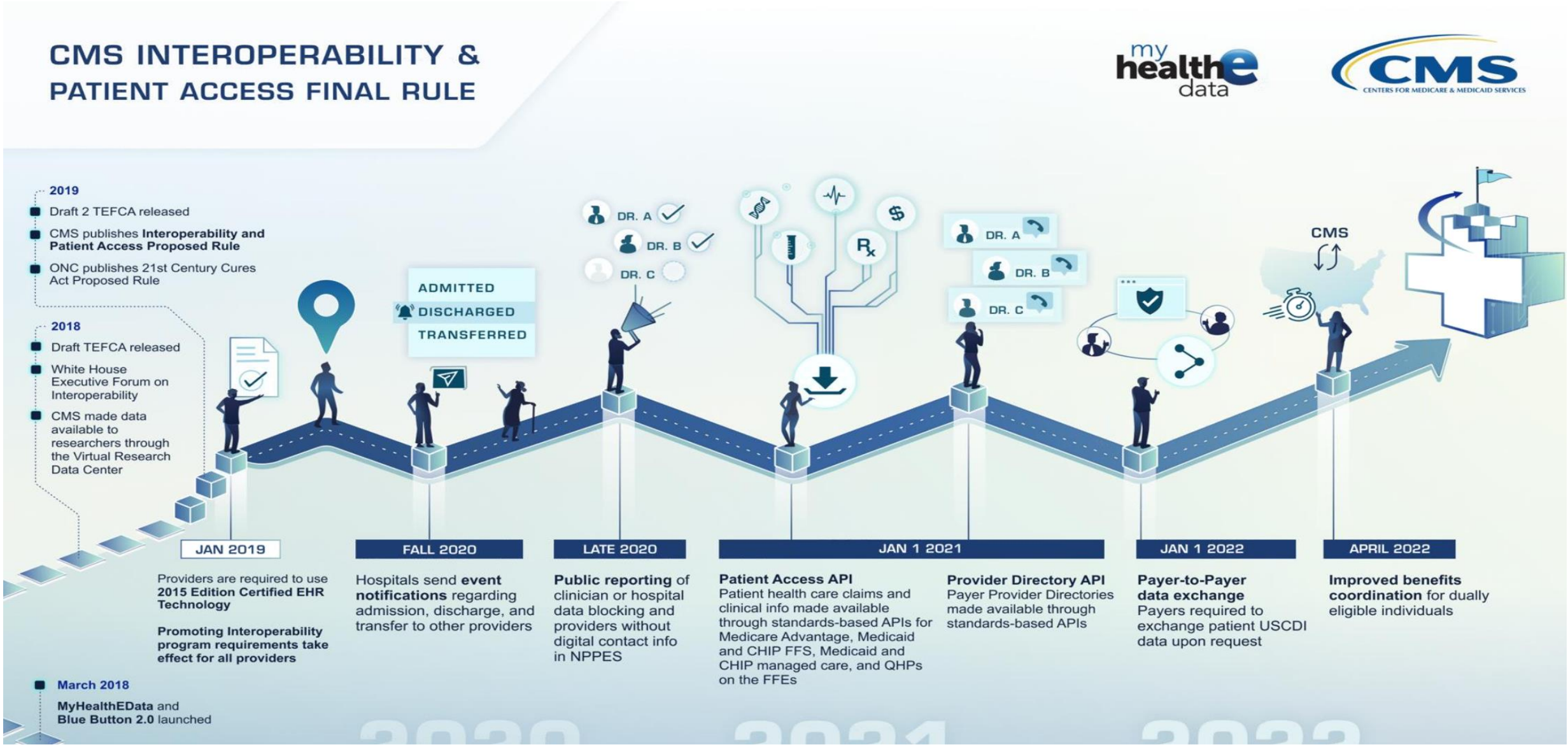
Federal Trade Commission (FTC)

- Works to prevent fraudulent, deceptive, and unfair business practices and provides information to help consumers to identify, stop, and avoid scams and fraud
- Enforces antitrust laws in health care markets to prevent anticompetitive conduct
- FTC's Health Breach Notification Rule requires businesses, organizations, and companies that experience a consumers' EHR breach to notify the affected consumers, the FTC, and in certain cases, the media
    - Failure to comply with the Rule may result in penalties of up to $46,517 per violation per day

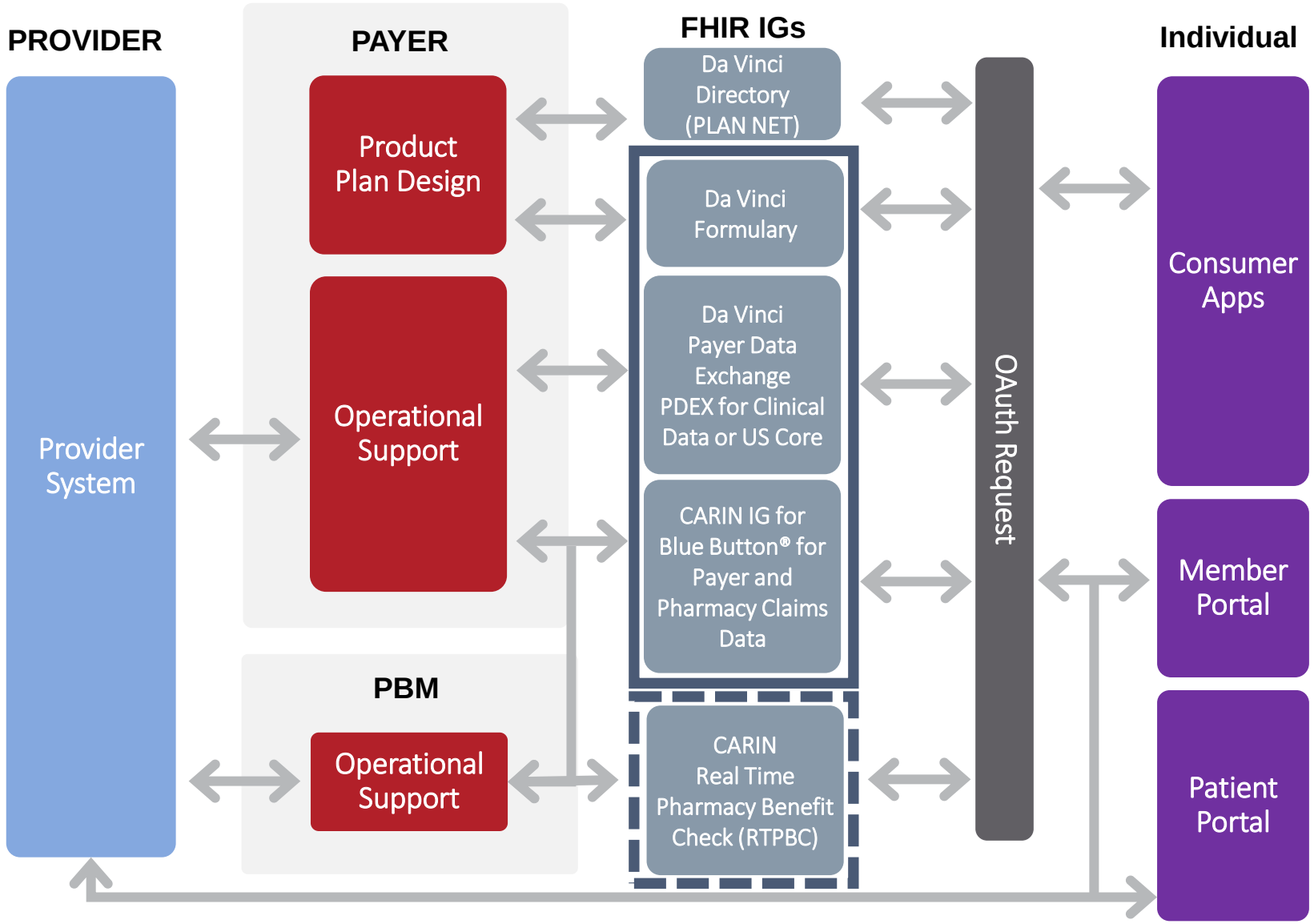
Centers for Medicaid and Medicaid Services (CMS)

- Provides health coverage to more than 100 million people through:
  - Medicare
  - Medicaid
  - Children's Health Insurance Program (CHIP)
  - Health Insurance Marketplace.
- CMS Rulemaking: CMS regulations establish or modify the way CMS administers its programs, which affects providers or suppliers entitled to benefits under CMS programs.

CMS Interoperability and Patient Access Final Rule



CMS final rule: FHIR Implementation Guide (IG) Options



FHIR Accelerator Commentary

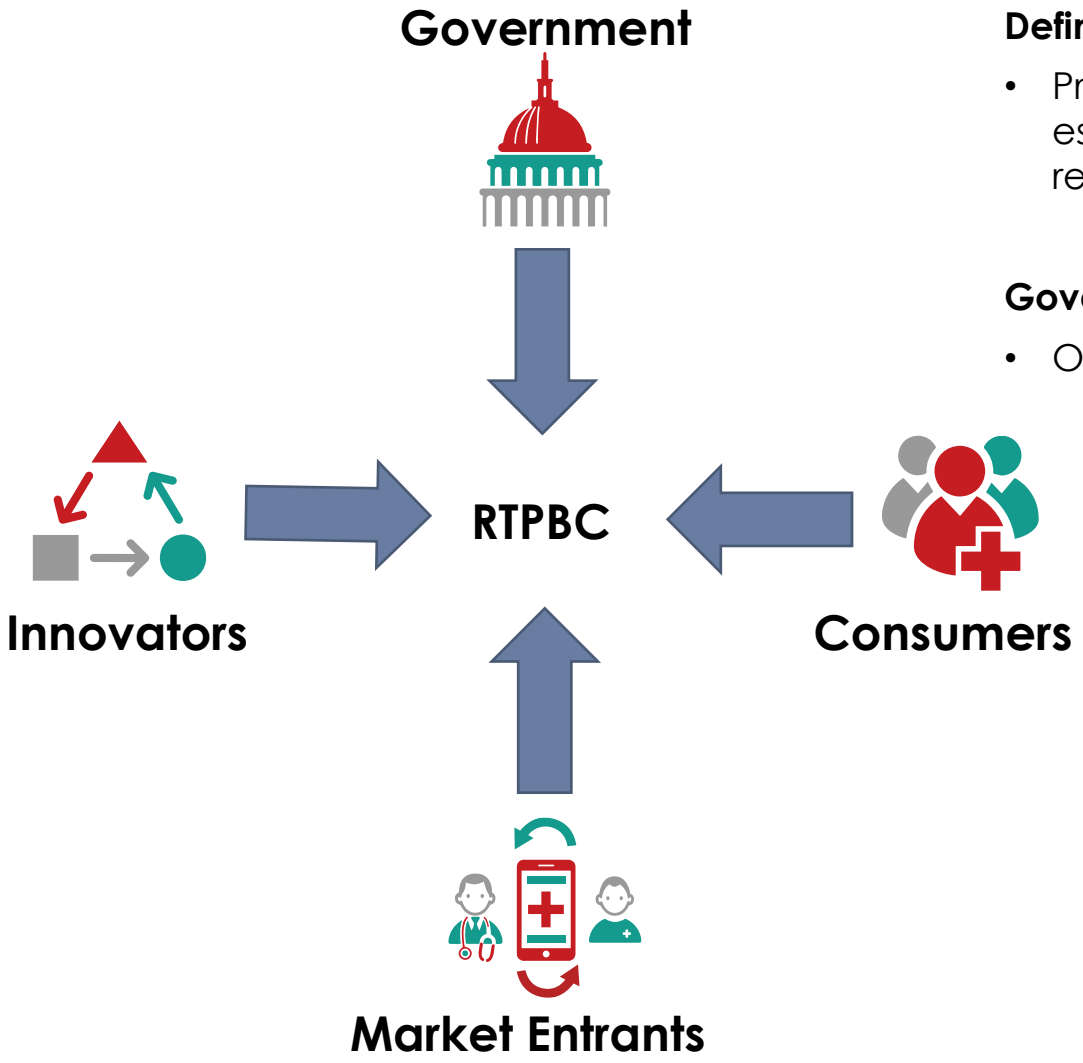
1. Goal is to reduce burden on payers, providers, vendors and patients to meet 7/1/21 req, excludes 1/1/22 requirements
2. There is no specific CMS requirement to use any HL7 Implementation Guide
3. FHIR Community is working collaboratively to ensure the specific guide meets CMS final rule
4. All guides are Draft Standards for Trial Use (DSTU) or moving towards a published version of STU1

Legend

CMS Patient Access API for 2021

Opportunity to expand CMS Patient Access API for 2022

Consumer-facing Real-time Pharmacy Benefit Check



Definition

- Provide consumers with access to their formulary and benefit information, estimated out of pocket costs, therapeutic alternatives, and cash price in real-time after a provider has prescribed a medication

Government

- One of few policy agenda items with bipartisan support.
  - Presidential Executive Orders and Drug Pricing Blueprint
  - **Electronic B2B Real-time Benefit Tool or "RTBT"**
    - Addressed in CMS Part D Drug Pricing Final Rule in May 2019 (CMS-4180-F)
    - Required for Part D plans by January 2023
  - **Transparency in Coverage Final Rule (CMS-9915-F) October 29, 2020**
    - "To that end, the final rules require plans and issuers to disclose in element (i), an individual's out-of-pocket cost liability for prescription drugs, and in element (iii), the negotiated rate of the drug."
    - Effective January 1, 2022
    - You can use the Consumer-facing real-time pharmacy benefit check API to be in compliance with this rule

Published HL7® FHIR® STU1 version: https://build.fhir.org/ig/HL7/carin-rtpbc/index.html

CMS-0057-P OVERVIEW

On December 6, 2022, CMS posted the Advancing Interoperability and Improving Prior Authorization Processes proposed rule. The proposed effective date for the provisions in this rule is January 1, 2026.

This rule signals CMS' continued commitment to increasing efficiency by ***ensuring that health information is readily available*** at the point of care by leveraging FHIR standards.

CMS also includes several proposals intended to reduce payer, provider, and patient burden by ***streamlining prior authorization processes*** to ***move the industry toward electronic prior authorization***, creating a ***more efficient and timely process***.

Ultimately, reduced provider burden means <u>more time</u> with patients.

PROVISIONS

- Patient Access Application Programming Interface (API)
- Provider Access API
- Payer-to-Payer Data Exchange API
- Prior Authorization Requirements, Documentation & Decision API
- Improving Prior Authorization Processes
- New measures for Electronic Prior Authorization for the Merit-based Incentive Payment System (MIPS) Promoting Interoperability Performance Category and the Medicare Promoting Interoperability Program

IMPACTED PAYERS

- Medicare Advantage
- State Medicaid and CHIP agencies
- Medicaid and CHIP Managed Care Plans
- Qualified Health Plans (QHPs) on the Federally-facilitated Exchanges (FFEs)

IMPACTED PROVIDERS

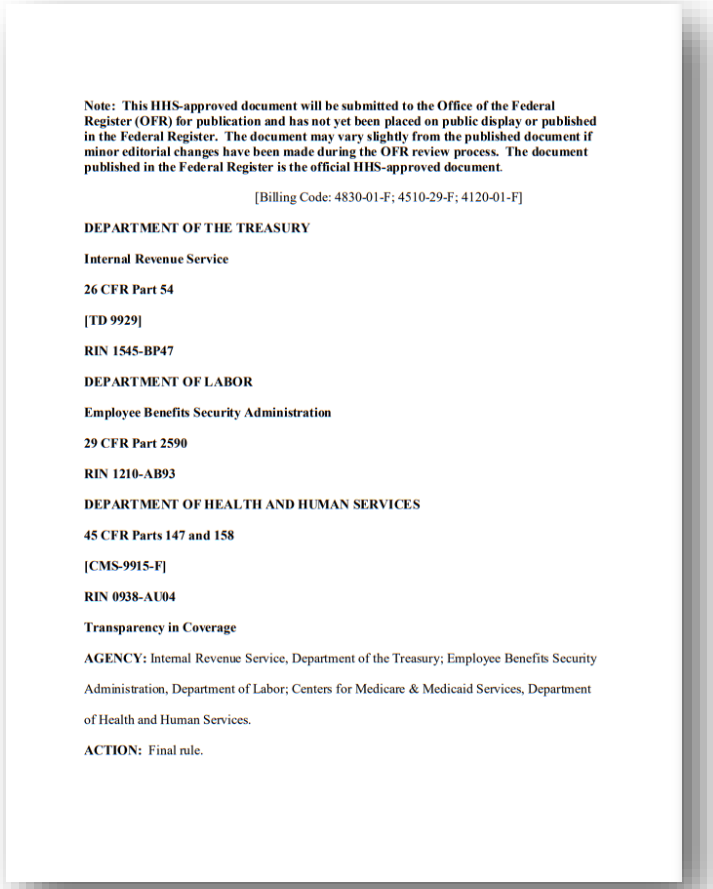
- Eligible hospitals and critical access hospitals (CAHs) under the Medicare Promoting Interoperability Program
- Eligible clinicians under the Promoting Interoperability performance category of Merit-based Incentive Payment System (MIPS)

REQUESTS FOR INFORMATION (RFI)

- Accelerating the Adoption of Standards Related to Social Risk Factor Data
- Electronic Exchange of Behavioral Health Information
- Improving the Electronic Exchange of Information in Medicare FFS
- Advancing Data and Interoperability for Maternal Health
- Advancing the Trusted Exchange Framework and Common Agreement (TEFCA)

Transparency in Coverage Final Rule (CMS-9915-F)

On October 28, 2020, the Department of Health and Human Services, along with the Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, published the Transparency in Coverage Final Rule. The rule:



Note: This HHS-approved document will be submitted to the Office of the Federal Register (OFR) for publication and has not yet been placed on public display or published in the Federal Register. The document may vary slightly from the published document if minor editorial changes have been made during the OFR review process. The document published in the Federal Register is the official HHS-approved document.

[Billing Code: 4830-01-F; 4510-29-F; 4120-01-F]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9929]

RIN 1545-BP47

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AB93

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 147 and 158

[CMS-9915-F]

RIN 0938-AU04

Transparency in Coverage

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rule.

- Requires most non-grandfathered group health plans and health insurance issuers in the group and individual market to disclose cost-sharing information to participants, beneficiaries, and enrollees.
- Aims to provide patients access to real-time price information prior to treatment.
- Requires seven content elements to be disclosed: estimated cost-sharing liability; accumulated amounts; in-network rates; out-of-network allowed amount; item and services content; notice of prerequisites for improved readability; and a disclosure notice.
- Requires health plans and health insurance issuers to make three separate machine-readable files with detailed pricing information available to the public.

No Surprises Act

The Act prohibits patients from receiving surprise medical bills.

The Act establishes a new Dispute Resolution Process.

HHS proposed implementation/ enforcement provi-sions.

CMS issued "Requirements Related to Surprise Billing" parts.

“Requirements Related to Surprise Billing; Part I” Interim Final Rule

On July 1, 2021, the Departments of Health and Human Services (HHS), Labor, and the Treasury, (the Departments) as well as the Office of Personnel Management, issued “Requirements Related to Surprise Billing; Part I.”

Restricted:

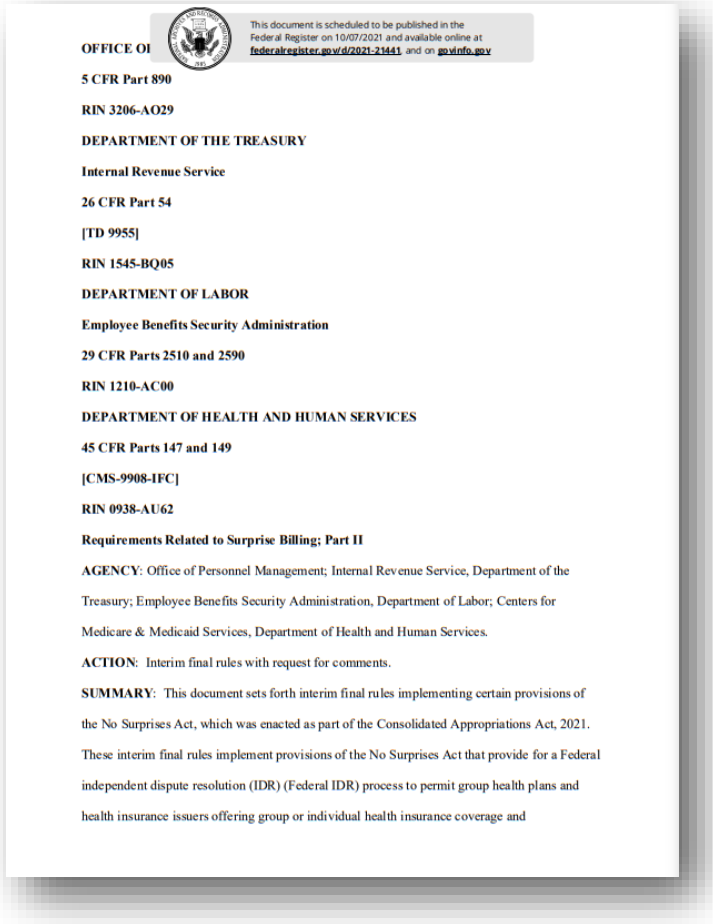
- Surprise billing in emergency care
- Non-emergency care from out-of-network providers at in-network facilities
- Air ambulance services from out-of-network providers

Applied to:

Group health plans and health insurance issuers offering group or patient health insurance coverage, including grandfathered health plans, health care providers and facilities, and air ambulance service providers.

“Requirements Related to Surprise Billing; Part II” Interim Final Rule

On September 30, 2021, the Departments of Health and Human Services, Labor, and Treasury (the Departments) along with the Office of Personnel Management issued the interim final rule with comment period (the rule), “Requirements Related to Surprise Billing; Part II.”



This document is scheduled to be published in the Federal Register on 10/07/2021 and available online at federalregister.gov/d/2021-21441, and on govinfo.gov

OFFICE OF

5 CFR Part 890

RIN 3206-AO29

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9955]

RIN 1545-BQ05

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Parts 2510 and 2590

RIN 1210-AC00

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 147 and 149

[CMS-9908-IFC]

RIN 0938-AU62

Requirements Related to Surprise Billing; Part II

AGENCY: Office of Personnel Management; Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document sets forth interim final rules implementing certain provisions of the No Surprises Act, which was enacted as part of the Consolidated Appropriations Act, 2021. These interim final rules implement provisions of the No Surprises Act that provide for a Federal independent dispute resolution (IDR) (Federal IDR) process to permit group health plans and health insurance issuers offering group or individual health insurance coverage and

Outlined:

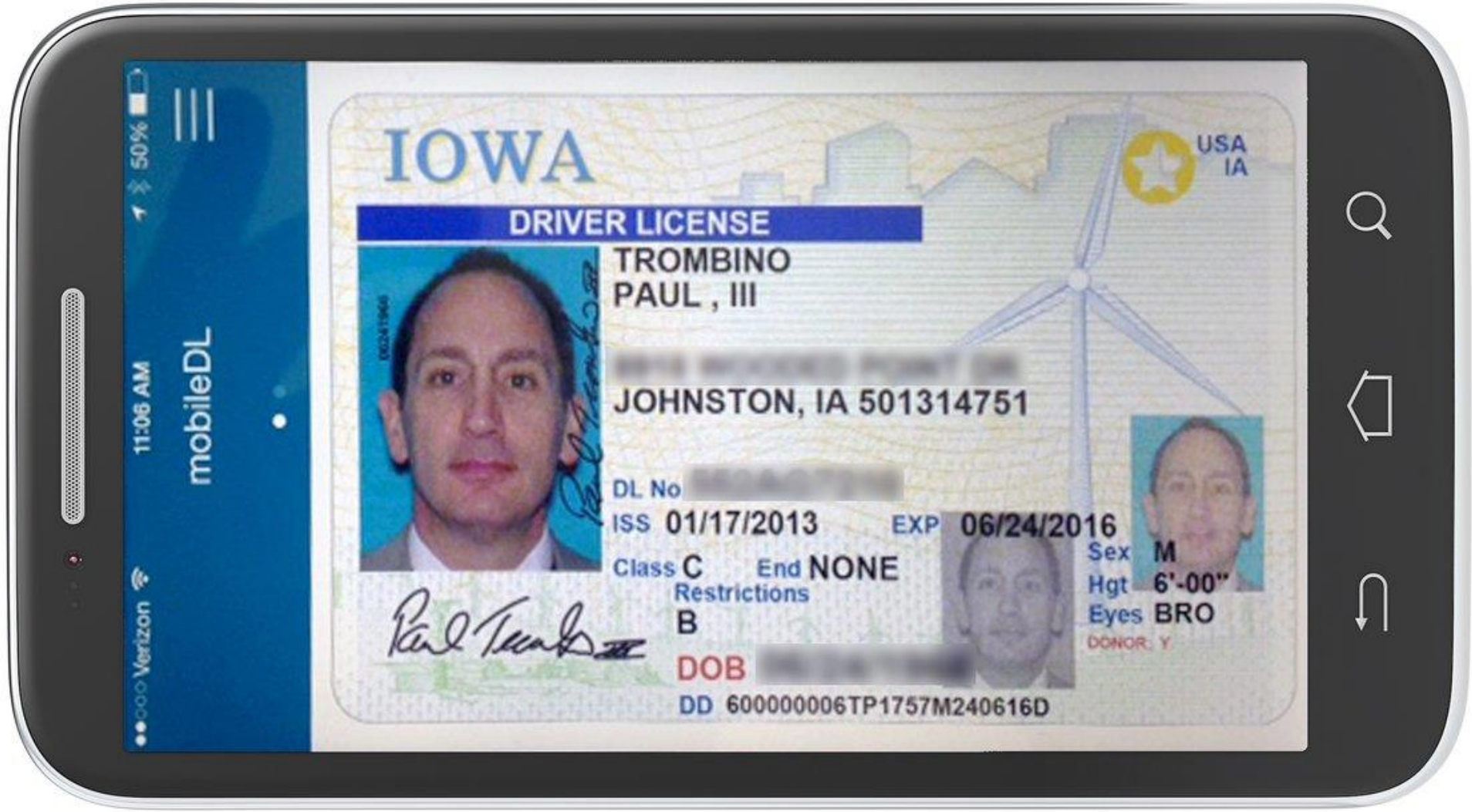
- Open negotiation process
- Federal independent dispute resolution process
- Good faith estimate requirements
- Patient-provider dispute resolution process provisions

No Surprises Act Final Rules

On August 19, the Departments of Labor, HHS, and the Treasury issued final rules to clarify the arbitration process standards for implementing the No Surprises Act.

- The final rules seek to increase transparency by requiring a plan or issuer to provide additional information when submitting an initial payment or a notice of denial of payment for items and services covered by the No Surprises Act changes if the plan or issuer changes a provider or facility's service code used for billing purposes to one of lesser value.
- The increased transparency provisions are intended to help facilitate the negotiations required under the No Surprises Act.
- The rules also finalize and include guidelines for the arbitration process known as the Independent Dispute Resolution process (federal IDR process) for payment determinations and their rationale for out-of-network services.

Federated Digital Identity – SSO for Health Care



Questions?

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