CALIFORNIA TELEHEALTH RESOURCE CENTER

Part of OCHIN

Payment and Regulatory Update for 2024: Advancing Equitable Access to Digital Health.

December 19, 2023

Before We Get Started

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Meeting **Agenda**

01 **Federal DEA Update**
Chris Adamec

02 **Medicare Physician Fee Schedule Update**
Chris Adamec
Sylvia Trujillo

03 **HRSA Update**
Sylvia Trujillo

04 **Federal AI Policy and Regulatory Update**
Alya Sulaiman

05 **California Privacy Update**
Alya Sulaiman

06 **Medi-Cal Update**
Sylvia Trujillo

07 **Questions**

Meet Your **Presenters & Moderator**

Chris Adamec

Vice President, Alliance for Connected Care

Alya Sulaiman

Partner, McDermott Will & Emery

Sylvia Trujillo

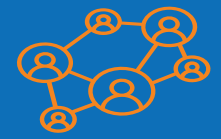
CTRC Executive Director

Digital Health Modalities

- **Live Video/Audio or Audio-Only Synchronous:** Live, two-way interaction between a patient and provider using telecommunications technology. A provider uses telecommunications technology to meet with a patient who is in their home or other location to discuss and provide treatment.
- **eConsult:** Transmission of pre-recorded health history from a practitioner through an electronic communications system to a practitioner who uses the information to evaluate the case or render a service outside of real-time or live interaction.
- **Remote Physiological/ Therapeutic Monitoring (RPM/RTM):** Persona health and medical data collection from an individual in one location via electronic communication technologies, which is transmitted to a provider in a different location for use in care and related support.
- **Asynchronous Store and Forward:** Transmission of pre-recorded health history from a patient through an electronic communications system to a practitioner who uses the information to evaluate the case or render a service outside of real-time or live interaction.
- **Health Care Artificial Intelligence Enabled Modalities:** These can be embedded in other modalities (like RTM/RPM/eConsult) or are a stand-alone modality that assistive, augmentative, or autonomous.

Facts:

Digital Health is a collection of methods for delivering care



Digital Health means utilizing technologies to deliver care

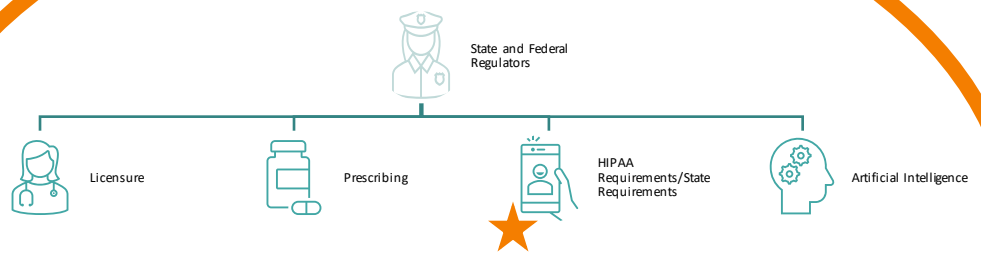
Digital Health enhances health care, public health, and health education delivery

COVID-19 PHE Sunset May 11, 2023

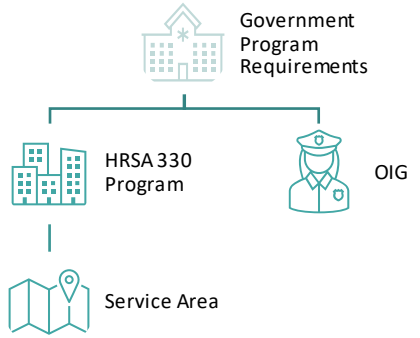
When the PHE concluded, many waivers and broad flexibilities provided to health care providers as a result of the PHE were either modified, extended temporarily, or terminated

Federal Flexibilities

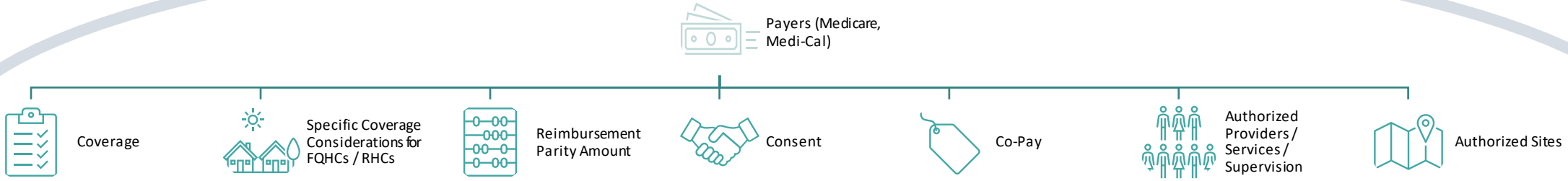
California Flexibilities



Regulation



Government Program Requirements

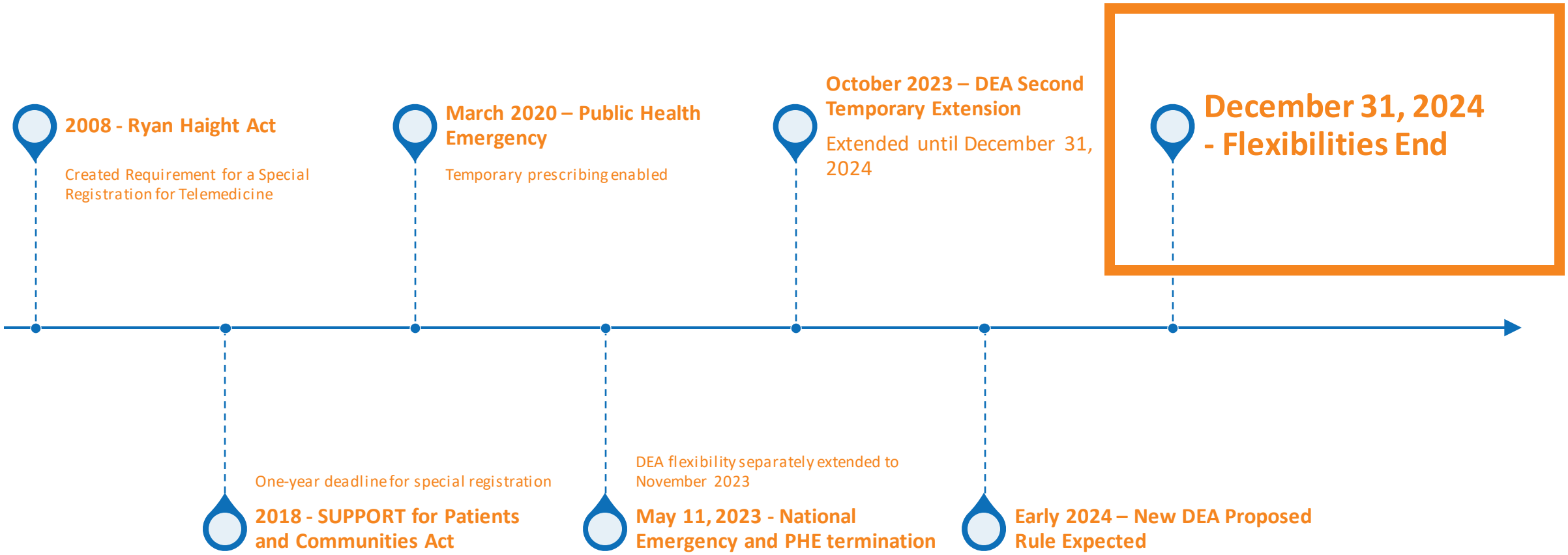


Payer Digital Health Coverage

Federal DEA Update

- Ryan Haight Act of 2008 and SUPPORT for Patients and Communities Act of 2018 Requirements
- Flexibility since 2020 – DEA registered practitioners
  - legitimate medical purpose by a practitioner in professional practice
  - using an audio-visual, real-time, two-way interactive communication system.
  - acting in accordance with applicable Federal and State law.
  - DEA recognition across state lines
- Ongoing pharmacy challenges
- Feb 2023 DEA Proposed Rule
  - 30-day supply limit
  - Require in-person referral
  - Limited to Schedule III-V
  - Detailed recordkeeping requirements
  - 38,000 public comments
- Extension through December 31 2024
- Forthcoming Proposed Rule

DEA Flexibilities – Establishing Valid Relationship Through Telehealth



Distinction between State and Federal Laws Regulating Prescribing, Establishing Patient Relationship, and Use of Telehealth for Controlled Substances

California Law on Prescribing and Telehealth

- Prescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022 without an appropriate prior examination and a medical indication, constitutes unprofessional conduct.
- An appropriate prior examination does not require a synchronous interaction between the patient and the licensee and can be achieved through the use of telehealth, including, but not limited to, a self-screening tool or a questionnaire, provided that the licensee complies with the appropriate standard of care.

SOURCE: CA Business & Professions Code Sec. 2242 (a)

California Remote Pharmacist Processing

- Effective September 1, 2023, California adopted a new telepharmacy rule that allows pharmacists licensed and located in California to verify medication chart orders for Schedules II-IV substances on behalf of hospitals and other healthcare facilities remotely.
- This change replaced a COVID-19 waiver that expired on August 9, 2023.
- Before this change, the Pharmacy Law in California made it a misdemeanor to remotely verify the aforementioned Scheduled substances.
    - A healthcare facility shall maintain a record of a pharmacist verifying medication chart orders pursuant to this subdivision.
    - Electronic entries must be entered consistent with a healthcare facility's policies and procedures.

HRSA Update

HRSA Service Area Telehealth Flexibilities

Health centers should focus services provided by telehealth on serving patients and other individuals located inside their service area or with areas adjacent to the covered entity's service area.

Health centers that continue to maintain services for target populations in their service area **and *provide occasional in-scope services* via telehealth to individuals outside these areas** would be providing services within the Health Center Program scope of project for all such activities.

Telehealth guidance will continue to be in effect until HRSA issues superseding policy guidance, which may include final scope of project and telehealth policy, or until December 31, 2024, whichever comes first. *updated on March 6, 2023*

Source https://bphc.hrsa.gov/initiatives/covid-19-information-health-centers-partners/faq?categories=All&keywords=telehealth

Medicare Physician Fee Schedule

Telehealth
(Interactive Video-Audio and in some cases Audio-Only)

Medicare – Telehealth

Extends the following telehealth flexibilities through December 31, 2024:

Home - Allow providers to bill for services delivered to patients located at any site in the United States, including their home

Expanded Practitioners - Occupational therapists, physical therapists, speech-language pathologists, and audiologists can provide and bill for telehealth services

FQHCs and RHCs can provide and bill for telehealth services furnished to patients in their homes or other locations within the United States;

Tele-Behavioral Physicians, mental health practitioners, FQHCs, and RHCs can initiate tele-behavioral health services without a prior in-person visit

Medicare – Telehealth

Extends the following telehealth flexibilities through December 31, 2024:

Audio-only: Some services can be delivered using **audio-only communication** platforms.

Hospice recertification: telehealth can be used for certifying hospice eligibility.

Frequency Limits: Removing frequency limitations for certain subsequent inpatient visits, subsequent nursing facility visits and critical care consultation services

Direct Supervision of Clinical Staff: Continuing to allow for "direct supervision" to permit the presence and "immediate availability" of the supervising practitioner through real-time audio and visual interactive telecommunications (pre-PHE "direct supervision" could only be met via in-person "immediate availability") (CMS sought comment on whether to extend the flexibilities related to direct supervision and virtual presence of teaching physicians beyond CY 2024 and will consider addressing this topic in possible future rulemaking)

Medicare – Telehealth

Extends the following telehealth flexibilities through December 31, 2024:

Telehealth in Teaching Settings: Continuing to allow teaching physicians to have a virtual presence in all teaching settings, but only in clinical instances when the service is furnished virtually (for example, a three-way telehealth visit with all parties in separate locations)

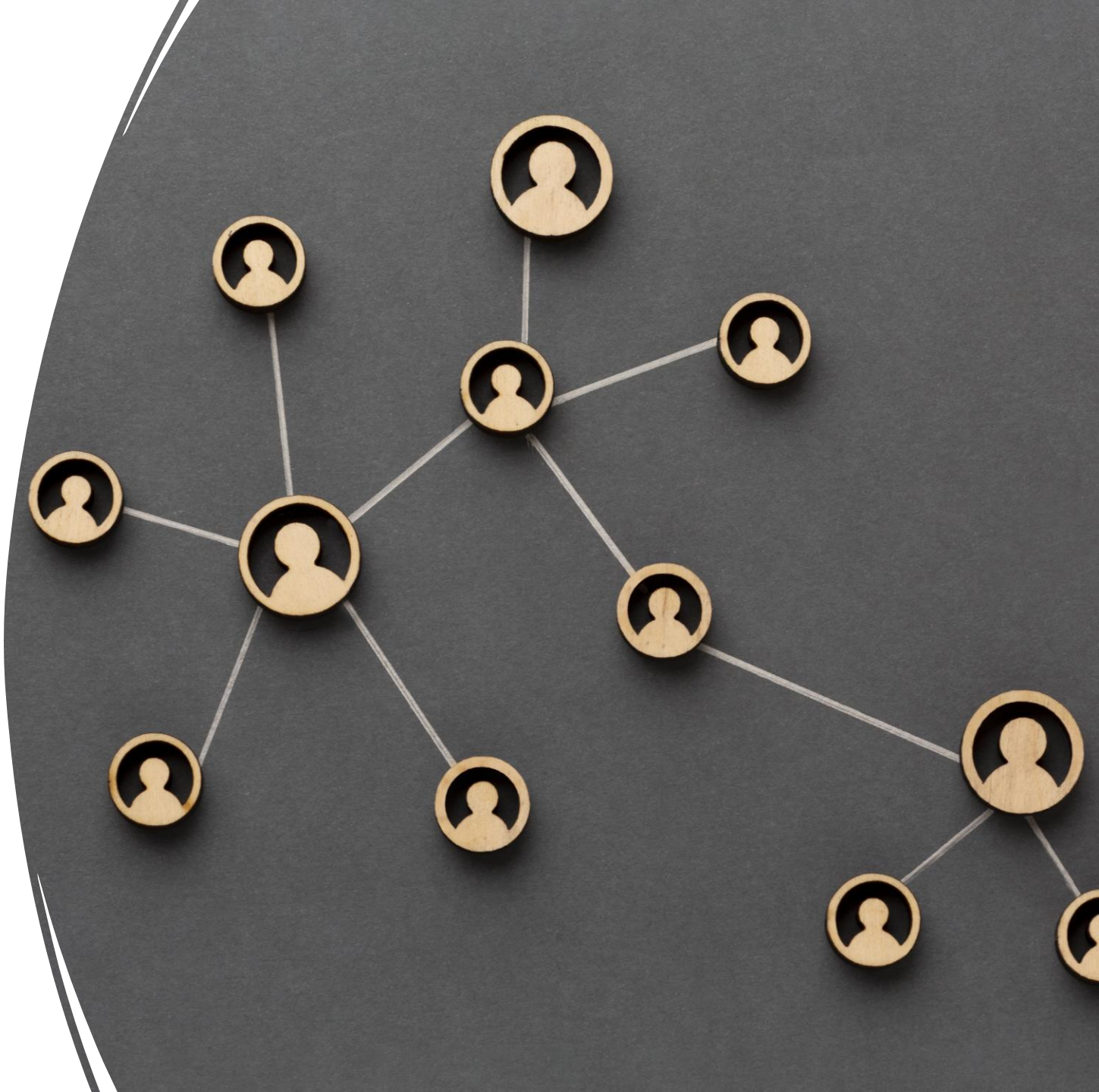
Outpatient Therapy, Diabetes Self-Management Training and Medical Nutrition Therapy: Continuing to allow outpatient therapy (physical therapy, occupational therapy, speech-language pathology), diabetes self-management training and medical nutrition therapy to be provided via telehealth when delivered by institutional staff

Telehealth for Opioid Treatment Providers: Allowing periodic assessments to be furnished via audio-only communications technology when video is not available, to the extent that use of audio-only communications technology is permitted under the applicable Substance Abuse and Mental Health Services Administration (SAMHSA) and Drug Enforcement Administration (DEA) requirements at the time the service is furnished and provided that all other applicable requirements are met

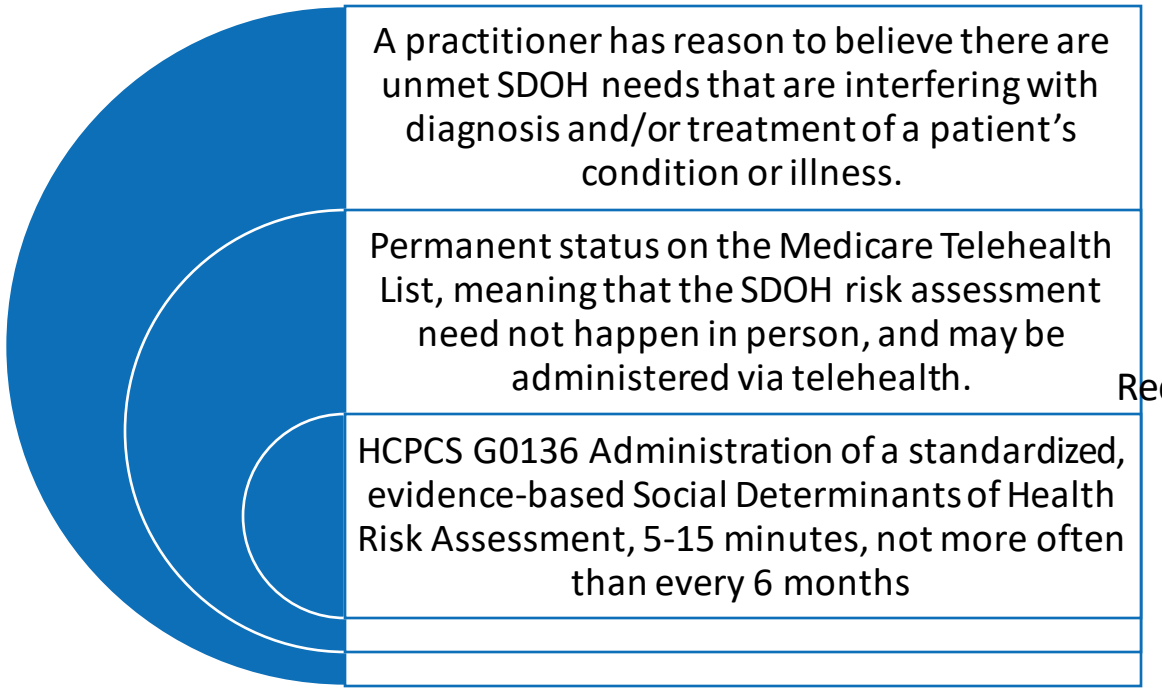
Practitioner Home Address Reporting: In response to provider safety concerns expressed by public commenters regarding the expiration of provider enrollment requirement flexibilities for distant site telehealth practitioners, CMS extended the flexibility to use the practitioner's currently enrolled location instead of their home address when providing services from their home through CY 2024 and will consider the issue further for future rulemaking.

Medicare - Telehealth and SDOH

Permanent addition of HCPCS code GXXX5 to Telehealth Code *"Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment tool, 5-15 minutes."*



Medicare - Social Determinants of Health Screening



Requirements:

- SDOH risk assessment must be furnished by the practitioner as part of an E/M or behavioral health visit and requires the administration of a standardized, evidence-based validated SDOH risk assessment tool
- Includes: food housing, transportation, and utility insecurities
- Limitation of one assessment per six-month timeframe.
- Must be tied to one or more known or suspected SDOH needs.
- The code can also be furnished with the psychiatric diagnostic evaluation code (90791) and the Health Behavior Assessment and Intervention services codes (96156, 96158, 96159, 96164, 96165, 96167, and 96168).
- The code may also be used in conjunction with an Annual Wellness Visit

Remote Physiological Monitoring & Remote Therapeutic Monitoring

Medicare - RPM and RTM

Concurrent RPM and RTM billing

RPM or RTM (but not both) may be billed concurrently with the code sets for Transitional Care Management ("TCM"), Chronic Care Management ("CCM"), Behavioral Health Integration ("BHI"), Principal Care Management ("PCM"), and Chronic Pain Management ("CPM") services.

Caveat: language related to using multiple devices in the final rule is still contradictory and indicates that there may be certain scenarios where providers can order RPM and RTM in the same month.

Remote monitoring for established patients

RPM, but not RTM, requires an established patient relationship.

Any patients receiving RPM services from the end of the Public Health Emergency ("PHE") forward will need to be established patients before receiving RPM services.

For RTM, billing practitioner must establish a treatment plan prior to providing RTM services.

- It is likely best practice for a billing practitioner to examine a patient and establish a treatment plan prior to beginning an RTM program.

Treatment management codes do not require 16 days of data

16-day requirement does not apply to treatment management codes 99457, 99458, 98980, and 98981.

RPM will not be considered "primary care" under the MSSP

Medicare - RPM and RTM

Global service payments	Practitioners may bill and receive separate payment for RPM or RTM during a global service period, "so long as the remote monitoring services are unrelated to the diagnosis for which the global service was performed" and "as long as the purpose of the remote monitoring addresses an episode of care that is separate and distinct from the episode of care for the global procedure."
	There are instances in which providers are permitted to continue monitoring patients' unrelated conditions and receive separate payment from CMS during a global period.
	Practitioners who did not perform the global service and did not receive a global payment may bill for RPM or RTM for any condition within their scope of practice.
	Providers who perform global procedures and receive global payment cannot receive separate payment for RPM or RTM when the monitoring is directly related to the condition the global procedure addresses.
Supervision requirements	Physical therapist assistants (PTAs) and occupational therapy assistants (OTAs) no longer require direct supervision by a physical therapist (PT)/occupational therapist (OT) as had previously been the case when providing RPM or RTM services. They may now be supervised under the general supervision of PTs/OTs. This is a big win for those in the rehabilitation space.

Medicare – FQHC & RHC & RPM and RTM

Includes remote physiologic monitoring and remote therapeutic monitoring in the general care management HCPCS code G0511 when t*hese services are furnished by RHCs and FQHCs.*

- The code can be billed multiple times in the same month for different care management services, as long as the resource costs associated with each of the services are separately accounted for.
- The Final Rule does not appear to establish a maximum number of times the code may be billed in a given month.

FQHCS AND RHCS – Important Clarification

General care management G code, G0511 can be billed multiple times in a month

Clinician may select G0511 care management services –

RPM

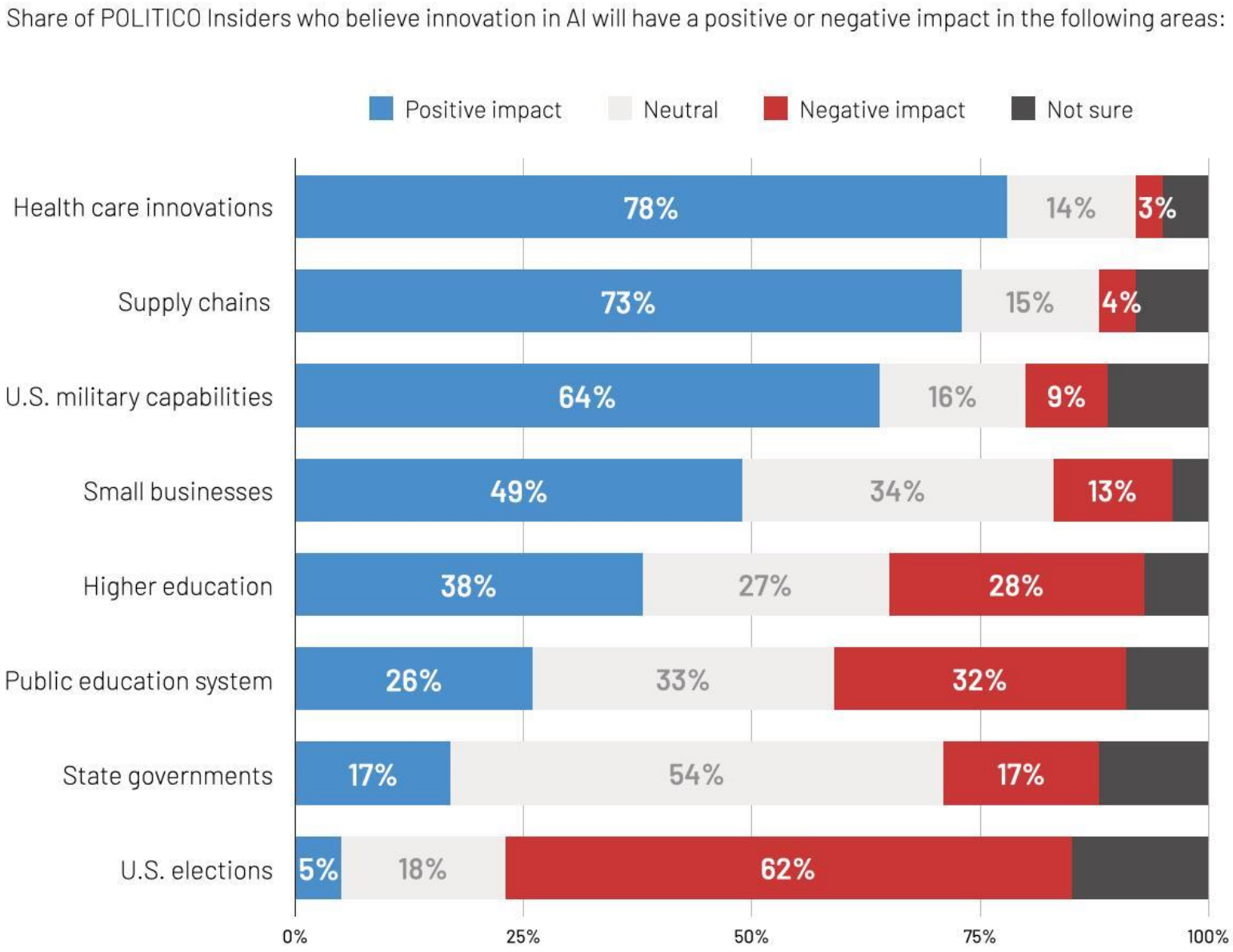
SDOH integration

CCM

Federal AI Policy Update

POLITICO
Insiders

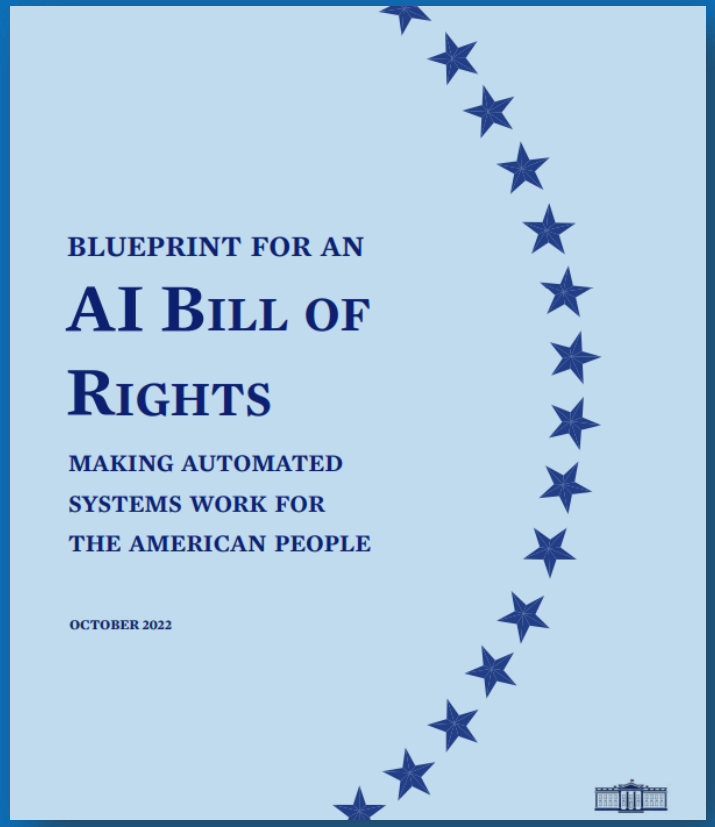
Where will AI make a positive impact?



Source: POLITICO Insiders

The Race to Regulate

Executive Orders	Federal Regulatory Enforcement	New Regulations (e.g., ONC HTI-1)	Sub-Regulatory Guidance
Federal Legislative Activity	State Regulatory Frameworks	State Legislative Activity	International Laws
Self-Regulatory Commitments and Attestations to Principles Frameworks	State Medical Boards	Non-Binding Policy Directives or Initiatives	Class Action and Malpractice Lawsuits



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SEPTEMBER 12, 2023

FACT SHEET: Biden-Harris Administration Secures Voluntary Commitments from Eight Additional Artificial Intelligence Companies to Manage the Risks Posed by AI

BRIEFING ROOM › STATEMENTS AND RELEASES

Builds on commitments from seven top AI companies secured by the Biden-Harris Administration in July

Commitments are one immediate step and an important bridge to government action; Biden-Harris Administration is developing an Executive Order on AI to protect Americans' rights and safety

Since taking office, President Biden, Vice President Harris, and the entire Biden-Harris Administration have acted decisively to manage the risks and harness the benefits of artificial intelligence (AI). As the Administration moves urgently on regulatory action, it is working with leading AI companies to take steps now to advance responsible AI. In July, the Biden-Harris Administration secured voluntary commitments from seven leading AI companies to help advance the development of safe, secure, and trustworthy AI.

DECEMBER 14, 2023

Delivering on the Promise of AI to Improve Health Outcomes

BRIEFING ROOM › BLOG

Lael Brainard, National Economic Advisor
Neera Tanden, Domestic Policy Advisor
Arati Prabhakar, Director of the Office of Science and Technology Policy

As President Biden has said, artificial intelligence (AI) holds tremendous promise and potential peril. In few domains is this truer than healthcare. The President has made clear, including by signing a landmark Executive Order on October 30, that the entire Biden-Harris Administration is committed to placing the highest urgency on governing the development and use of AI safely and responsibly to drive improved health outcomes for Americans while safeguarding their security and privacy.

The Administration is pulling every lever it has to advance responsible AI in health-related fields. We cannot achieve the bold vision the President has laid out for the country with U.S. government action, alone.

That's why we are excited that in response to the Administration's leadership, leading healthcare providers and payers have today announced voluntary commitments on the safe, secure, and trustworthy use and purchase and use of AI in healthcare. These voluntary commitments build on ongoing work by the Department of Health and Human Services (HHS), the AI Executive Order, and earlier commitments that the White House received from 15 leading AI companies to develop models responsibly. All told, 28 providers and payers have joined today's commitments: Allina Health, Bassett Healthcare Network, Boston Children's Hospital, Curai Health, CVS Health, Devoted Health, Duke Health, Emory Healthcare, Endeavor Health, Fairview Health Systems, Geisinger, Hackensack Meridian, HealthFirst (Florida), Houston Methodist, John Muir Health, Keck Medicine, Main Line Health, Mass General Brigham, Medical University of South Carolina Health, Oscar, OSF HealthCare, Premera Blue Cross, Rush University System for Health, Sanford Health, Tufts Medicine, UC San Diego Health, UC Davis Health, and WellSpan Health.

White House Executive Order on AI October 30, 2023

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Guiding Principles

Safety and Security | Innovation and Competition | Commitment to Workforce | Equity and Civil Rights | Consumer Protection | Privacy | Government Use of AI | Global Leadership

Requires development of guidelines, standards, and best practices for AI safety and security

Requires identifying and creating tools for content authentication and other provenance tracking

Certain developers have ongoing reporting obligations

Directs leaders of executive bodies to conduct risk assessments, develop strategies, and issue rules and guidance on pertinent AI issues in their respective sectors (e.g., health, intellectual property, employment)

Creates the White House Artificial Intelligence Council to coordinate agency activities

TBD: How agencies and other stakeholders will implement the EO's directives

SERIES: AI Enabled Digital Health Services

California Privacy Update

New California Privacy Laws

AB 352: Requires certain businesses that electronically store or maintain medical information (including on behalf of healthcare providers) to, by July 1, 2024, enable privacy, data segmentation, security and interoperability features to protect information related to abortion, contraception and gender-affirming care.

- Prohibits healthcare providers, service plans, contractors or employers from cooperating with an out-of-state investigation by providing medical information that could identify a person seeking or obtaining an abortion or abortion-related services.
- Prohibits healthcare providers from sharing medical information that would identify an individual and is related to abortion care via their electronic health record system or through a health information exchange (subject to certain exceptions).
- Providers could be subject to liability for noncompliance beginning January 31, 2026. Excludes health information related to abortions and abortion-related care from information sharing requirements under the California Health and Human Services Data Exchange Framework. Read more about AB 352 in McDermott's *On the Subject*.

AB 254: Revises the definition of "medical information" under the CMIA to include reproductive or sexual health application information, which the bill defines to mean information about a consumer's reproductive or sexual health collected by a reproductive or sexual health digital service.

- Makes a business that offers a reproductive or sexual health digital service to a consumer for the purpose of allowing the individual to manage the individual's information, or for the diagnosis, treatment or management of a medical condition of the individual, a provider of healthcare subject to the requirements of the CMIA. These businesses would also be liable for penalties for the improper use of disclosure of medical information under CMIA. Effective January 1, 2024.

Medi-Cal Update

Medi-Cal Range of Telehealth Policies

Consent

Requires providers to obtain consent once before the initial delivery of telehealth services. Enhances existing consent requirements to require additional information be shared regarding:

- Right to in-person services
- Voluntary nature of consent
- Availability of transportation to access in-person services when other available resources have been reasonably exhausted
- Limitations/risks of receiving services via telehealth, if applicable
- Notification of the beneficiary's right to make complaints about the offer of telehealth services in lieu of in-person care or about the quality of care delivered through telehealth

Medi-Cal Range of Virtual Services Policies

Medi-Cal including Federally Qualified Health Centers & Rural Health Clinics

Audio Only Reimbursement Requirements A patient may not be "established" using an audio-only synchronous interaction unless

- the visit is related to a "sensitive service", such as health care services related to mental or behavioral health, sexual and reproductive health, sexually transmitted infections, substance use disorder, gender affirming care, and intimate partner violence, as defined in the California Civil Code, section 56.05, subdivision (n), or
- if the patient requests "audio only" or
- does not have access to video

Source: https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/rural.pdf

Medi-Cal Range of Virtual Services Policies

Federally Qualified Health Centers & Rural Health Clinics

New Patient

May establish a new patient relationship through a **synchronous video interaction or asynchronous store** and forward **if all the following conditions are met**:

- The patient is physically present at an originating site that is a licensed or intermittent site of the FQHC or RHC at the time the service is performed.
- The individual who creates the patient records at the originating site is an employee or contractor of the FQHC or RHC, or other person lawfully authorized by the FQHC or RHC to create a patient record.
- The FQHC or RHC determines that the billing provider is able to meet the applicable standard of care.
- An FQHC or RHC patient who receives telehealth services shall otherwise be eligible to receive in-person services.

Established Patient

A Medi-Cal eligible recipient who meets **one or more of the following** conditions:

- The patient has a health record with the FQHC or RHC that was created or updated during a visit that occurred in the clinic **or during a synchronous telehealth visit in a patient's residence or home** with a clinic provider and a billable provider at the clinic. The patient's health record must have been created or updated within the previous three years.
- The patient is homeless, homebound or a migratory or seasonal worker (HHMS) and has an established health record that was created from a visit occurring within the last three years that was provided outside the originating site clinic, but within the FQCH's or RHC's service area. All consent for telehealth services for these patients must be documented.
- The patient is assigned to the FQHC or RHC by their managed care plan (MCP) pursuant to a written agreement between the plan and the FQHC or RHC.

Non-telehealth services: an e-consult, e-visit, or remote patient monitoring are not reimbursable telehealth services for FQHCs or RHCs.

Source: https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/rural.pdf

QUESTIONS?

Thank **You**

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