Center for Connected Health Policy

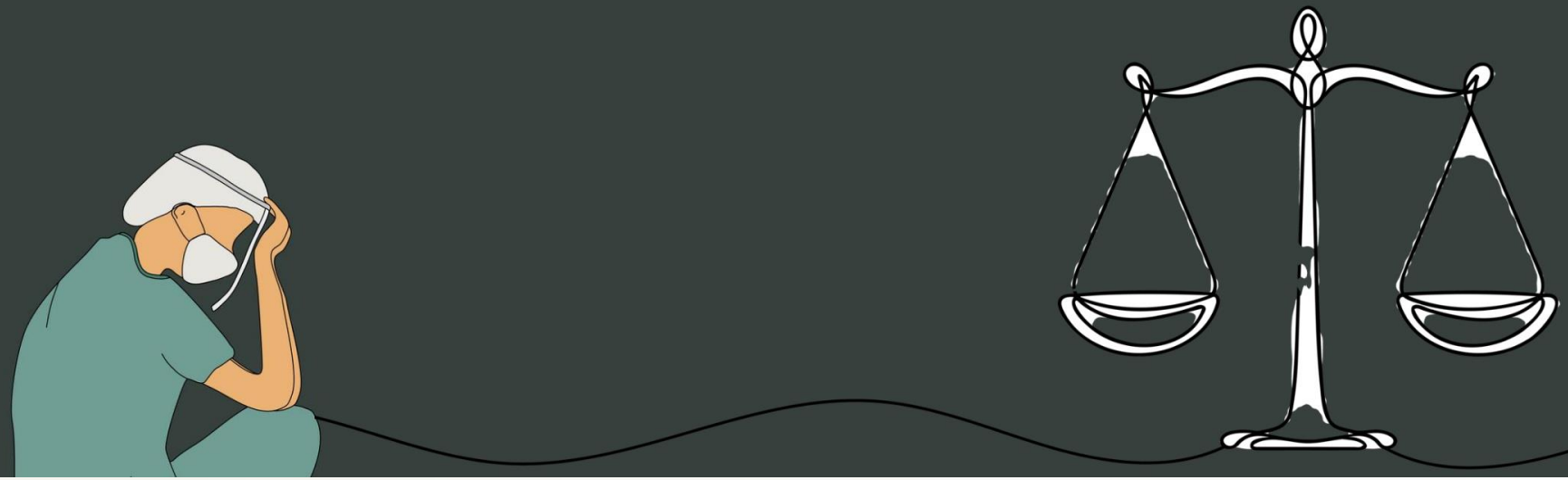
THE NATIONAL TELEHEALTH POLICY RESOURCE CENTER

The Webinar Series

THE IMPACT OF RECENT COURT CASES ON TELEHEALTH POLICY:

LOPER BRIGHT/ CHEVRON

AUGUST 28, 2024
11:00 AM PT



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- Please use the Q&A Button for your questions.
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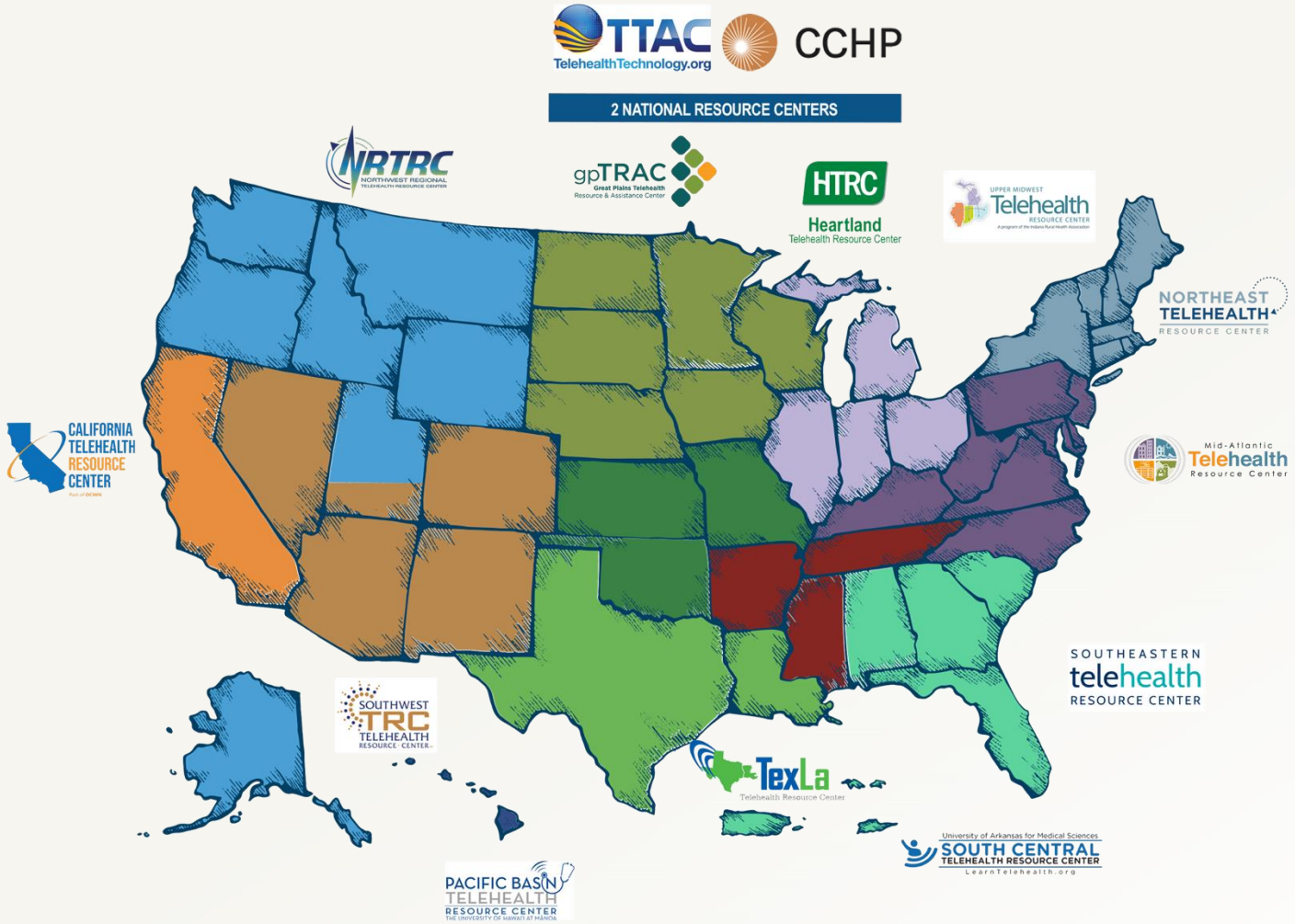
ABOUT CCHP

- Established in 2009 as a program under the Public Health Institute
- Became federally designated national telehealth policy resource center in 2012 through a grant from HRSA
- Work with a variety of funders and partners on the state and federal levels
- Administrator National Consortium of Telehealth Resource Centers
- Convener for California Telehealth Policy Coalition

NATIONAL CONSORTIUM OF TRCS



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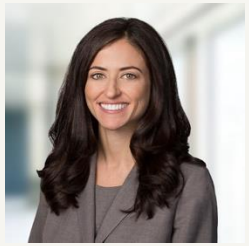
TODAY'S AGENDA

- What are the *Loper Bright* and *Chevron* cases?
- Why are these cases important in general to policymaking?
- How may the decision in *Loper Bright* impact telehealth policy?
- What might happen next?

SPEAKERS



Lori Rubin Garber
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Foley & Lardner LLP
Washington, D.C.

Lori Garber leads Foley & Lardner's Government Enforcement Defense & Investigations Practice Group. She is a government enforcement defense lawyer, health care litigator, and False Claims Act attorney. Lori defends clients all over the country in government investigations and enforcement actions, conducts internal investigations particularly as related to allegations of fraud or other wrongdoing, and files and defends health care litigation. She has significant experience litigating cases challenging regulations and other agency action by HHS and FDA. She has filed and won Administrative Procedure Act cases in federal district courts across the country.

Leah D'Aurora Richardson
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Leah D'Aurora Richardson focuses her practice on health law, representing academic medical centers, health systems, hospitals, hospices, and a range of ancillary service providers. She advises health care clients on complex regulatory, compliance, and transactional matters related to new business initiatives and existing service lines. Her experience includes compliance with fraud and abuse laws, anti-kickback statutes and physician self-referral laws, HIPAA and state privacy, security, breach notification rules, state licensure rules, government and commercial reimbursement issues, enterprise-wide health care and supply chain contract negotiations, and regulatory diligence.

Randi Seigel
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Randi Seigel provides legal and strategic counsel to health care providers, emerging health tech and services companies, women's health companies, insurers, and post-acute care providers. Randi brings substantial knowledge of complex health care regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and state privacy laws, state licensure and scope of practice laws, telehealth, artificial intelligence, Medicare and Medicaid conditions of participation and billing, fraud and abuse laws, and other regulatory and enforcement matters. Randi's deep understanding of the health care players—from commercial and government payors to providers—brings valuable insights to her clients to assist them as they develop and execute their strategic goals.

The APA, *Chevron*, & *Loper Bright*

The APA, *Chevron*, & *Loper Bright*

The Administrative Procedure Act (APA) (to extent pertinent here)

- A court must set aside agency action (rulemakings etc.) if "not in accordance with law."
- "To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action."

Chevron deference (1984-2024) (R.I.P.)

- If a statute is ambiguous, courts defer to the agency's interpretation so long as agency interpretation is a permissible reading of statute

Loper Bright (2024)

- "Courts need not and under the APA may not defer to an agency interpretation of the law simply because a statute is ambiguous."

What does an agency interpretation of statute have to do with anything?

- **Statutes** set forth requirements for federal healthcare programs (e.g., Medicare, Medicaid) regarding the coverage of items and services, and how, when, and by whom items and services may be furnished.
  - Congress authorizes agency action through statutes
- **Regulations** by HHS's components—CMS, FDA, CDC, etc.—implement the statutes and reflect the agency's statutory interpretation.
  - **If a regulation misconstrues statute, it could be invalidated under the APA**
  - Chevron deference made it difficult to win APA cases, as agencies did not need to have the correct or best interpretation of statute, only a permissible one
  - *Loper Bright* emphasizes statutory interpretation is firmly in the hands of the judiciary
- **Other agency action** may also reflect agency interpretation of statute (beyond regulations)
- **Beyond federal programs**: many states & private insurers tie requirements to those of federal programs

What will happen now?

Courts may invalidate regulatory provisions (or other final agency action) that go beyond what statute permits or that are based in an "incorrect" interpretation of statute.

This was the law before *Loper Bright* too, but what's new is that courts are no longer required—or even permitted—to defer to agencies on their "reasonable" interpretations of ambiguous statutory provisions.

What Does it Mean for Telehealth?

Telehealth Federal Enabling Legislation

Soc. Sec. Act 1834(m)	• Medicare will pay for telehealth services delivered in certain rural areas of the country (geographic site restrictions) and certain physical locations such as hospitals and physicians' offices (originating site restrictions) • A few exceptions for certain services such as home dialysis, stroke health, etc.
Ryan Haight Online Pharmacy Consumer Protection Act of 2008	• Requires practitioners to see a patient **in person** before prescribing controlled substances, including medications used to treat opioid use disorder (MOUD), unless one of seven statutory exceptions is met.
FDA (nexus)	• Regulates digital health and telehealth products; generally, takes a tailored, risk-informed regulatory approach to guidance (focusing on functionality that poses a risk to patient safety) • Examples include Mobile Medical App Guidance, Medical Device Guidance, Premarket and Post-market Cybersecurity Guidance, Interoperability Guidance

Summary of Medicare Coverage Prior to the PHE

Historically, Medicare coverage of telehealth has been limited, focusing on providing access to individuals in rural areas.

Telehealth

Medicare defines "telehealth as services that normally would occur in-person but instead are conducted via an interactive audio and video telecommunications technology; telehealth is paid at 100% of the in-person rates."

- Historically, only available to individuals in rural areas (Section 1834(m) of the Social Security Act) and located in certain provider settings (hospitals, physician offices).
- In most cases, the patient could not receive services from their home.
- Phones could not be used to deliver telehealth services.
- Practitioners generally could provide only evaluation and management or mental health services via telehealth.

Virtual Care Services

Medicare "virtual care services" are not normally delivered in-person. These are brief communications, including virtual check-ins and remote patient monitoring (RPM), that are paid at a lower rate.

- Previously could only be offered to established patients only.
- As with telehealth, could only be offered by practitioners who could bill evaluation and management-related codes.
- In 2019, Medicare started covering virtual check-ins and some monthly RPM codes, but limited RPM to patients with multiple chronic conditions.

These services were created as a workaround to statutory restrictions on telehealth.

Sources: The State of Telehealth Before and After the COVID-19 Pandemic; Kaiser Family Foundation, Medicare and Telehealth: Coverage and Use During the COVID-19 Pandemic and Options for the Future

Several Telehealth Policies Extended Through a Combination of Congressional Action, Regulation and Regulatory Preamble

In December 2023 Congress passed the Consolidated Appropriations Act, 2023, an omnibus funding bill that included several telehealth flexibilities extensions through December 31, 2024; CMS implemented these extensions through the Final CY 2024 MPFS.

Medicare telehealth flexibilities, which are central to enabling Medicare enrollees' access to a broad range of services via telehealth from any location, were been extended through December 31, 2024*:

- **In-Person Requirements for Mental Health Services:** Delaying the in-person visit requirement for telemental health services furnished by RHCs and FQHCs.
- **Originating Site and Geographic Restrictions:** Expanding the scope of telehealth originating sites for services furnished via telehealth to include any site in the United States where the enrollee is located at the time of the telehealth service, including an individual's home.
- **Eligible Providers:** Expanding the definition of telehealth practitioners to include qualified occupational therapists, qualified physical therapists, qualified speech-language pathologists and qualified audiologists (and adding marriage and family therapists (MFTs) and mental health counselors (MHCs) to the list of eligible providers).
- **Audio-Only:** Continuing coverage of certain audio-only telehealth services on the Medicare Telehealth Services List.

- Source: CY 2024 Physician Fee Schedule, Manatt, Final CY 2024 Medicare Physician Fee Schedule Extends Many Telehealth Flexibilities Through 2024

Drug Enforcement Administration Extension of PHE Telehealth Flexibilities for Prescription of Controlled Medications

In response to the PHE, the DEA implemented temporary flexibilities to enable prescribing of schedule II-V controlled substances via telehealth.

Timeline of DEA Activities

During the PHE

DEA granted temporary exception to allow for the prescription of schedule II-V controlled substances via telehealth encounters, even in situations where the prescribing practitioner had not conducted an in-person medical evaluation with the patient.

February 2023

DEA issued proposed rules that would reinstate strict limitations on the virtual prescribing of controlled substances:

- Schedule II medications or narcotics would require an in-person prescription.
- Schedule III or higher medications, including buprenorphine, could be prescribed for 30 days via telehealth but would require an in-person visit before a refill.

March 2023

DEA issued a temporary rule extending the full set of telehealth flexibilities regarding prescription of controlled medications in place during the PHE through November 11, 2023.

October 2023

DEA issued a second temporary rule, extending the PHE's telehealth flexibilities through December 31, 2024.

Anticipates further DEA guidance by the end of 2024.

Sources: Manatt Health, Federal and State Telehealth Policy Tracker (December 2023); Fierce Healthcare; DEA Proposed Rules; DEA First Temporary Rule; DEA Second Temporary Rule; White House Announcement

Note: In February 2024, the Biden Administration announced new actions to expand access to opioid use disorder treatment, including allowing initiation of methadone and buprenorphine treatments via telehealth.

Medicaid Coverage of Telehealth

- No Federal Medicaid law and regulations specifically address telehealth delivery methods or the criteria for implementation of telehealth
  - States have broad flexibility in designing the parameters of telehealth delivery methods to furnish services with few exceptions
- Medicaid Four-Walls Limitation (see 42 CFR 440.90)

Challenging Federal Agency Oversight:
What Has *Loper Bright* Changed & Not Changed?

What Hasn't Changed

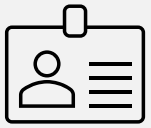
- Provisions/pronouncements may be safe unless/until challenged (and invalidated or withdrawn)
- Requirements to exhaust administrative remedies, standing, etc.
- Deference to agency when statute delegates discretion to the agency
- Deference to agency interpretation of agency's own regulations, where appropriate (*Kisor/Auer* deference)
- Deference to agency fact-finding and policy decisions
- Persuasive power of agency expertise to convince court of its interpretation of statute

What Changes are Expected?

- More legal challenges to regulations & other agency action (affirmative & defensive)
- Higher probability of success of legal challenges
- Less latitude to HHS to implement new requirements/programs
- Even slower rulemaking
- Risk of inconsistent judicial interpretations
- More express statutory language affording discretion to agencies

State Laws and Requirements

Key State Telehealth Legal Considerations



Provider Licensure

- Providers must be licensed to practice in the state where the patient is located
- Some states enable providers to practice across state lines via licensure compacts, telehealth registries or special licenses, or reciprocity agreements

Scope of Practice

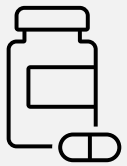
- State laws determine specific provider types eligible to deliver telehealth services

Establishment of New Patient Relationships

- Some states require providers to have an established relationship with a patient prior to the delivery of telehealth services

Eligible Telehealth Modalities

- State laws can limit eligible covered modalities (e.g., video visits, audio-only visits, among others)

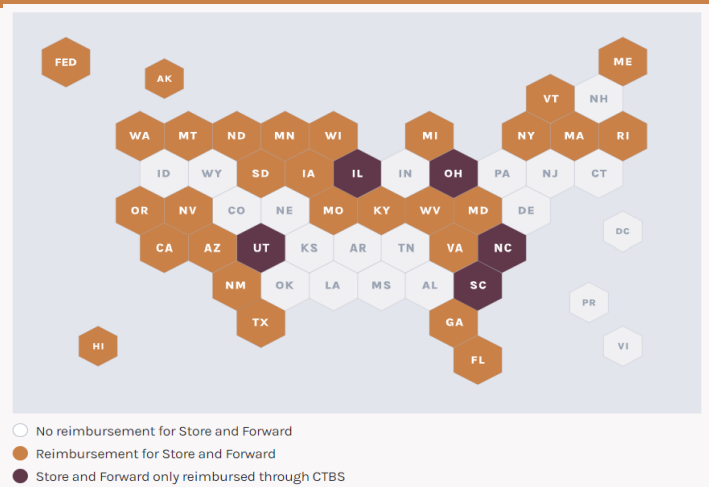


Pharmacy Prescribing and Dispensing Requirements

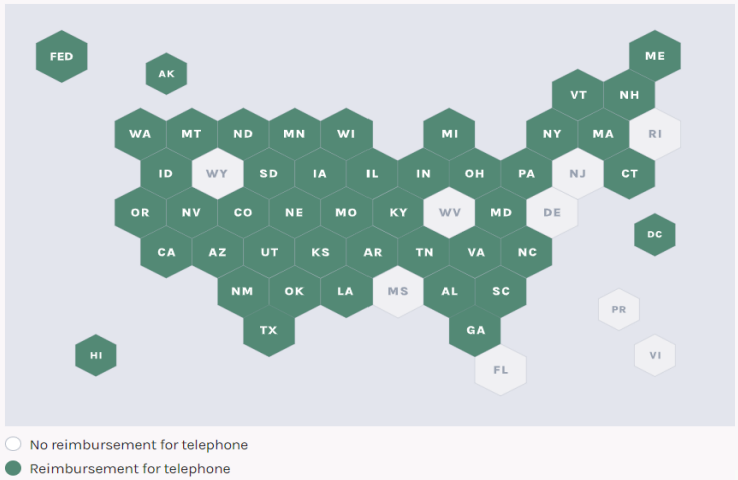
National Medicaid Reimbursement Landscape

Live Video Reimbursement
50 states/DC provide reimbursement

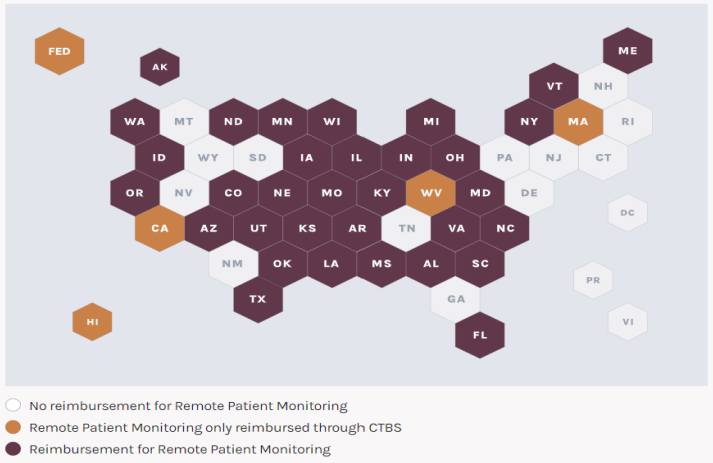
Store and Forward Reimbursement
33 states provide reimbursement



Telephone Reimbursement
43 states/DC provide reimbursement



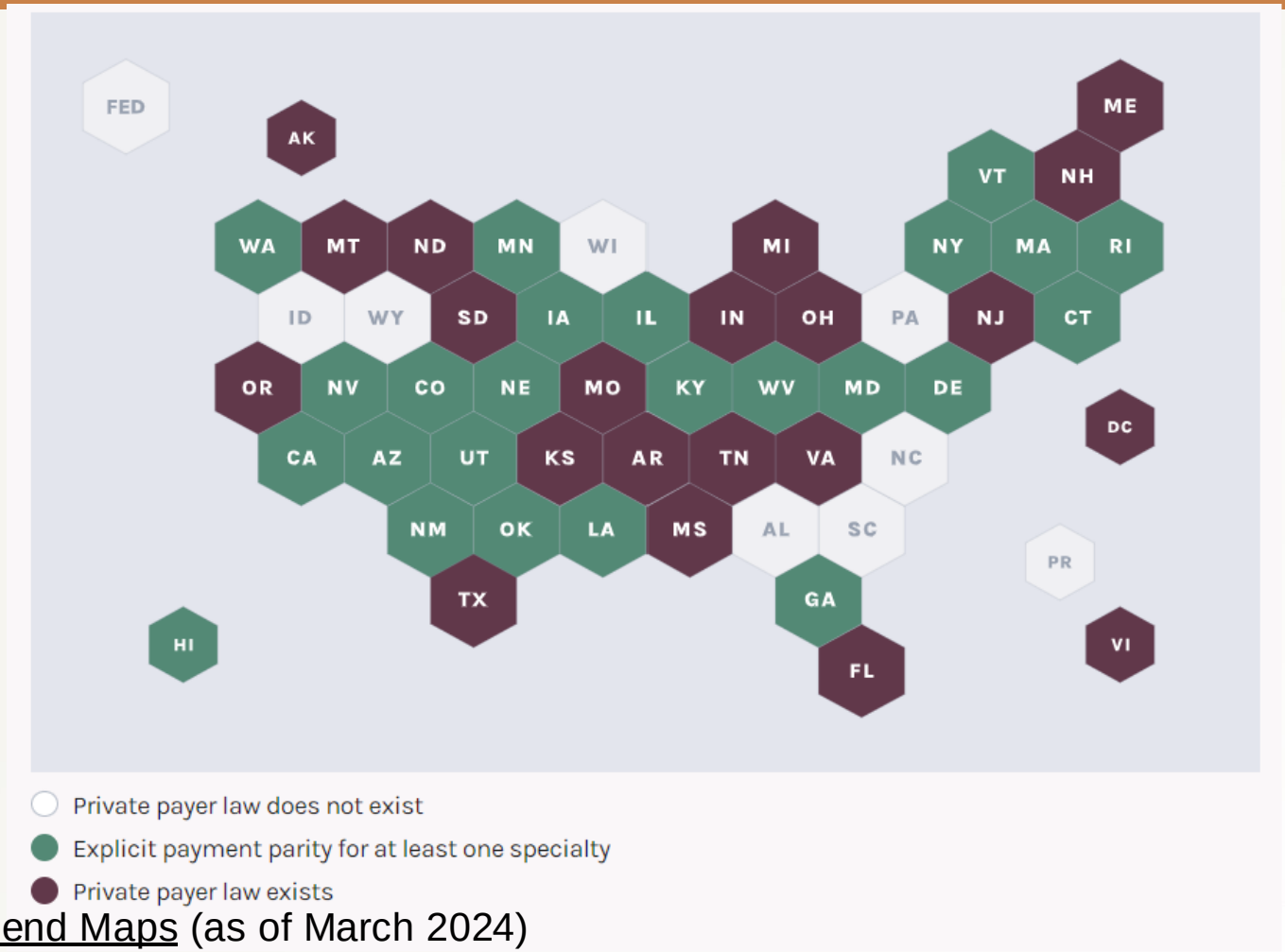
RPM Reimbursement
37 states provide reimbursement



- Source: CCHP, Policy Trend Maps (as March 2024)

National Commercial Reimbursement Landscape

Private Payer Laws
37 states provide reimbursement



- Source: CCHP, Policy Trend Maps (as of March 2024)

Loper Bright & State Policy

- *Loper Bright* does not directly impact whether state courts defer to state agencies on interpretation of state law (varies by state law).
- Prior to *Loper Bright*, there was already a patchwork in terms of which states permitted or required their courts to defer to state agency interpretations of statute.
- We could see a trend where more states follow suit under *Loper Bright*, though there is no legal mechanism compelling them to do so.
- HHS decisions to approve Medicaid state plans and amendments are subject to challenge under the APA. Thus, if HHS approved a Medicaid state plan amendment in a manner inappropriate under statute, *Loper Bright* could come into play.

Loper Bright & Telehealth Predictions

- Challenges are less likely against agency generosity (vs. agency restrictiveness)
  - And less likely to be viable, too
- Congress may amend statute to expressly permit agency discretion or be more express in terms
- States & private payors may follow suit

Panel Q&A

Please submit questions using the Q&A function.

THANK YOU!

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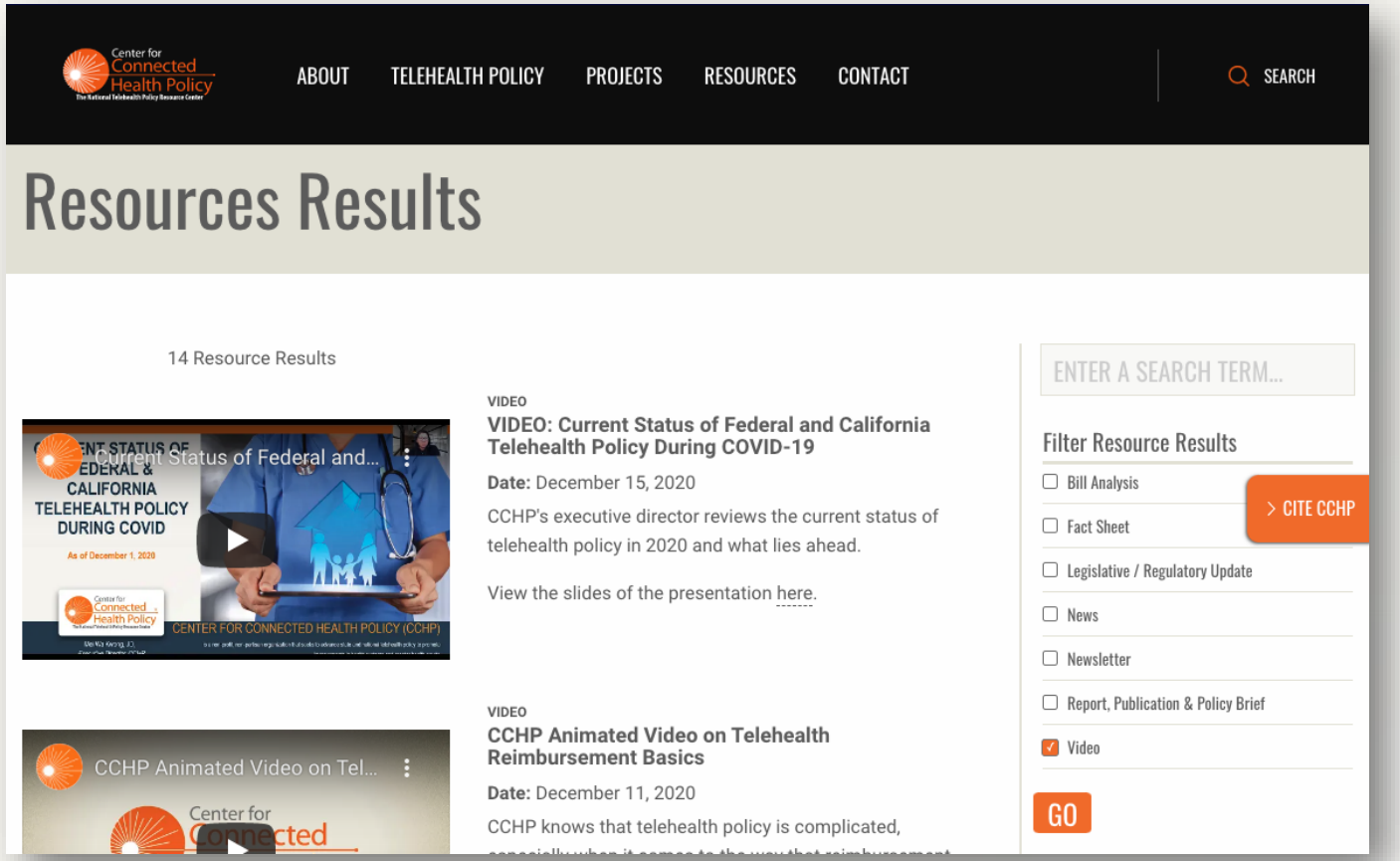

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CROSS-STATE LICENSURE COURT CASES

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