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TELEHEALTH: COVID-19 PANDEMIC UNLEASHES NEW PRACTICE MODALITY

Jake Harper, Ariel Seiersen & Paul St. Clair
June 1, 2020

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21st Century Workplace	Cybersecurity, Privacy and Big Data	Medtech, Digital Health and Science
Artificial Intelligence and Automation	Fintech	Mobile Tech
COVID-19	Global Commerce	Regulating Tech

Agenda

Telehealth in Our New Normal

Federal and State Approaches to Telehealth Services

Fraud and Abuse Enforcement

Increasing Scrutiny About Telehealth as Use Increases

Funding for Telehealth Initiatives

Role of FCC in Expanding Telehealth

TELEHEALTH: WHERE ARE WE NOW?

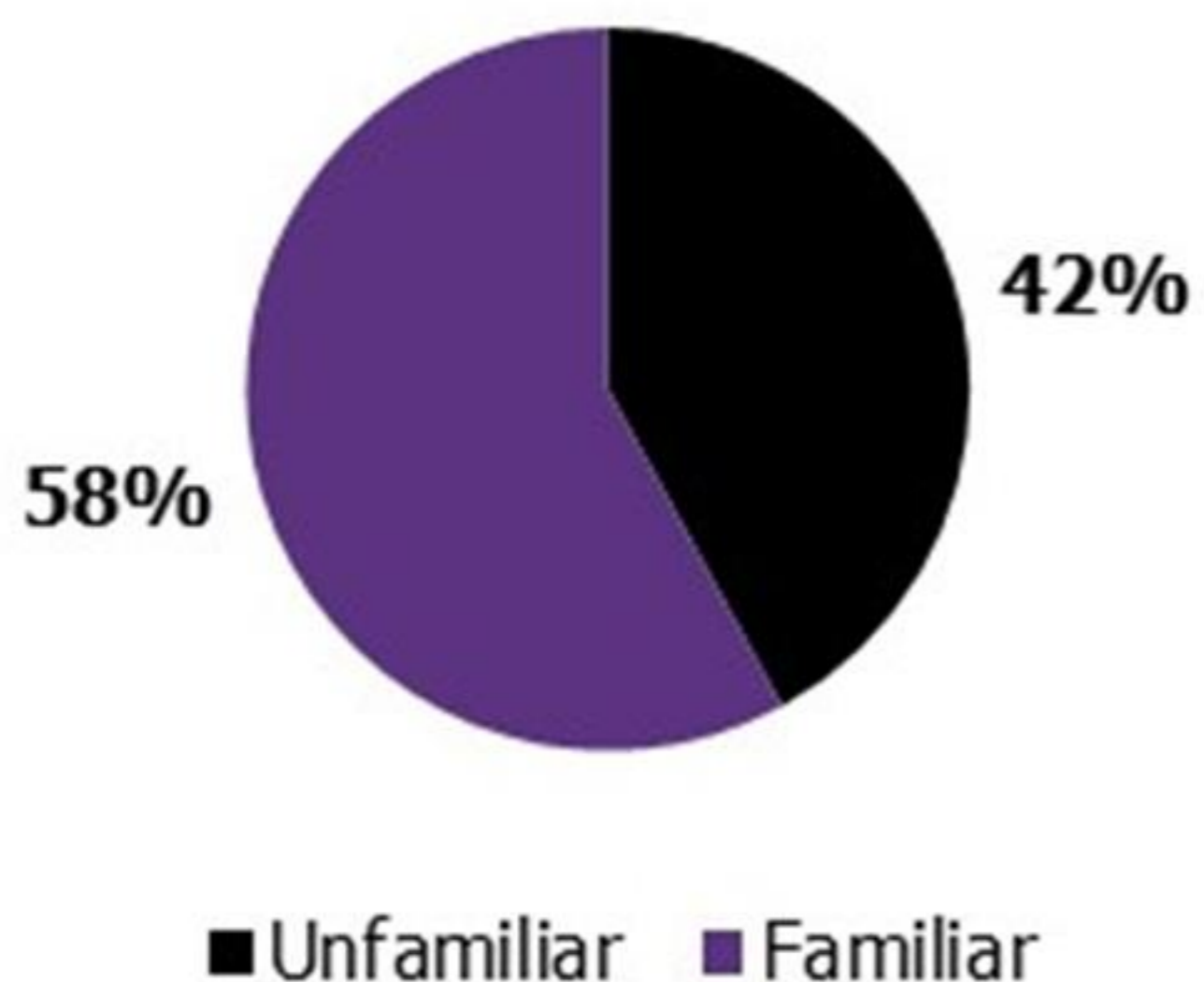
Public Perception of Telehealth

- Long viewed as an ancillary mode of treatment
 - Low acuity “check-ins”
 - Oversight for low risk medications
 - Limited to only a few subspecialties (i.e. dermatology)
- Skepticism of telehealth from medical community/boards
 - Internet questionnaires and online pharmacies in early 2000’s (Ryan Haight Act in response)
 - Standard-of-care questions
 - Need for specific set of rules regarding modalities, interaction between patient and provider

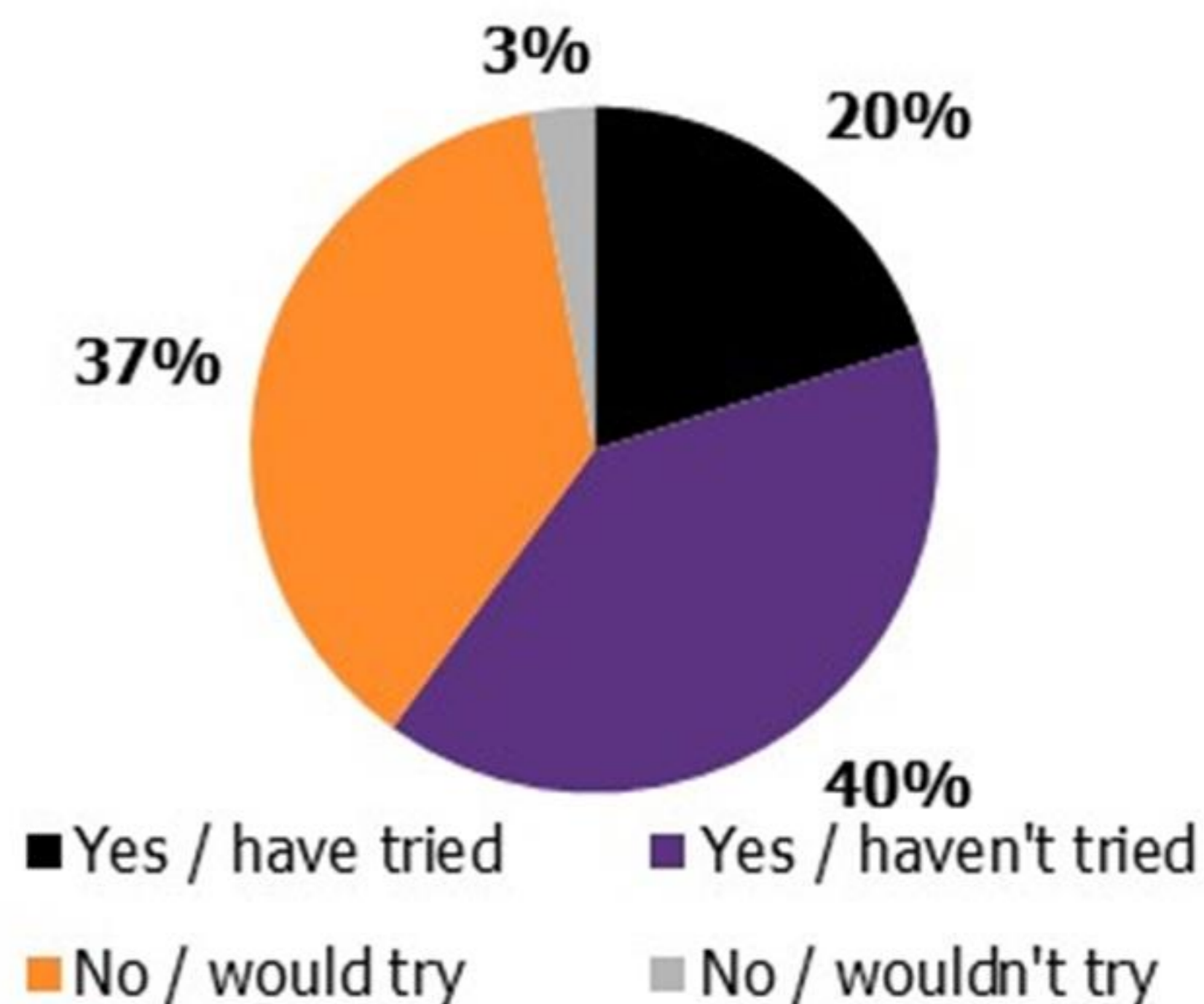
Public Perception of Telehealth

- COVID-19 Pandemic has immediately changed attitude toward telehealth, but much remains to be done:

Familiar with Telehealth?



Considered Telehealth?

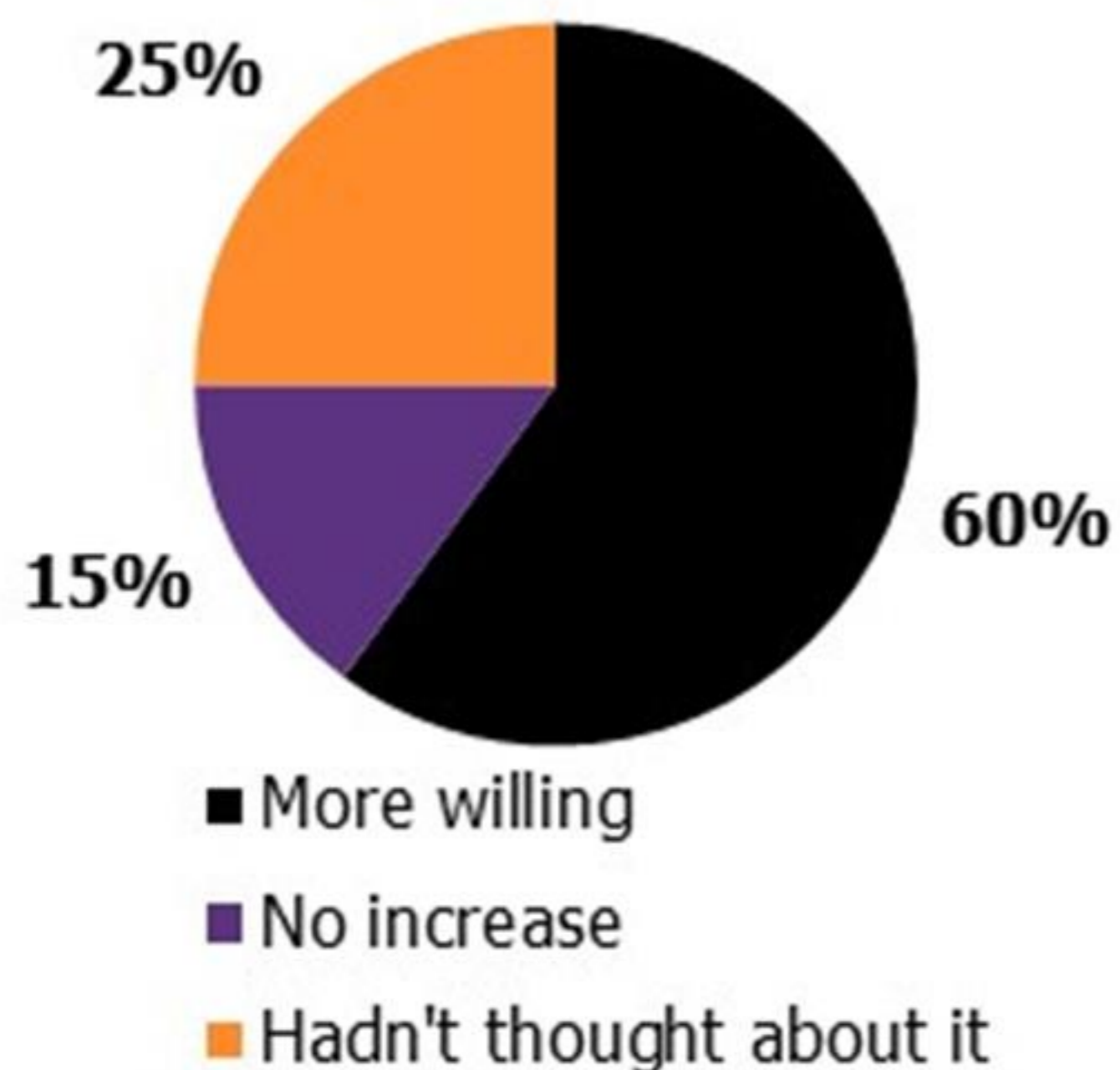


Source: Sykes 2020 Telehealth Survey, April 3, 2020

Public Perception of Telehealth

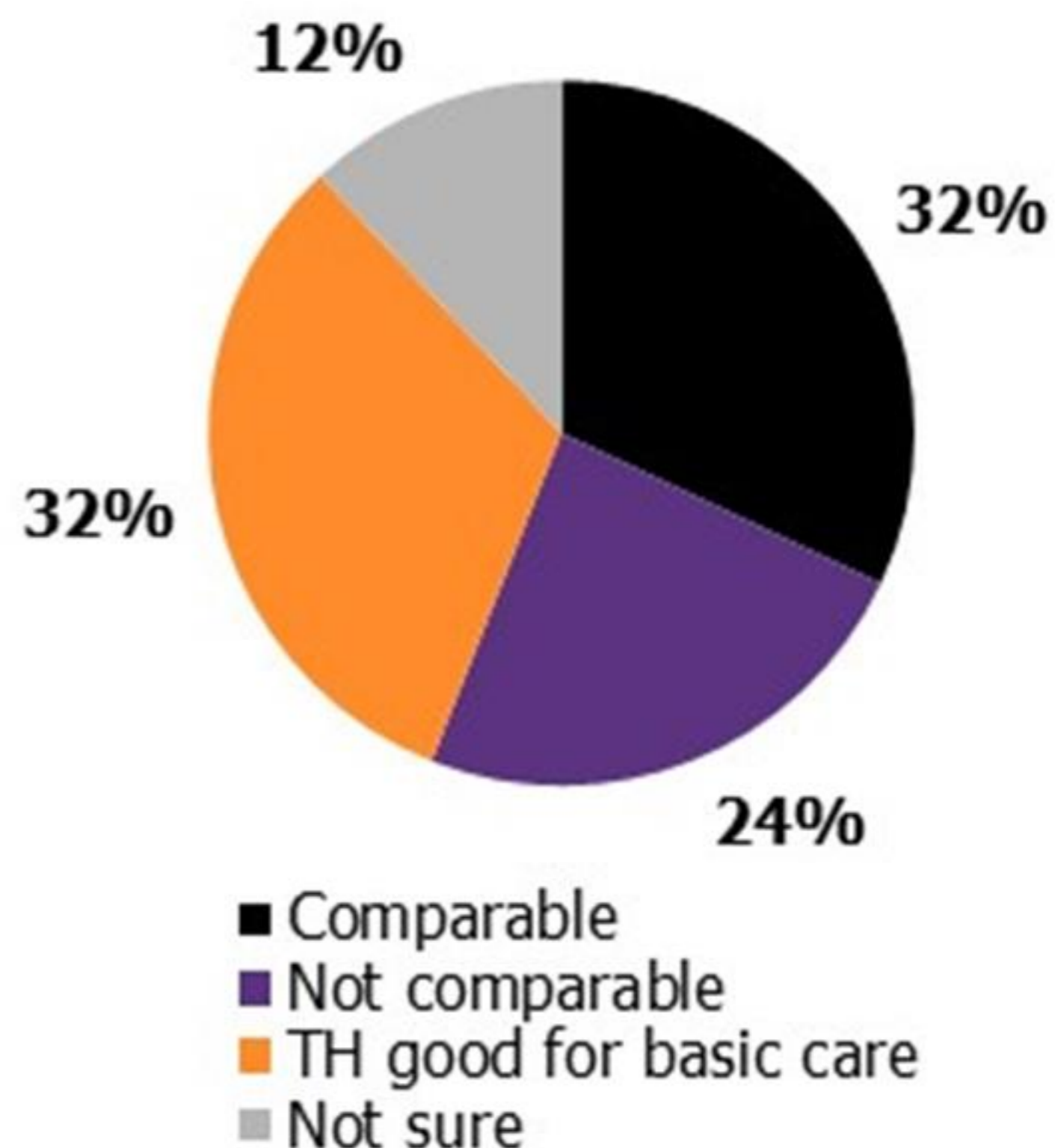
- COVID-19 Pandemic has immediately changed attitude toward telehealth, but much remains to be done:

COVID Effect on Telehealth?



Source: Sykes 2020 Telehealth Survey, April 3, 2020

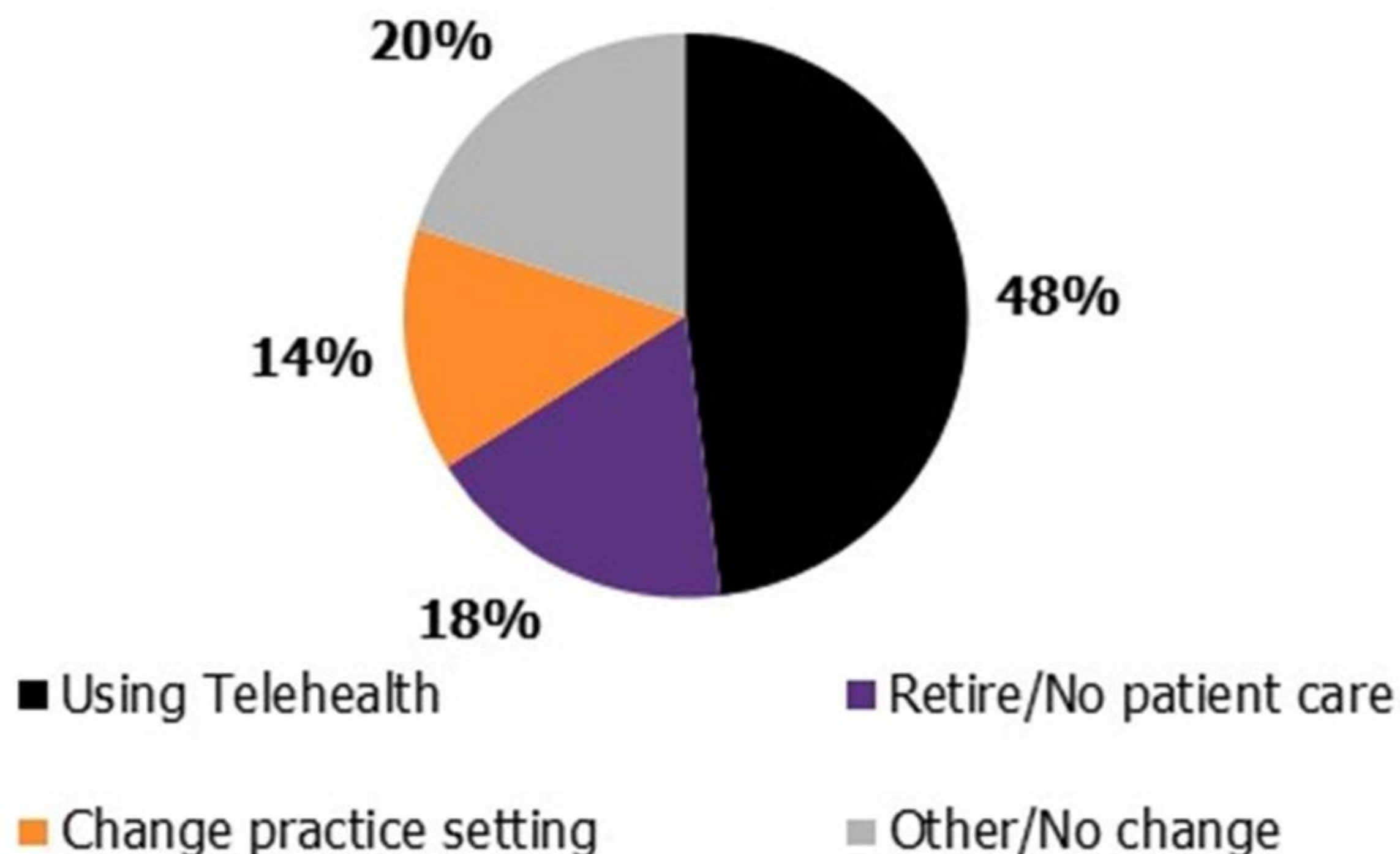
Compared to In-person?



Practitioner Reaction to COVID-19

- Similar results in physician community:

Practice Pattern Changes Due to COVID-19



Source: Merritt Hawkins Physician Survey, April 22, 2020

State Authorities on Telehealth

- In response to COVID-19 Pandemic, every state medical board and other professional licensure boards have made significant concessions related to practice modalities
 - Significant flexibilities related to licensure both on acceptable types of services and cross-state licensing
 - However, no indication of permanence
- Most state Medicaid programs have expanded telehealth access
 - Even audio-only encounters

Why now? Has standard of care changed or does telehealth meet the standard of care?

State Authorities on Telehealth

Reopening Dilemma



What goes back to pre-COVID framework?

What remains the same?

Most flexibilities only a result of gubernatorial emergency declarations, but what is in the power of the medical board?

Federal Telehealth Response

- Substantial response from federal government to address COVID issues, but most providers have been crippled
 - Loss of elective procedures
 - Increased administrative costs
 - Staff upheaval and patient behavioral change

Nearly every health system anticipating multi-million dollar loss this year

Federal Telehealth Response

On March 6, Congress passed its first COVID-19 related bill

- Coronavirus Preparedness and Response Supplemental Appropriations Act (CPRSAA)
- This law temporarily sets aside geographic area and originating site restrictions

On March 27, Congress passed the CARES Act, which contained several important telehealth related provisions

- Emphasis on treating patients at home, remotely
- Allowance for home health, hospice, and SNF providers

Federal Telehealth Response

On March 29, CMS issued a massive rule that enhances access to telehealth services for Medicare patients

- The IFR is far-reaching and creates substantial flexibility for nearly all healthcare services to be rendered via telehealth
- Removes certain service limitations and practice modality requirements

On April 28, CMS followed up with another rule that further

- Addresses the provision of telehealth services, including through audio-only modes,
- Provides limited reimbursement to hospitals through a complex "provider-based" methodology

Federal Telehealth Response

OIG and OCR Enforcement Policy Discretion Statements and CMS Waivers

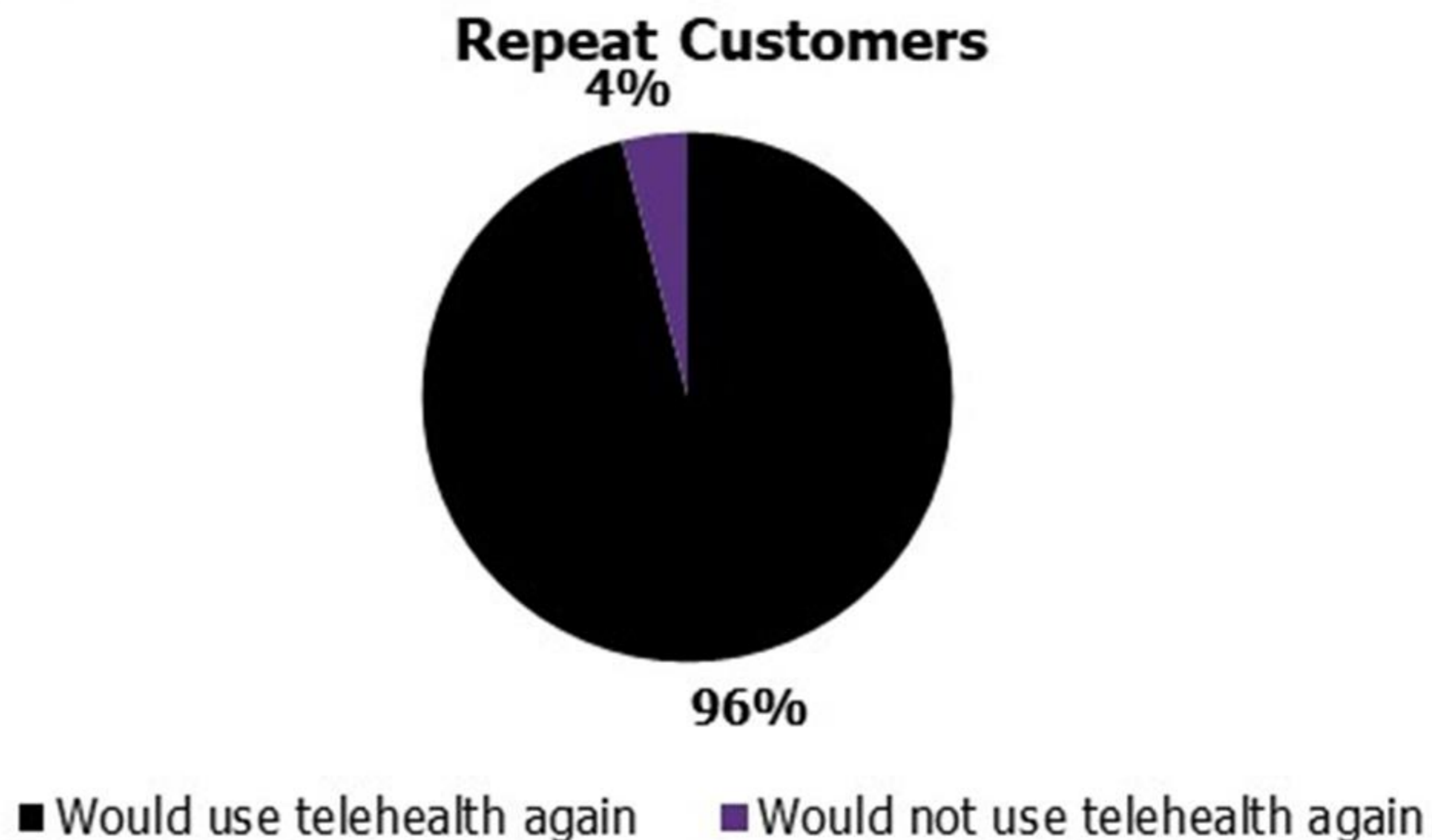
- Nearly all laws still apply in the current environment, but most will not be enforced against provider operating in good faith

Federal Licensure Waivers

- No requirement for in-state licensure for purposes of Medicare/Medicaid reimbursement (but note this depends on state law as well)

What Do We Do Now?

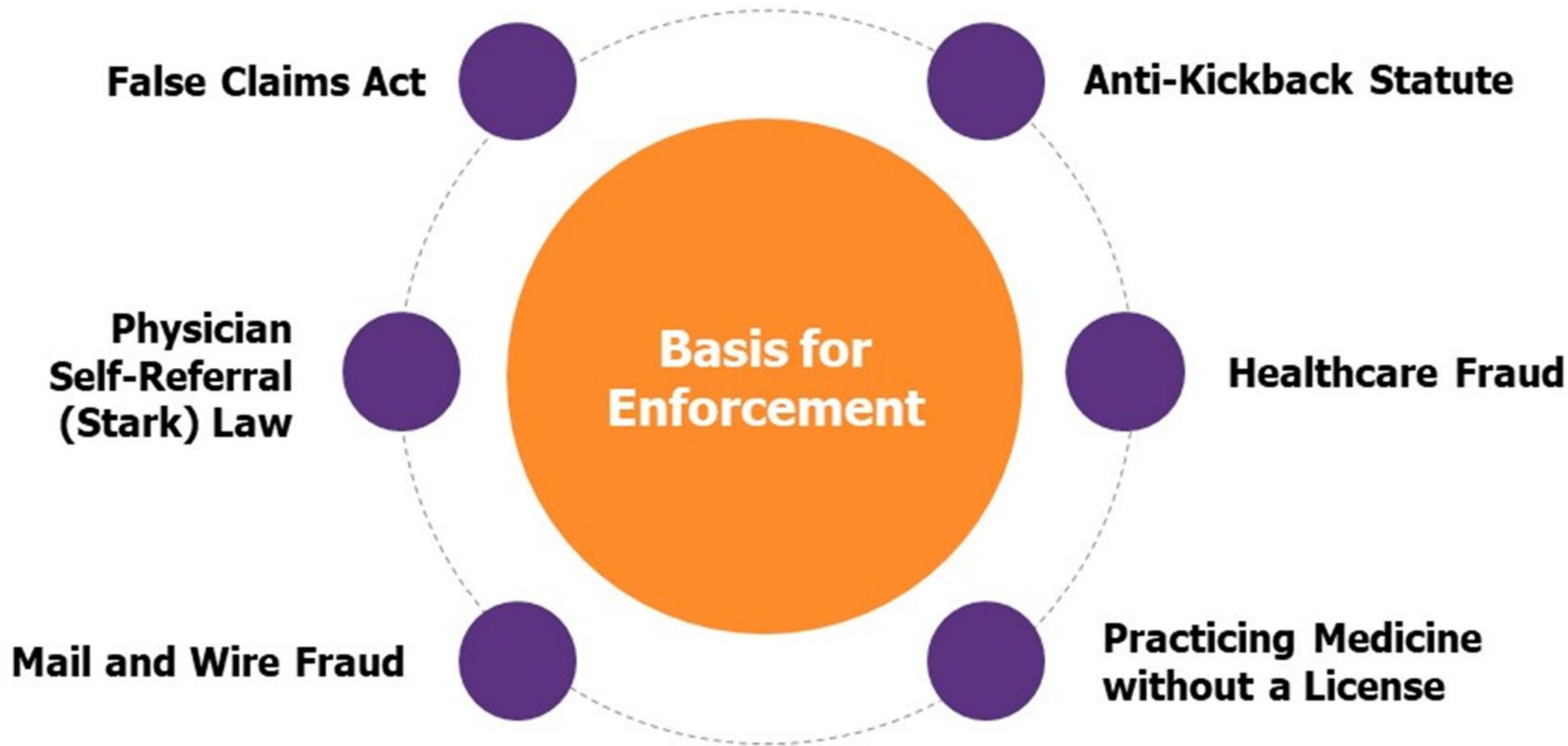
- Is telehealth here to stay?
 - Survey says...



What Do We Do Now?

- But, practice is limited by state licensure boards and payors
 - What is allowed?
 - What will be reimbursed?
- Public demand does not necessarily equate to permission.
 - Will changing infrastructure, public expectations, and practitioner feedback and response force the hand of governmental authorities?

TELEHEALTH & GOVERNMENT ENFORCEMENT



Medicare Fraud

- US Department of Health and Human Services Report, April 2018
 - Originating site fraud
 - Unallowable means of communication
 - Cross-state licensing
 - Non-covered services
 - Non-US doctor
 - Relatively small Medicare spending, room for compliance development with technology growth

Recent Federal Actions

CASE NAME

United States v. Wilson (D. N.J. 2020)

United States v Harry, et al (D. N.J. 2019)

United States ex rel. Medrano and Lopez v. Diabetic Care Rx LLC (S.D. Fl. 2019)

DETAILS

- Two telehealth company owners indicted in conspiracy to defraud Medicare receive illegal kickbacks in \$56 million scheme for orders of orthotic braces and prescriptions.
- Owner and CEO of a telemedicine company pleaded guilty in conspiracy to defraud Medicare and receive illegal kickbacks in exchange for orders of durable medical equipment stemming from role in one of the largest healthcare fraud schemes ever investigated. The scheme involved more than \$800 million in loss.
- Settlement resolving allegations that Diabetic Care Rx paid kickbacks to outside marketers to target military members for compounded creams and vitamins formulated to ensure highest possible TRICARE reimbursement. Marketers allegedly paid telemedicine physicians to prescribe these creams and vitamins without seeing or speaking to patients.

Recent Federal Actions

CASE NAME

United States v. Hoobler
(N.D. Ga. 2020)

United States v. Garipoli
(S.D. Fl. 2019)

DETAILS

- Woman arrested for alleged role in conspiracy to defraud Medicare by paying illegal kickbacks to co-conspirators at telemedicine companies to obtain orders for unnecessary genetic testing. Beginning in February 2020, she agreed with others to be paid kickbacks on a per-test basis for COVID-19 tests bundled with other more expensive tests.
- 35 individuals charged for allegedly engaging in a \$2.1 million kickback scheme between cancer genetic testing laboratories and medical professionals working with telemedicine companies.

Recent State Actions

CASE NAME

Hageseth v. Superior Court
(Cal. Ct. App. 2017)

Golob v. Arizona Medical Board
(Ariz. Ct. App. 2008)

DETAILS

- Physician sentenced to nine months in prison for contracting with a web-based prescription service to review patient responses to questionnaires and prescribing medications.
- State medical board's sanctions upheld for physician's issuing of prescriptions based almost entirely on online questionnaires.

Future of Enforcement

- The Department of Justice and US Department of Health and Human Services continue to prioritize the investigation and prosecution of healthcare fraud.
- New fraud schemes are emerging in light of the COVID-19 pandemic.

TELEHEALTH: TELECOM PERSPECTIVE

Federal Communication Commission Response

- Keep Americans Connected Pledge
- Waiver of Gift Rules
- Dept. of Education Remote Learning
- COVID-19 Telehealth Program (CARES Act)
- Existing Mechanisms
 - Connected Care Pilot Program
 - Rural Health Care (RHC) Program



FCC Funding for Telehealth

**CARES Act –
COVID-19 Telehealth
Program**

**Connected Care
Pilot Program**

**Rural Health
Care Program**

CARES ACT

- “Phase 3” coronavirus response legislative package
- 800+ pages
- FCC Telehealth - \$200 million
- Rural Utilities Service Broadband Program - \$125 million
- Emergency loans for small businesses – utility payments
- Telemedicine

COVID-19 Telehealth Program Overview

1

\$200m, available until exhausted

2

As of May 28, 2020, the FCC approved funding for 185 health care providers in 38 states + DC for a total of over \$68 million in funding

3

Public and nonprofit, urban and rural HCPs receive up to \$1 million

4

Average award is ~\$360,000

5

Reimbursement program based on invoices (not a grant program)

COVID-19 Telehealth Program

- Who is Eligible?
 - **Non-profit or Public**
 - Urban or Rural
 - (1) post-secondary educational institutions offering health care instruction, teaching hospitals, and medical schools;
 - (2) community health centers or health centers providing health care to migrants;
 - (3) local health departments or agencies;
 - (4) community mental health centers;
 - (5) not-for-profit hospitals;
 - (6) rural health clinics;
 - (7) skilled nursing facilities and
 - (8) consortium of health care providers consisting of one or more entities falling into the first seven categories.

COVID-19 Telehealth Program

- What Devices and Services are Eligible?
 - Eligible services must use broadband Internet access service-enabled technologies to directly serve patients and be:
 - Remote
 - Medical, diagnostic, patient-centered, and treatment-related
 - Outside of traditional brick and mortar medical facilities
 - Integral to patient care
 - Telecommunications Services and Broadband Connectivity Services
 - Information Services
 - Connected Devices/Equipment
 - “themselves connected;” Bluetooth, WiFi.

COVID-19 Telehealth Program

- What can device manufacturers and service providers do?
 - Reach out to existing health care provider (HCP) customers/partners
 - Waiver of gift rules, competitive bidding requirements for existing relationships



FCC Funding for Telehealth

**CARES Act –
COVID-19 Telehealth
Program**

**Connected Care
Pilot Program**

**Rural Health
Care Program**

Connected Care Pilot Program

- Contemplated by the FCC prior to COVID-19 emergency
- Three-year pilot program
- Provides \$100 million in support to fund up to 85% of the costs of broadband services and equipment for health care providers
- Focuses on serving low-income and veteran patients
- Proposed pilot projects will need to be able to measure, report on patient outcome and impact data

Rural Health Care Program

- Longstanding Universal Service initiative consisting of:
 - Telecommunications Program
 - subsidizes the difference between urban and rural rates
 - Healthcare Connect Fund
 - Expansion of access in rural areas, regional broadband networks

Other Regulatory Considerations

- “Phase Four” Coronavirus Response Package
 - Draft HEROES Act includes funding for E-Rate program, Emergency Broadband Connectivity Fund, RHCP
 - Codifies Keep America Connected Pledge
 - Accelerates RDOF Auction by fast-tracking uncontested applicants
- Federal Trade Enforcement
 - Privacy, HIPAA, the FTC Act, the FTC Health Breach Notification Rule, and the patchwork of state laws

QUESTIONS?

The image features a complex digital environment with a perspective view of a central path. The path is defined by glowing lines and dotted patterns in shades of orange, yellow, pink, and blue. The background is filled with a dense network of similar glowing elements, creating a sense of depth and data flow. The overall aesthetic is futuristic and high-tech.

Morgan Lewis Coronavirus/COVID-19 Resources

We have formed a multidisciplinary **Coronavirus/COVID-19 Task Force** to help guide clients through the broad scope of legal issues brought on by this public health challenge.

Find resources on how to cope with the post-pandemic reality on our [NOW. NORMAL. NEXT. page](#) and our [COVID-19 page](#) to help keep you on top of developments as they unfold.

If you would like to receive a daily digest of all new updates to the page, please visit the resource page to [subscribe](#) using the purple "Stay Up to Date" button.

Biography



Jake Harper
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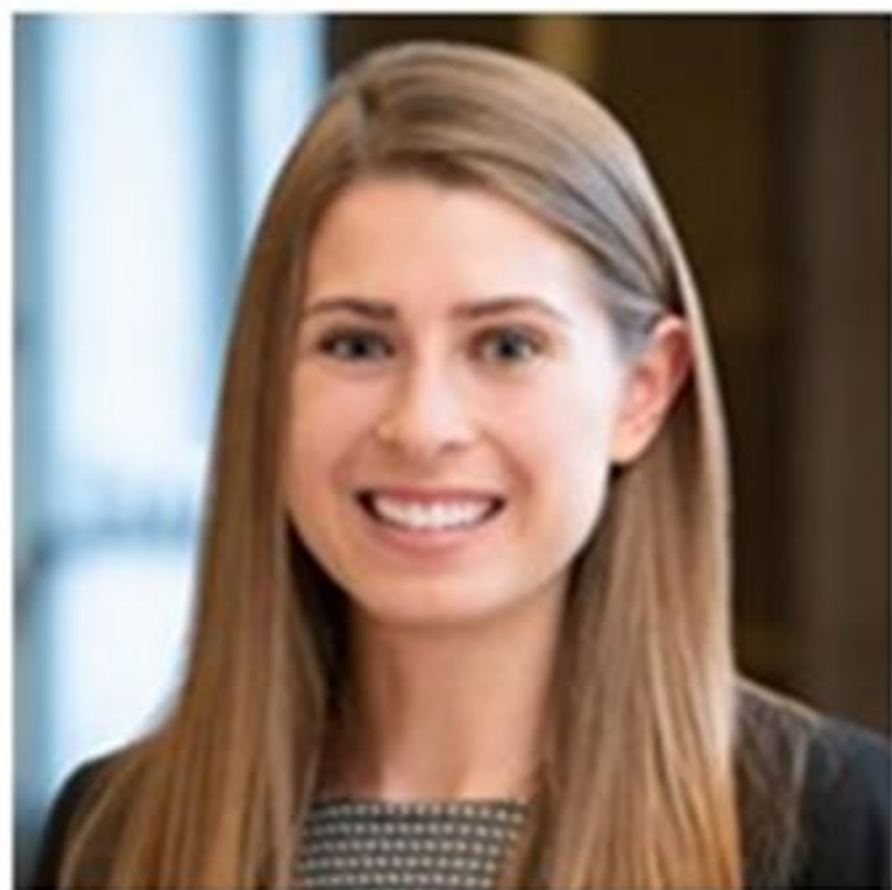
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Jake Harper advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, practice management companies, hospices, chain pharmacies, manufacturers, and private equity clients, on an array of healthcare regulatory, transactional, and litigation matters. Jake is a frequent speaker on telehealth operational and regulatory issues and is a Board Member for the Center for Telehealth and eHealth Law. His practice also focuses on compliance, fraud and abuse, and reimbursement matters, self-disclosures to and negotiations with OIG and CMS, internal investigations, provider mergers and acquisitions, and appeals before the PRRB, OMHA, and the Medicare Appeals Council.

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Ariel Landa-Seiersen represents clients in a variety of healthcare and litigation matters. Ariel works with a team of lawyers to advise clients in diverse areas, including government investigations, healthcare regulatory compliance, and antitrust matters. Ariel also maintains an active pro bono practice.

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Paul St. Clair has experience at the intersection of law, technology, and public policy. He works on regulatory, transactional, and compliance issues for US and international technology and communications clients. Prior to his position at Morgan Lewis he served as a legal intern at the Federal Communications Commission in the Office of Commissioner Brendan Carr, at the US Department of Commerce's Office of Policy Analysis and Development in the National Telecommunications & Information Administration, and in the nonprofit sector with the Open Technology Institute's Wireless Future Project. Prior to law school, Paul worked at Microsoft in the government affairs office in Washington, DC.

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