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## Reminder

The information contained in this presentation and delivered as part of this presentation are for educational and informational purposes only.

The views, opinions and positions expressed are mine alone and do not necessarily reflect the views, opinions or positions of my employers or affiliated organizations.



#### Federal

- Public Health Emergency
- Virtual Prescribing of Controlled Substances \*
- Regulatory Oversight and Drug Advertising

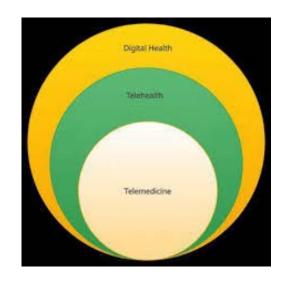
## State Level – (Arizona)

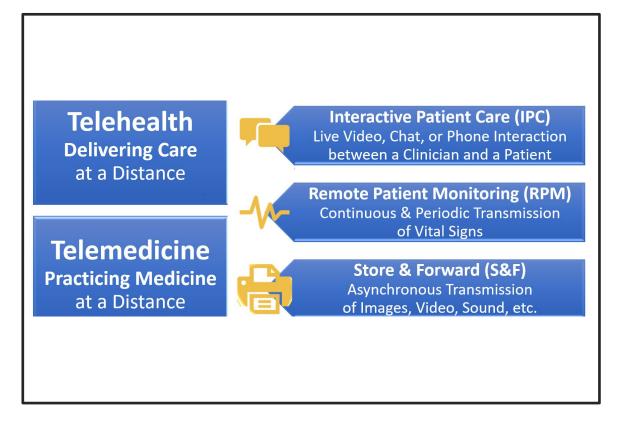
- Licensure Pathways
- Uniform Telehealth Act

## **Looking Ahead**

• Digital Equity Infrastructure

### **Definitions and Advancements**





## **Emerging Digital Health Tools and Patient's Role**

Services carried out using a variety of digital health technologies such as:

Only 5% of Medicare beneficiaries use RPM. <u>Estimates</u> project 25% by 2025.



**Synchronous Tools** (videoconferencing)



Asynchronous Tools (secure messaging, SMS)



Audio Digital Tools (phone calls)



**Digital Self-Care Tools** (applications that collect and store biometric data)



**Remote Home Monitoring** 



HTTPS://WWW.OUTSOURCING-PHARMA.COM/ARTICLE/2021/04/07/PATIENT-CENTRIC-APPROACH-MORE-IMPORTANT-THAN-EVER-DELOITI













### **Legislative Telehealth Definition**

Interactive use of audio, video or other electronic media, including asynchronous store-and-forward technologies and remote patient monitoring technologies, for the practice of health care, assessment, diagnosis, consultation or treatment and the transfer of medical data; and

Audio-only if an audio-visual telehealth encounter is not reasonably available due to the patient's functional status or lack of technology or infrastructure limits, as determined by the healthcare provider.



AZ HB 2454 Enacted May 2021

Title 36, Chapter 36
Public Health & Safety,
Telehealth

Sec. 3601: Definitions

Sec: 3601-3608

## **Legislative Telehealth Definition**

Delivery of medical services through HIPAA-compliant telecommunications systems, while the patient is located at an originating site and the licensee is located at a distant site.

CO HB 1190 Enacted May 2021

### **Legislative Telehealth Definition**

Use of synchronous or asynchronous telecommunication technology by a practitioner to provide health care to a patient at a different physical location than the practitioner.

#### **Uniform Telehealth Act**

drafted by the

NATIONAL CONFERENCE OF COMMISSIONERS ON UNIFORM STATE LAWS

and by it

APPROVED AND RECOMMENDED FOR ENACTMENT IN ALL THE STATES

at its

ANNUAL CONFERENCE
MEETING IN ITS ONE-HUNDRED-AND-THIRTY-FIRST YEAR
PHILADELPHIA, PENNSYLVANIA
JULY 8-13. 2022



WITH PREFATORY NOTE AND COMMENTS

#### **Telehealth Definition Impacts Reimbursement and Access**

## MEDICAID REIMBURSEMENT BY SERVICE MODALITY (Fee-for-Service)



Live Video



Store and Forward





Remote Patient Monitoring

34 states



As of Fall 2022



© Center for Connected Health Policy/Public Health Institu



#### Telehealth Advisory Committee on Telehealth Best Practices

Submitted <u>report</u> re: **audio-only** on 12/2021 and <u>amended</u> on 3/2022.

Payment parity between audio and video visits helps ensure there are no financial incentives to limit modalities that meet the standard of care.

## Federal

Public Health Emergency
Virtual Prescribing of Controlled Substances

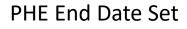
# PHE is Ending Key Dates for Telehealth

Consolidated Appropriations Act of 2023

Dec 29, 2022

PHE End Date (12<sup>th</sup> extension)

May 11, 2023



Jan 30, 2023

Telehealth Flexibilities End

Dec 31, 2024

#### **Disentangling Telehealth from the Public Health Emergency**

By Tara Sklar, JD, MPH on Jan 12, 2023



Five Key Telehealth Takeaways from the Consolidated Appropriations Act of 2023

https://telemedicine.arizona.edu/blog/disentangling-telehealth-public-health-emergency

#### **Extended to December 31, 2024**

<u>Legislation</u> signed on 12/29/22.

**Sec. 4113**. Advancing Telehealth Beyond COVID–19.

**#1**: Home is considered an originating site.

**#2:** Medicare reimbursement for audio-only telehealth services.

**#3:** In-person visits for telebehavioral health waived under CAA, but virtual prescribing for controlled substances tied to PHE.

**#4:** Extend pre-deductible telehealth waiver.

**#5:** Expand care options with eligible practitioners, safety net providers, and acute hospital care at home programs.

#### DEA's Proposed Rules for Telehealth Prescribing of Controlled Substances Post-PHE

Join us: March 23, 2023

9am PDT, 10am MDT, 11am CDT, 12pm EDT

#### Objectives:

- 1. Understand key provisions of the proposed rules and new process if the rules go into effect.
- 2. Increase understanding of the current public comment period and how to participate.
- 3. Learn what to do now in case the proposed rules go into effect post-PHE.

#### Presenters:

Christa Natoli, CTeL Executive Director

Ben Steinhafel, CTeL Director of Policy & External Affairs

Tara Sklar, JD, MPH, ATP Associate Director Telehealth Law & Policy
Facilitator: Elizabeth Krupinski, PhD, SWTRC Director





To register visit: www.Telemedicine.Arizona.edu

### Webinar recording:

https://swtrc.wistia.com/medias/xrud2yhaq2

## 30-day public comment period ended on March 31, 2023





Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation

**35,466** comments submitted

https://www.regulations.gov/document/DEA-2023-0029-0001



# Federal PHE ends on May 11, 2023 with return of:





Ryan Haight Online Pharmacy Consumer Protection Act (2008) in-person requirement for virtual prescribing of controlled substances returns unless DEA proposed rules become final.



Office of Civil Rights will no longer be exercising enforcement discretion on HIPAA non-compliance. 90-day transition without penalties to August 9, 2023.

https://www.hhs.gov/about/news/2023/04/11/hhs-office-for-civil-rights-announces-expiration-covid-19-public-health-emergency-hipaa-notifications-enforcement-discretion.html

# **Exceptions to the Ryan Haight Act's in-person requirement**



Patient is being treated in a DEA-registered hospital or clinic.

Patient is being treated in the physical presence of a DEA-registered practitioner.

Telehealth visit conducted by a DEA-registered practitioner for Indian Health Service.

Telehealth visit conducted during a PHE as declared by Secretary of the U.S. DHHS.

Telehealth visit conducted by a practitioner with a special telemedicine registration.

Telehealth visit conducted by a VHA practitioner during a medical emergency.

Telehealth visit conducted under other circumstances specified by DEA regulations.







## Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation

- ☐ Establish a qualified telemedicine referral pathway.
- □ Practitioner who issue a "telemedicine prescription," must have a DEA registration in both the state where the patient is located and the state where the practitioner is located. DEA registered practitioners do not need a "physical address" in each state they practice medicine.
- **180-day waiver** for in-person requirement for patients with an established telemedicine relationship.

## **Qualifying Telemedicine Referral**



Referring practitioner has conducted at least one inperson medical evaluation of the patient.

A qualifying telemedicine referral must note the name and National Provider Identifier (NPI) of the practitioner to whom the patient is being referred.

If the prescribing telemedicine practitioner receives a qualifying telemedicine referral for the patient, a prescription may be issued for any controlled substance.



#### Is my prescription a controlled medication?

#### NO, IT'S A NON-CONTROLLED MEDICATION

Many common prescriptions are non-controlled medications and will not be impacted by these rules, including:

- o Acne creams
- Blood pressure medications
- o Antibiotics
- Cholesterol medications
- o Birth control
- o Insulin

#### YES, IT'S A CONTROLLED MEDICATION

Controlled medications are classified into one of five schedules based on medical use and potential for abuse or dependency. Examples of common controlled medications include:

SCHEDULE II	Adderall
	Oxycodone
	Ritalin
	Vicodin
SCHEDULE III	Anabolic Steroids
	Buprenorphine
SCHEDULE IV	Ambien
	Tramadol
	Valium
	Xanax
SCHEDULE V	Lomotil
	<ul><li>Lyrica</li></ul>



or a complete list of controlled medications visit: tps://www.deadiversion.usdoj.gov/schedules/orangebo

#### Schedule III-V

UP TO 30-DAY INITIAL PRESCRIPTION







I have seen my medical practitioner in person I have seen another medical practitioner in person who referred me to a new medical practitioner I have not seen a medical practitioner in person and need a Schedule III, IV, or V medication or buprenorphine for medication for opioid use disorder

I have not seen a medical practitioner in person and need a Schedule II medication or narcotic

All prescriptions can be prescribed via telehealth

All prescriptions can be prescribed via telehealth

Prescription can be prescribed for 30 days via telehealth Prescription cannot be prescribed via telehealth

FOR REFILL

Must see a medical practitioner in person before

prescription

Must see a medical practitioner in person before prescription

## What happens next?

DEA has 41 days - April 1 to May 11<sup>th</sup>

DEA must conclude that proposed rule accomplishes the goals of the problems identified.

DEA must also consider whether alternate solutions would be more effective or cost less.

## Mismatch Between the Problem the DEA is Trying to Solve and the Proposed Rules

Effective oversight already exists via safeguards and data monitoring

#### **Safeguards**

- Business practices that confirm patient identity
- Policies that monitor for potential abuses
- Compliance with state law
- ☐ Approaches that assure effective oversight without limiting access via in-person visits

#### **Data**

Lack of evidence indicating abuse and diversion (aggregate or anecdotal)

## Disproportionate impact on marginalized groups, Medicaid beneficiaries, and counter to other federal efforts.

Gender affirming care and access to testosterone.

Veterans Health
Administration and Biden
Administration efforts to
improve access to
behavioral health
for veterans.

Patients at end of life on palliative care and hospice at home.

## **Health Affairs**

DEA Telehealth Proposal Brings Risks, Not Patient Protections

Georgia Gaveras, DO

MARCH 23, 2023

"Choosing a psychiatrist should not simply be determined by proximity.

Expertise, ability, and therapeutic alliance — the trust and safety a patient feels with their psychiatrist— are all critical for successful outcomes."

## Alternatives to a blanket in-person requirement

- ☐ Proposal not tenable given demand far exceeding supply.

  Half of U.S. counties have zero psychiatrists.
- ☐ Recognize short notice and lack of infrastructure.
  Change care delivery and business models (providers)
  Compliance and enforcement (DEA)
- Propose enforcement discretion by not require in person visit for established provider-patient relationships (beyond proposed 180-days) until end of December 31, 2024 (CAA 2023).

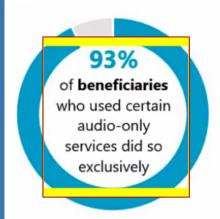
Almost 1 in 5 beneficiaries used certain audio-only telehealth services, with the vast majority of these beneficiaries using them exclusively.

- Older beneficiaries were more likely to use these audio-only services than younger beneficiaries.
  - Notable because older beneficiaries were less likely to use all telehealth services than younger beneficiaries.

Medicare Telehealth Services During the First Year of the Pandemic: Program Integrity Risks

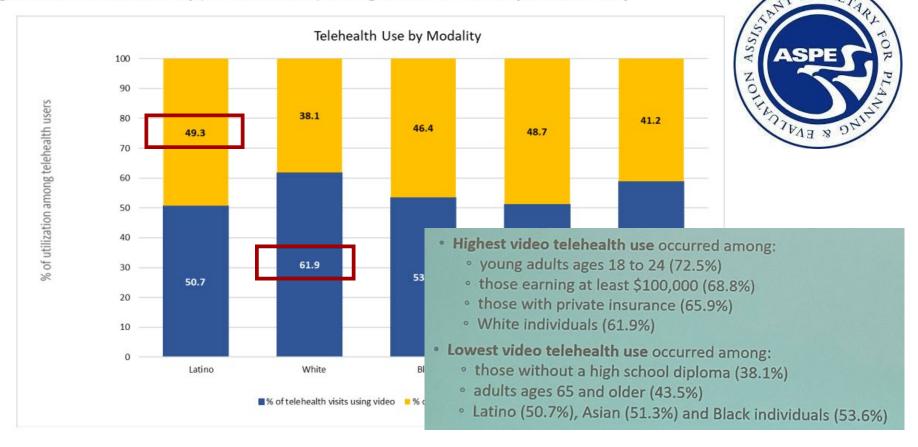
https://oig.hhs.gov/oei/reports/OEI-02-20-00720.pdf

The vast majority of beneficiaries who used certain audio-only services did not use any audio-video telehealth services.



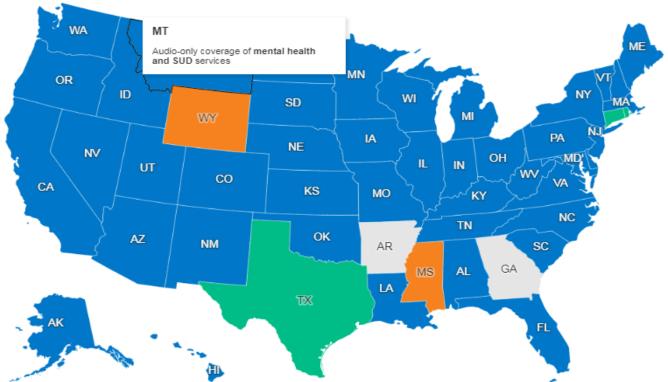
Source: OIG analysis of CMS data, 2022.

Figure 2. Telehealth Modality (Video vs. Audio) Among Telehealth Users, By Race/Ethnicity



## States Providing Medicaid Coverage of Behavioral Health Services Delivered via Audio-Only Telehealth, as of 7/1/2022

Audio-only coverage of mental health and SUD service (44 states incl DC) Audio-only coverage of mental health services (not SUD) (3 states) No audio-only coverage of mental health or SUD services (2 states) NR (2 states)



Telehealth Delivery of Behavioral Health Care in Medicaid: Findings from a Survey of State Medicaid Programs

es (HMA). **KFF** 

## **Prepare for the impact**

- DEA registration required in states where provider is located and where patients reside otherwise in violation of federal law.
- Strategy to schedule current patients for an in-person visit within 180-days of post-PHE. One in-person visit establishes a virtual prescribing relationship.
- Set up process for new patients to have an in-person visit.
- Utilize the 'qualifying telemedicine referral'
- Hybrid visit: In-person exam with provider, patient, and telehealth prescriber.
- Inform patients of potential new requirement and schedule in-person visits.

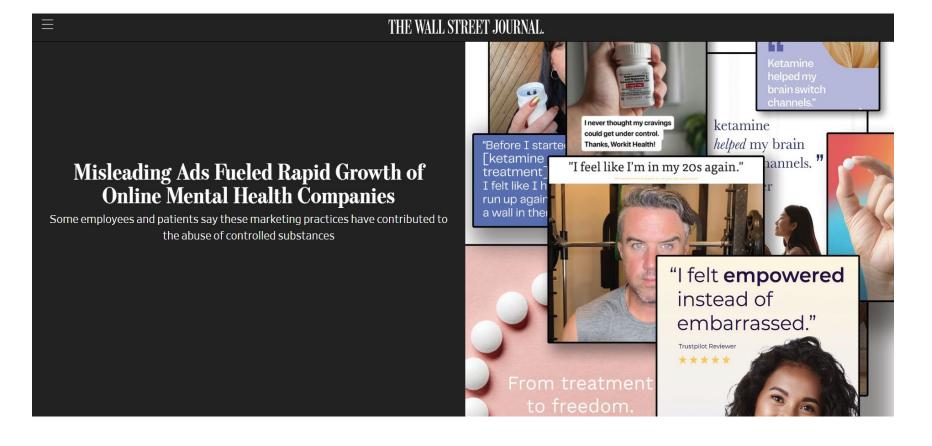
## Prepare for the impact

- **☐** Use communication channels
  - Inform clinicians, patients, and colleagues
  - Use social media to inform the general public

- ☐ Connect to congressional representatives
  - Congress can push back on these proposed rules and some members already have published statements about the potential harm.
- ☐ Keep going
  - Document safeguards and publish data

## Federal

**Regulatory Oversight and Drug Advertising** 



"Digital ad spending by telehealth companies swelled to more than \$100 million in 2021 from around \$10 million in 2020."



Supports a full ban of direct-to-consumer ads.

"It turns the healthcare interaction on its head where you're starting with the treatment instead of starting with the problem," - Jack Resneck, AMA president.



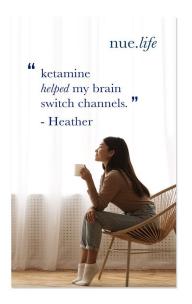
Has oversight over drug manufactures or distributors.

- ☐ Present information on each side effect and contraindication and effectiveness a "true statement of information"
- Not false or misleading
- Approved or permitted for use
- ☐ Fair balance (benefits and uses with side effects and risks)



Takes action against misleading ads, but it doesn't require prescription-drug ads to include risk information and potential side effects when the ads discuss drug benefits.





Telehealth companies under investigation argue they facilitate interactions between patients and providers and do not engage in prescription process.



# Licensure Pathways Uniform Telehealth Act



#### At A Glance

#### MEDICAID REIMBURSEMENT

- Live Video: Yes
- Store-and-Forward: Yes
- Remote Patient Monitoring: Yes
- Audio Only: Yes

#### PRIVATE PAYER LAW

- Law Exists: Yes
- Payment Parity: Yes

#### PROFESSIONAL REQUIREMENTS

- Licensure Compacts: IMLC, NLC, OT, PSY, PTC
- Consent Requirements: Yes

https://www.cchpca.org/

https://www.cchpca.org/pending-legislation/

## Virtual Prescribing in Arizona



#### Arizona State Law § 32-1401(27)(tt) – defines unprofessional conduct as:

"Prescribing, dispensing or furnishing a prescription medication or a prescription-only device... licensee first conducts a physical or mental health status examination of that person or has previously established a doctor-patient relationship. The physical or mental health status examination may be conducted through telehealth as **defined** in section 36-3601."

#### Arizona State Law § 36-3602(E)

Schedule II drugs may be prescribed only after an in-person or audio-visual examination and only to the extent allowed by federal and state law.

### THE

### NATIONAL LAW REVIEW

Trending in Telehealth: March 13 – March 19, 2023
Friday, March 24, 2023

111day, 11dreii 24, 202

Trending in the past week:

- Interstate Compacts
- Medicaid Reimbursement
- Prescribing
- Health Practitioner Licensing
- Behavioral Health

In Arizona, proposed bill (SB 1457) permit <u>licensed psychologists</u> to prescribe psychotropic medications by obtaining a "**prescription certificate**" from the Arizona Board of Psychologist Examiners.

certificate" from the Arizona Board of Psychologist Examiners.

Conditional prescription certificate under the supervision of a licensed

Full prescribing authority under a "prescription certificate" by satisfying the proposed requirements, including the following:

physician in-person, by phone or via video conference.

- Complete an additional practicum of at least 400 hours treating at least 100 patients with mental disorders under physician supervision.

- Complete a practicum of at least 80 hours in clinical assessment and pathophysiology under physician supervision

Withdrawn on 3.31.23

1.23 https://www.natlawreview.com/article/trending-telehealth-march-13-march-19-2023

### Recent and pending AZ legislation



**Bill Number: SB 1218** 

[signed by governor on 3.29.23]

Specifies that a doctor patient relationship can be established through telehealth as **defined** in section 36-3601.

Bill Number: SB 1053

Allows a veterinarian to establish a veterinarian client patient relationship using audio-video.

Bill Number: SB 1466

Allows an assessment for purposes of a medical marijuana certification to be completed either in person or by the use of telehealth.

Bill Number: HB 2687

Enacts the Counseling **Compact** in Arizona.

### **Compact Nation**

Increasing in number of states, applications, and new compacts

- Interstate Medical Licensure Compact (IMLC)
- Nurse Licensure Compact (NLC)
- Advanced Practice Registered Nurse Compact (APRN Compact)
- Emergency Medical Services Personnel Licensure Compact (The EMS Compact)
- The Physical Therapy Compact (PT Compact)
- The Psychology Interjurisdictional Compact (PSYPACT)
- Audiology and Speech-Language Pathology Interstate Compact (ASLP-IC)
- The Occupational Therapy Licensure Compact (OT Compact)
- Counseling Compact (CC) [introduced in AZ]

### **Compacts in development**

- Social Work Compact
- Physician Assistant Compact
- Dentists and Dental Hygienists Compact

## Interstate practice to allow telehealth registration, not a license, and rise in licensure compacts

### **Telehealth Registration**

- Current, valid, and unrestricted license in another state;
- Not subject to any past disciplinary proceedings in any state where the provider holds a professional license;
- Must maintain and provide evidence of professional liability insurance;
- Must not open an office or offer in-person treatment in that state; and
- Must annually register and pay a fee with the appropriate state licensing board.

# Telehealth registration active in seven states:

- Arizona
- Florida
- Indiana
- Kansas
- Minnesota
- Vermont
- West Virginia

#### **Uniform Telehealth Act**

drafted by the

NATIONAL CONFERENCE OF COMMISSIONERS ON UNIFORM STATE LAWS

and by it

APPROVED AND RECOMMENDED FOR ENACTMENT IN ALL THE STATES

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ANNUAL CONFERENCE MEETING IN ITS ONE-HUNDRED-AND-THIRTY-FIRST YEAR PHILADELPHIA, PENNSYLVANIA JULY 8–13, 2022



WITH PREFATORY NOTE AND COMMENTS

### **Current Version Legislation**

Jurisdiction	Year ▼	Bill Number	Status
District of Columbia	2023	25-125	Introduced
Nevada	2023	AB 198	Introduced
Rhode Island	2023	HB 5556	Introduced
Washington	2023	SB 5481	Introduced

If enacted, provides a telehealth registration system for out-of-state providers, as alternative to licensure.

https://www.uniformlaws.org/committees/community-home?CommunityKey=2348c20a-b645-4302-aa5d-9ebf239055bf



FOR:

Occupational Therapists

**Physical Therapists** 

**Psychologists** 

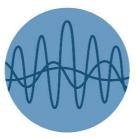
Social Worl



### Licensing resources for



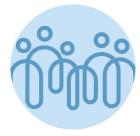
**Occupational Therapists** 



**Physical Therapists** 



**Psychologists** 



**Social Workers** 

### Looking Ahead

Digital Equity Infrastructure

We talk about medical innovation, and we talk about regulation, but we rarely talk about regulatory innovation.

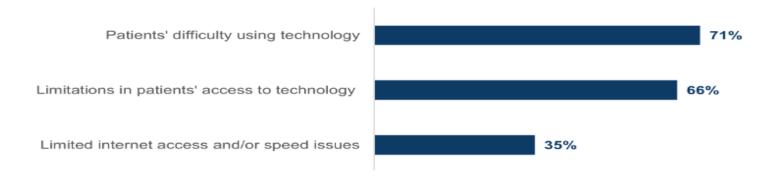




Patients' difficulty using telemedicine tools was the most common reported barrier affecting physicians' use of telemedicine.

#### **FINDINGS**

- ★ The most common barriers for telemedicine use experienced by physicians involved patients' difficulties using and accessing telemedicine technology.
- ★ Over 1 in 3 physicians reported internet access and speed issues as an issue affecting their use of telemedicine.
- ★ Less than 1 in 4 physicians reported temelemedicine is not appropriate for their practice (26%) and telemedicine platform is not easy to use (18%).



## **Population Groups** Disproportionately Impacted by the Digital Divide

- Older adults
- Racial and ethnic minority groups
- Disability
- Low socioeconomic status
- Living in rural areas
- Limited English Proficiency



### Infrastructure Investment and Jobs Act

## \$65 billion for digital equity

\$42.5 billion for broadband infrastructure

\$14.2 billion for \$30 internet subsidy

\$2.8 billion for digital literacy

Additional funds

Opportunities for Health Care Organizations to Increase Digital Inclusion through Infrastructure Initiatives.			
Infrastructure Investment and Jobs Act Policy Area	Opportunities for Health Care Organizations		
Broadband infrastructure	Collect information on patients' broadband access to identify broadband coverage gaps and guide allocation of infrastructure-building resources  Ensure that digital health tools can adapt to potential bandwidth limitations		
Broadband and device affordability	Develop workflows that integrate digital-inclusion resources into existing care (e.g., screening for social determinants of health)  Perform targeted outreach to patients who would benefit from broadband and device-subsidies programs (e.g., Emergency Broadband Benefit)  Join existing digital-inclusion efforts (e.g., programs addressing digital divides in education) led by community organizations		
Digital discrimination	ocate for equitable broadband-deployment practices at the local, state, and national levels ect patient data regarding digital disparities (e.g., disparities in broadband and device access) to support multimodal care options at digital inclusion as a social determinant of health		
Digital literacy	Apply for funding with community organizations to codevelop digital-literacy programs that extend beyond the health care setting Integrate digital navigation as part of the deployment of digital health tools		
Impact	Evaluate the effects of digital-infrastructure initiatives on health care dispari- ties to guide future investment and policies related to digital inclusion		

SENATE DOCKET, NO. 1984 FILED ON: 1/20/2023

### **SENATE . . . . . . . . . . . . . . . No. 655**

The Commonwealth of Massachusetts

PRESENTED BY:

Adam Gomez

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

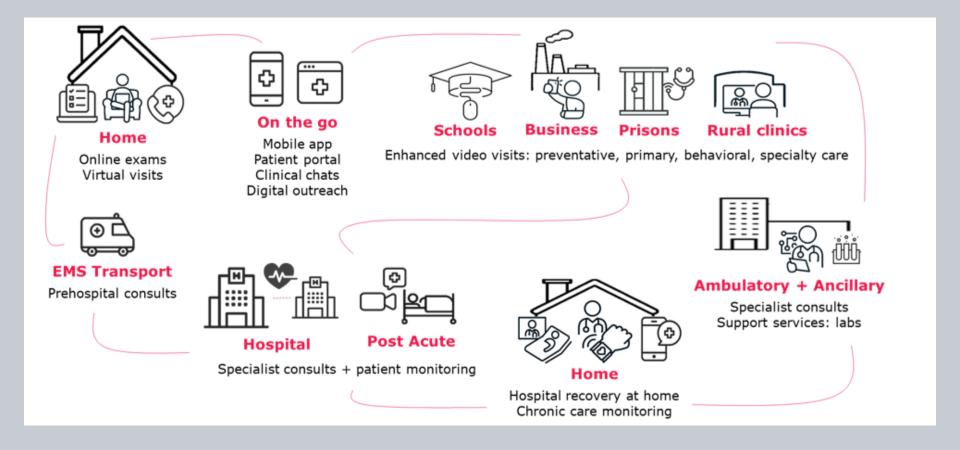
The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act relative to telehealth and digital equity for patients.

### Digital health literacy screening program

to identify low digital health literacy and support effective use of telehealth technology, including:

- educational materials about how to access telehealth in multiple languages, and in alternative formats;
- hold digital health literacy workshops;
- integrate digital health coaching;
- offer in-person digital health navigators; and
- partner with local libraries and/or community centers that offer digital health education services and supports.



### **Expanding care venues into the community – libraries**

19-driven capacity issues

Dec 14, 2020

Jun 14, 2021, 08:30µm EDT | 1,405 views

Where Hospital-At-Home Programs Are Heading After Last Year's Boom

CMS waiver for hospital-at-home designed to address COVID-



Launch Alliance To Advance Care In The Home

Leading Health Innovators

Coalition to focus on site of service flexibility for clinical care in the wake of pandemic

Amazon Care, Intermountain, Ascension launch hospital-at-home healthcare alliance

Jackie Drees - Wednesday, March 3rd, 2021 Print | Email

Global Edition Telehealth

Kaiser, Mayo, Medically Home found coalition to promote advanced hospital-at-home services

Federal regulators should "put guardrails on, but let us continue the good work," says Mayo Clinic's Dr. Michael Maniaci.

Hospital at Home: Users Group

182 hospitals/systems now have a program- up from 5-10 pre-pandemic

To date:
277 hospitals
across 37 states
participate in the
Acute Hospital Care
at Home program

THE NEW OLD AGE

### What if You Could Go to the Hospital ... at Home?

Hospital-at-home care is an increasingly common option, and it is often a safer one for older adults. But the future of the approach depends on federal action.









Raymond Johnson of Boston spent four days as an inpatient while he was being treated for heart failure: one day in a hospital followed by three in his own apartment receiving hospital-level care in an alternative called hospital at home. Sophie Park for The New

Late last month, Raymond Johnson, 83, began feeling short of breath. "It was difficult just getting around," he recently recalled by A New York City study found that hospital-at-home care also worked well for economically disadvantaged patients.

"Twenty percent of people over 65 become delirious during a hospital stay...

Studies have found that patients in hospital-at-home programs spend less time as inpatients and, afterward, in nursing homes.

They are less sedentary, less likely to report disrupted sleep and more apt to rate their hospital care highly."

HEALTH INC

### With Workers In Short Supply, Seniors Often Wait Months For Home Health Care

June 30, 2021 - 5:03 AM ET

PHIL GALEWITZ

ROM KH



## Waitlists for Medicaid's Home-and Community-Based Services:

- Nearly 820,000 people across 41 states
- Average wait time is three years

The New York Times

Ohimon

# 50 Million Americans Are Unpaid Caregivers. We Need Help.

Ratio of working age people to seniors stands at 7:1 in 2021. By 2050, it will be less than 3:1.

More articles







### Thank you

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@trsklar

https://telemedicine.arizona.edu/ https://southwesttrc.org/

https://law.arizona.edu/health