PROGRAM MATERIALS
Program #2969
April 23, 2019

Rapid Adoption: A Telehealth Primer

Celesq® AttorneysEd Center
www.celesq.com

5301 North Federal Highway, Suite 180, Boca Raton, FL 33487
Phone 561-241-1919 Fax 561-241-1969

Rapid Adoption: A Telehealth Primer

Presented by

Andrew B. Wilson, Esq.

&

Carolyn Morris, MHSA

April 2019

WE'RE GOING TO COVER

1. What is Telemedicine?
2. Where did it come from?
3. Where will it go?
4. What are the compliance areas to be aware of?
5. What are its challenges & opportunities?

SIMPLE DEFINITION - WHAT IS TELEMEDICINE?

Over 100 technical definitions, the unifying basic definition--

"The remote diagnosis and treatment of patients by means of telecommunications technology."

or

HRSA – "The use of electronic information and telecommunications technologies to support distance clinical health care, patient and professional health-related education, public health and health administration."

BASIC TERMINOLOGY

Telemedicine: Patient-to-Practitioner

Telehealth: Everything Else & Including Telemedicine

Originating Site: Patient Location

Distant Site: Provider Location

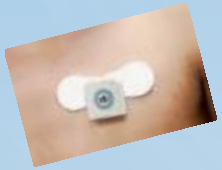
Hub: Location of a treating healthcare organization

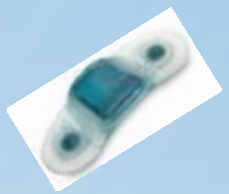
Spoke: Location of one or more originating sites served by the hub

- More terms available at http://thesource.americantelemed.org/resources/telemedicine-glossary

Basic Modalities beyond Telephone (Types of Telehealth)

- Live videoconferencing (Synchronous)
- Store-and-forward (Asynchronous)
- Remote patient monitoring (RPM)
- mHealth





LEVEL-SETTING: SOME HISTORY

HOW BIG AN INDUSTRY?

- In 2016 Accenture predicted that the telemedicine market would quadruple from $250 million to $1billion by 2018.

- In 2018 the US market was predicted to be $9.5 billion by 2022…

- …And globally $66 billion.

https://mhealthintelligence.com/news/report-telehealth-will-be-a-billion-dollar-industry-by-2018

https://www.forbes.com/sites/quora/2018/07/31/what-are-the-latest-trends-in-telemedicine-in-2018/#4de235476b9e

https://www.marketwatch.com/press-release/telehealth-market-size-is-projected-to-be-around-us-950-billion-by-2022-2018-08-13

GREATER CONTEXT?

In 2018 the Centers for Medicare & Medicaid Services reported that health care spending in the United States has reached **17.9% GPD**

This is $3.5 trillion or $10,739 per person

Ex) Delaware's spending is on track to rise from

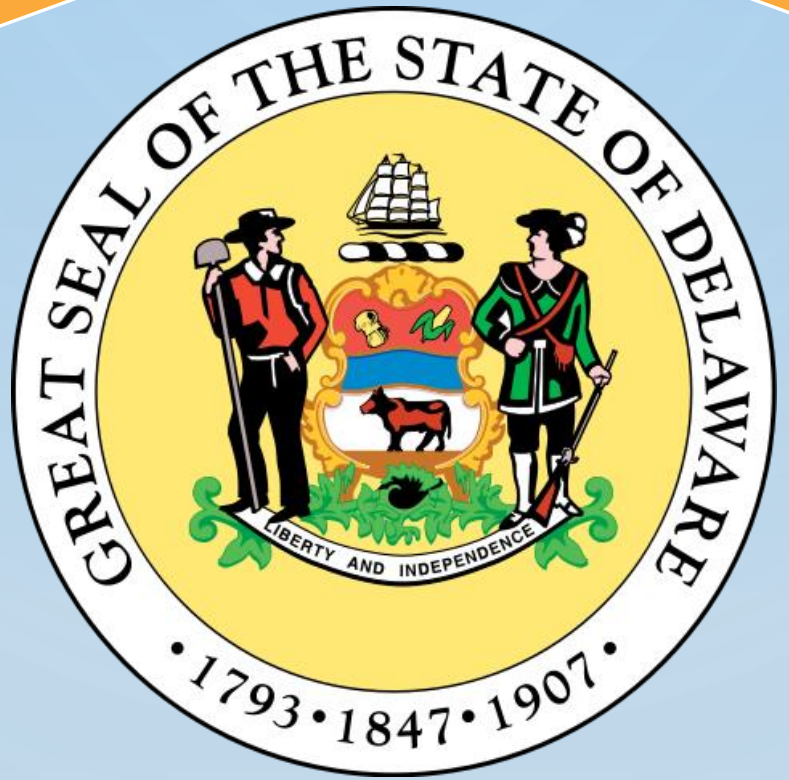
$9.5 billion in 2014 to $21.5 billion in 2025

Regulation/ Legislation

Billing

Implementation

Standard of Care




University of Delaware
College of Health Sciences

WHY LEGISLATION : TELADOC, INC. V. TEXAS MEDICAL BOARD (2016)

- Texas Medical Board (TMB) passes rule requiring an in-person visit before the use of telemedicine
- Teladoc files an antitrust lawsuit
- US Supreme Court *North Carolina Dental Board* implicated for restraint of trade by active market participants
- Texas liberalizes its rules

DELAWARE HOUSE BILL 69 PHYSICIAN-PATIENT RELATIONSHIP 24 DEL CODE 1769D

(h) Physicians using telemedicine … must, prior to a diagnosis and treatment … either provide: (1) an appropriate examination in-person, (2) have another Delaware-licensed practitioner at the originating site with the patient at the time of the diagnosis, (3) the diagnosis must be based using both audio and visual communication, or (4) the service meets standards of establishing a patient-physician relationship included as part of evidenced-based clinical practice guidelines in telemedicine developed by major medical specialty societies.

FIRST COMPLIANCE AREA: MECHANICAL STEPS

1. Identify both patient and location; Provide identity and credentials
2. obtaining appropriate consents, including informed consents regarding the use of telemedicine technologies;
3. "establishing a diagnosis through the use of acceptable medical practices, … and appropriate diagnostic and laboratory testing … as well as identify underlying conditions or contra-indications, or both, to treatment recommended or provided;"
4. Discussing with the patient the diagnosis and the evidence for it, the risks and benefits of various treatment options;
5. ensuring the availability of the distant site provider or coverage of the patient for appropriate follow-up care;
6. Provide a written summary to the patient; share it with DHIN if practicable

SECOND COMPLIANCE AREA: STANDARD OF CARE, PRESCRIBING & LICENSURE

STANDARD OF CARE & ETHICS

"establishing a diagnosis ***through the use of acceptable medical practices***, … and appropriate diagnostic and laboratory testing … as well as identify underlying conditions or contra-indications, or both, to treatment recommended or provided"

AMA TELEMEDICINE ETHICS
CODE OF MEDICAL ETHICS OPINION 1.2.12

"Yet as in any mode of care, patients need to be able to trust that physicians will place patient welfare above other interests, provide competent care, provide the information patients need to make well-considered decisions about care, respect patient privacy and confidentiality, and take steps to ensure continuity of care."

https://www.ama-assn.org/delivering-care/ethics/ethical-practice-telemedicine

LICENSURE

All states differ in how telehealth is defined and regulated, but:

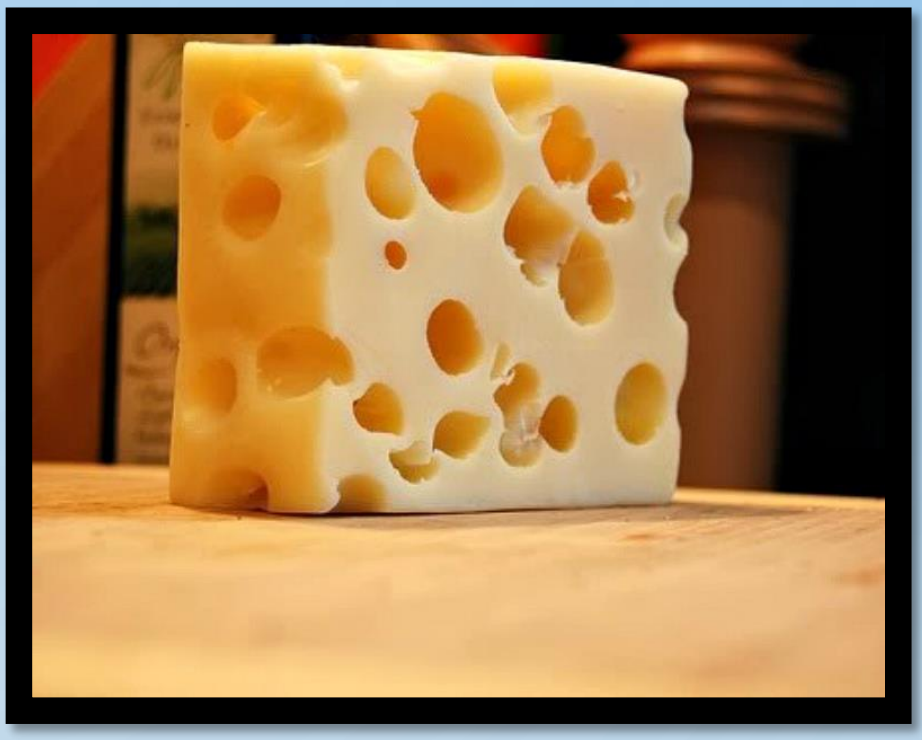
- All disciplines must be state-licensed (or otherwise legally allowed to practice) at the originating site
- Many states require adherence to accepted practice standards
- Some require dual licensure
- Physicians
  - FSMB Interstate Licensure Compact
  - 9 states have special "telemedicine" license (requires full license in another state)
- Other providers (licenses, compacts, reciprocity)
  - Examples: Nurses, Physical therapists, Psychologists

PRESCRIBING

- Online prescribing
  - Different from “e-prescribing”
  - Controlled Substances Act
  - Ryan Haight Online Pharmacy Consumer Protection Act
- State laws and regulations
  - Controlled Substances
  - Patient-provider relationship/in-person exam req.
  - Prescription drug monitoring programs (PDMP)
  - Consent

THIRD AREA: BILLING

- Commercial/Private Insurance
- ERISA
- Medicare
  - Federal (law & regulation)
  - Medicare Advantage, NextGen ACO, CCM, RPM
- Medicaid
  - Federal and State Law
  - Plan Amendments



https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/TelehealthSrvcsfctsht.pdf

TELEMEDICINE: MODEL CONFUSION

Telemedicine: Continuity of Care

Implementation in Existing Practices

VS.

Telemedicine: The Physician Network

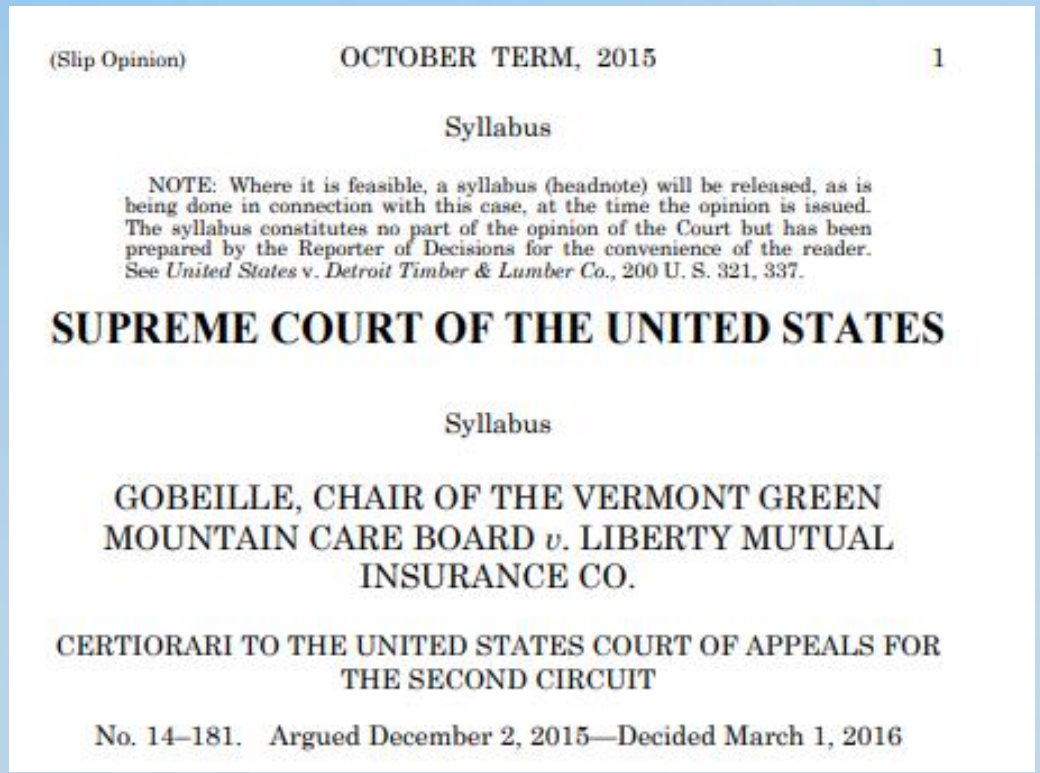
"Direct-to-Consumer"

DELAWARE HOUSE BILL 69
REIMBURSEMENT - PARITY

"An insurer…shall reimburse the treating provider or the consulting provider for the diagnosis, consultation, or treatment of the insured delivered through telemedicine services ***on the same basis and at least at the rate*** *that the insurer…is responsible for coverage for the provision of the same service through in-person consultation or contact."*

18 Delcode 3370(e)

EMPLOYEE RETIREMENT INCOME SECURITY PROGRAM
29 U.S. CODE CHAPTER 18
(ERISA)



(Slip Opinion) OCTOBER TERM, 2015 1

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

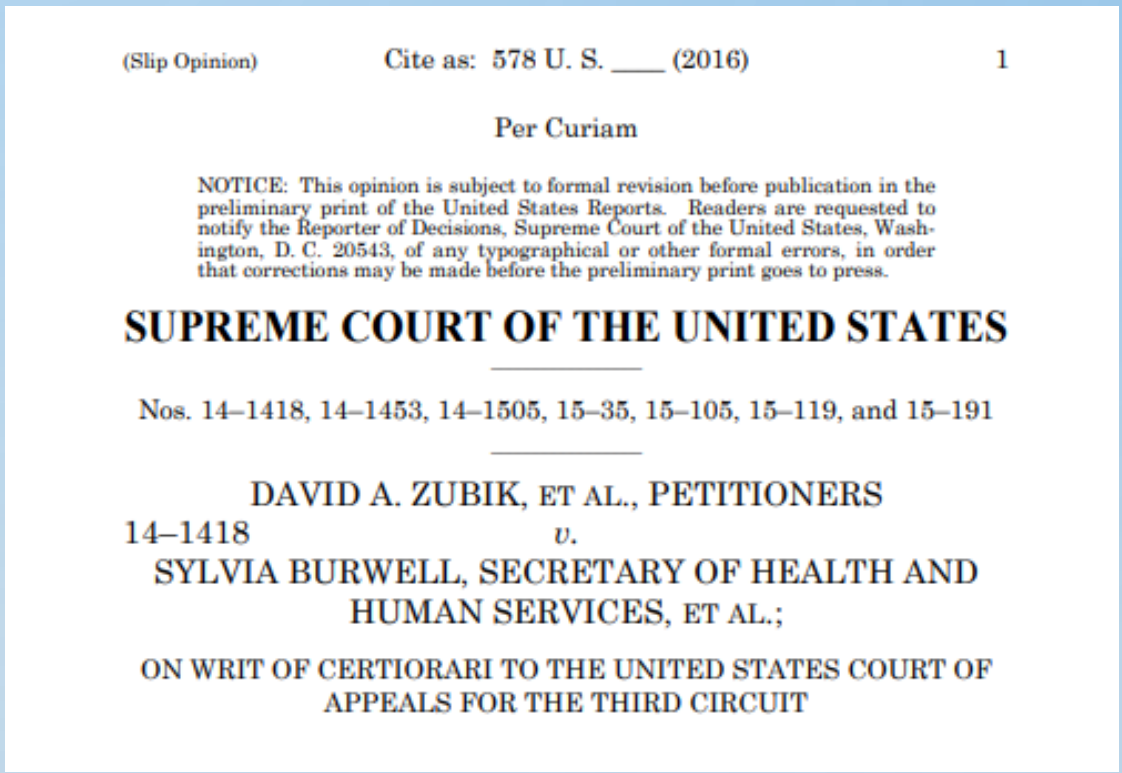
SUPREME COURT OF THE UNITED STATES

Syllabus

GOBEILLE, CHAIR OF THE VERMONT GREEN MOUNTAIN CARE BOARD *v.* LIBERTY MUTUAL INSURANCE CO.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

No. 14–181. Argued December 2, 2015—Decided March 1, 2016



(Slip Opinion) Cite as: 578 U. S. ____ (2016) 1

Per Curiam

NOTICE: This opinion is subject to formal revision before publication in the preliminary print of the United States Reports. Readers are requested to notify the Reporter of Decisions, Supreme Court of the United States, Washington, D. C. 20543, of any typographical or other formal errors, in order that corrections may be made before the preliminary print goes to press.

SUPREME COURT OF THE UNITED STATES

Nos. 14–1418, 14–1453, 14–1505, 15–35, 15–105, 15–119, and 15–191

DAVID A. ZUBIK, ET AL., PETITIONERS
14–1418 *v.*
SYLVIA BURWELL, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.;

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

MEDICARE REIMBURSEMENT

- Limited to services as provided in 1834(m) of the Social Security Act
  - certain services
  - certain providers
  - certain technology (mainly live video)*
  - certain patient locations (i.e., certain types of healthcare facilities in **rural** areas)
- Payments
  - Originating site
  - Distant site

* S&F allowed in demonstration projects (i.e., AK, HI)

MEDICARE DEFINITION OF RURAL

- (I) in an area that is designated as a rural health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A));
- (II) in a county that is not included in a Metropolitan Statistical Area; or
- (III) from an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000.

MEDICARE EXPANDED COVERAGE

1. RPM Reimbursement (eff. Jan. 2019)
2. Home Health Agencies include the costs of RPM among their reimbursable administrative expenses (beg. 2018 for potential future increases)
3. Expanding telestroke coverage (eff. Jan. 2019)
4. Improving access to telehealth-enabled home dialysis oversight (eff. Jan. 2019)
5. Enabling patients to be provided with free at-home telehealth dialysis technology
6. Allowing Medicare Advantage (MA) plans to include telehealth in basic benefits (public comment 9/2018; eff 2020)
7. ACOs can expand use of telehealth (Next Gen, MSSP Track II, MSSP Track III, and certain two-sided risk models). (Eff. Jan. 2020)

MORE EXPANDED COVERAGE

- Brief Communication Technology-based Service, e.g. Virtual Check-in (HCPCS code G2012)
- Remote Evaluation of Pre-Recorded Patient Information (HCPCS code G2010) – (i.e., S&F)
- Interprofessional Internet Consultation (CPT codes 99452, 99451, 99446, 99447, 99448, and 99449)
- SUPPORT for Patients and Communities Act services – (SUD treatment)
  - Amends 42 U.S.C. § 1395m(m) – eff. July 1, 2019
  - US Attorney General must promulgate regulations by Oct. 24, 2019.
- Smartphone Continuous Glucose Monitoring (near future)

MEDICAID NATIONWIDE

As of Spring 2018:

- All states & DC have *some* coverage for video encounters
- 15 states cover *some* store-and-forward
- 20 states cover RPM
- 9 states cover all 3 with some limitations

FOURTH COMPLIANCE AREA: PRIVACY & SECURITY RISKS

- HIPAA
  - Secure Protected Health Information (PHI)
  - Covered Entities: Health plans; Health care providers; Health care clearing houses; Business associates
- HITECH
  - EHR
  - Meaningful Use (MU)
- State Privacy Laws and Regulations

DEVICE REGULATION – PERIPHERALS AND OTHERS

- Food and Drug Administration (FDA)
  - Medical devices
  - Medical apps
- Federal Trade Commission
  - Data breaches (non-HIPAA)
  - False claims
- Federal Communication Commission (FCC)
  - Devices that communicate
  - Mobile Body Area Network (MBAN)
  - MOU with FDA
  - Control of data
  - Use of data

ONGOING CONVERSATION

2016 Tweaks - HB201

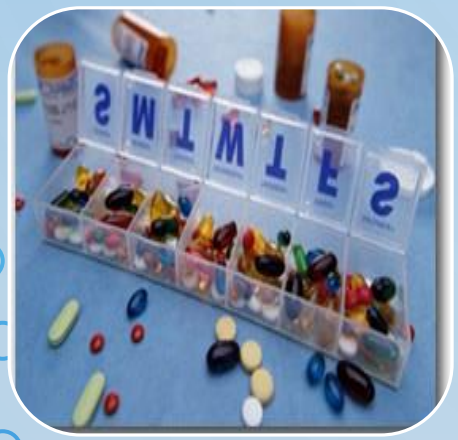
- Pathology and Radiology explicitly carved out
- Clarifies that once a relationship is established, it doesn't need to be re-established, nor does it limit existing practices like phone follow-ups

Future Potential Tweaks:

- *MAT*
- *Medication Dispensing*
- *On-Call Language*

PREPARING FOR THE FUTURE: VALUE BASED CARE

Remote Patient Monitoring



Medication Adherence

"Value-based healthcare is a healthcare delivery model in which providers, including hospitals and physicians, are paid based on patient health outcomes. Under value-based care agreements, providers are rewarded for helping patients improve their health, reduce the effects and incidence of chronic disease, and live healthier lives in an evidence-based way."

-NEJM Catalyst

https://catalyst.nejm.org/what-is-value-based-healthcare/

THINK: BIG

- Enhanced Access to Care
- 24/7 Access to Healthcare Professional
- Reducing ED Overutilization & Readmissons
- Population Management
- Care Management & Coordination
- Behavioral Health Planning

Andrew Wilson, Esq.
Morris James LLP
302-888-6878
awilson@morrisjames.com

Carolyn Morris, MHSA
State of Delaware
302-255-9370
Carolyn.Morris@Delaware.gov