An Update on the New Policy and Legal Issues in Telehealth

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Disclosures

• I am NOT an attorney! Please consult one if you have a critical question

• I chair the Washington State Telehealth Collaborative, but views expressed today are my own and not those of the collaborative

• The landscape is changing fast, be sure to check latest information

• This presentation benefitted greatly from UW Law School course and co-director Cindy Jacob (RN, JD) input as well as CTeL webinar by Joseph McMenamin, MD, JD Feb 22, 2019
Objectives

• To describe recent changes in CMS Physician Fee Schedule
• To delineate examples of state telehealth laws and how a collaborative can advance telehealth
• To list the pros/cons of artificial intelligence and mobile medical apps
## Types of Telehealth

<table>
<thead>
<tr>
<th>Live Video and Chat “Synchronous”</th>
<th>Store-and-Forward “Asynchronous”</th>
<th>Remote Patient Monitoring</th>
<th>mHealth</th>
<th>Provider Education</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical devices and communication technology to deliver healthcare remotely</td>
<td>Provider-provider or provider-patients consults that include data storage, transfer, review and response</td>
<td>Health data collected from an individual and transmitted electronically to a provider</td>
<td>Use of mobile and wireless devices to improve health outcomes, services and research</td>
<td>Remote case review to upskill providers and peers working in rural and urban communities</td>
</tr>
<tr>
<td>Examples: eICU, TelePsychiatry, TeleStroke</td>
<td>Examples: eConsults, e-visit questionnaires</td>
<td>Examples: Blood glucose or blood pressure monitoring from home</td>
<td>Examples: medical apps, decision support, data collection</td>
<td>Examples: Project ECHO for HIV or Hepatitis C</td>
</tr>
</tbody>
</table>

**Established**

**Emerging**
Why Telehealth?

Technology has transformed the way people work, shop and socialize. Patient demands, providers shortages, rising costs and payment reform are forcing stakeholders to assess & adopt technology solutions to meet their needs & objectives.

**Key Statistics**
1. Rapid growth anticipated – by 2020 virtual visits to reach 26.2 million*, telehealth spend to reach $66.7M (18.8% annual growth)**.
2. In 2016 Kaiser completed 52% of their patient interactions virtually.
3. 76% of patients prefer access over human interaction*
CMS and Telemedicine

• Definitions of Telemedicine and conditions for reimbursement

• Section 1834(m) of Social Security Act

• Defined as professional consultations, office visits and office psych services and any additional services specified by Secretary

• HRSA definition: “Telehealth is the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration.”

What are the requirements for telemedicine reimbursement by CMS?

- **Technology**: live, face to face interactive video OR store and forward (only AK, HI)
- **Geographic Restrictions**: must be located in Rural Health shortage area or medical service area deemed as rural ([https://data.hrsa.gov/tools/shortage-area](https://data.hrsa.gov/tools/shortage-area))
- **Originating Sites**: NOT HOME, 11 listed facilities (CAHs, doctor’s offices, etc)
CMS and Telemedicine

- When all of these conditions are met, Medicare telehealth services are paid as though the service was performed in person.
- Originating (spoke) site may qualify for facility fee (Q3014, $26.15).
- Look for proposed changes every July, open comment period and then final rule in Nov each year.
- Rates change annually.
- Public can suggest new codes at any time, but deadline is Feb for following calendar year.
New CMS Codes for Telehealth

• Remote Evaluation of Pre-Recorded Patient Information (HCPCS code G2010)
• New code to describe remote professional evaluation of patient-transmitted information conducted via pre-recorded “store-and-forward” video or image technology.
• Interpretation of image and communication back to patient must occur within 24 hrs
• Limited to established pts
• Can occur via phone, video, text, email or portal
• Consent must be documented; PATIENT MUST ORIGINATE
New CMS Codes for Telehealth

• Interprofessional Internet Consultation (CPT codes 99452, 99451)
• Aka « eConsult »
Ordering an eConsult

NOTE: please start a beta blocker if symptomatic without contraindications.

I am requesting an eConsult for this 58 year old male with hyperthyroid.

My clinical question is: ***

Please have the following results available in EpicCare or ORCA: TSH, free T4, total T3

Lab Results

<table>
<thead>
<tr>
<th>Component</th>
<th>Value</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSH</td>
<td>0.768</td>
<td>06/12/2018</td>
</tr>
<tr>
<td>T3</td>
<td>115</td>
<td>06/12/2018</td>
</tr>
</tbody>
</table>

If this clinical question is deemed too complex for eConsult, please:

(conversation continues...)

Lisa D Chew, MD
10/31/2018

Schedule this patient for in-person consultation. This patient understands that they may receive a phone call from the specialty practice to schedule an appointment. Route back to me and I will discuss further with the patient.
1. **Recommendation(s):** Patient is mildly overweight and does have hyperlipidemia, so a diagnosis of fatty liver disease would make sense, although no obvious evidence of glucose intolerance, hypertension or morbid obesity. Would clarify with the patient that she is not drinking alcohol or taking any herbal supplements, as these can also cause fatty liver. Otherwise, because she is ruled out for viral hepatitis and her transaminases are very mildly elevated, reasonable to advise on 5-10 lb weight loss with diet and exercise with follow up. If LFTs continue to rise despite weight loss, would consider broadening work up to include AIH serologies, ferritin/iron panel. She’s above the age range for which we would be concerned for Wilson’s disease.

2. **Rationale and/or evidence for recommendation:** Patient has chronic, low level LFT elevations without obvious signs for cirrhosis and excellent synthetic function. Her NAFLD fibrosis score is also very low and would not suggest that she had advanced fibrosis.

3. **Contingency Plan:** If LFTs continue to be elevated despite weight loss of 5-10 lbs in the next 6 months, refer to Hepatology clinic to consider liver biopsy vs other serologic
UW Medicine Experience with eConsult

# eConsult Encounters

- Dermatology
- Endocrinology
- Hematology
- Gastroenterology
- Pulmonary
- Hepatology
- Cardiology
- Urology
- Neurology
- Nephrology
- Psychiatry
- Allergy
- Infectious Disease
- Rheumatology
- Neurology
- Allergy
eConsult helped improve patient access

Avg. 30% improvement across 3 specialties
eConsult CMS Requirements

• Payment of 0.7 wRVU to consulting provider (99451); payment of 0.7 wRVU to treating/requesting provider (99452)

• Only providers who independently bill Medicare are eligible to conduct eConsults under these codes

• Patient consent is required for each eConsult, and must be documented in the chart

• No restrictions on who sends nor who receives eConsults (PCP or specialist)

• If seen by specialty receiving eConsult within 14 days for same problem, then eConsult will be denied (no double coverage)
New CMS Codes for Telehealth

• Remote patient monitoring (99451, 99453-7)

• Update of 16 yr old 99091 code, biggest difference being inclusion of “clinical staff” not just MDs/ARNPs

• Need to spend at least 20 minutes per calendar month; Patient must have been seen at least once in person in last year; **Consent required**; can concurrently bill for chronic care management

• The 99451 code is for collection and interpretation and includes weight, blood pressure, pulse oximetry, respiratory flow rate

• The 99953, 54 are for initial set up and patient education

• The 99457 is for physician interpretation

Relaxation of location requirements

• SUPPORT Act passed and signed into law 2018: aims at preventing opioid addiction and misuse and enhancing access to care for those who have substance use disorders. Clinicians may now be reimbursed for providing eligible substance use disorder services to Medicare beneficiaries in their homes via telehealth and non-rural locations. Requires AG to give guidance on Rx of controlled substances via telemedicine by Oct 2019.

• CHRONIC Care Act/Bipartisan Budget Resolution: removed geographic and site location requirements for Medicare patients receiving home dialysis or TeleStroke services.

• VETS Act: allow VA providers to cross state lines to practice telemedicine. Just need to be licensed in at least one state.
State Telehealth Laws

- 2018 was busy! Among 39 states and DC, 65 legislative bills passed in the 2018 legislative session
- Center for Connected Health Policy listing of which states have laws on books
- Payment parity vs. service parity
- ERISA law of 1974 and self-insured commercial plans
- Interstate Compact
- Recent updates from WA State, including learning points about process

https://imlcc.org/
Payment vs. Service Parity

• Vast majority of so-called “parity” laws pertain to service

• Payment parity = same $ amount for a telemedicine visit as an in-person visit

• Seven states have payment parity laws on the books: HI, AR, CO, DE, KY, MN, NJ

• Three states passed payment parity in 2019: GA, NM, MS; Five states failed: OR, WA, NY, MA, NC

• Arguments for payment parity: same amount of time for clinician, other kinds of overhead costs (IT, technology), less efficient than in-person care, no incentive to provide same care at lower cost, avoiding facility fee

• Arguments against: not reducing cost of care, avoiding nurse/MA time and use of an exam room, not equivalent visit to in-person care
Payment Parity Bill: WA SB 5385

• Requires health plans to pay the same rate for a health care service provided through [live/synchronous] telemedicine as an in-person service.

• Permits hospitals, hospital systems, telemedicine companies, and provider groups of 11 or more to negotiate and agree to a telemedicine reimbursement rate that differs from in-person rates.

• Requires reimbursement for facility fees to be subject to a negotiated agreement.

• Removes the requirement that services provided through store and forward technology have an associated office visit.
<table>
<thead>
<tr>
<th>State</th>
<th>Physician License?</th>
<th>Nurse License?</th>
<th>Prescribing Medication</th>
<th>Other</th>
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</thead>
<tbody>
<tr>
<td>Alaska</td>
<td>Yes. No presenter</td>
<td>Yes</td>
<td>Must be licensed to prescribe without in-person exam</td>
<td>Business Registry</td>
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<tr>
<td>Idaho</td>
<td>Yes. Consultation exception</td>
<td>NLC</td>
<td>“Abortion-inducing drugs” prohibited</td>
<td>IMLC</td>
</tr>
<tr>
<td>Montana</td>
<td>“Occasional” case exception</td>
<td>eNLC effective Jan. 2018</td>
<td>Same professional accountability as in-person</td>
<td>IMLC</td>
</tr>
<tr>
<td>Washington</td>
<td>Yes. Licensure exemption does not apply to telemedicine</td>
<td>Yes</td>
<td>Same professional accountability as in-person</td>
<td>IMLC</td>
</tr>
<tr>
<td>Wyoming</td>
<td>Consultation exception</td>
<td>Yes, NLC.</td>
<td></td>
<td>IMLC</td>
</tr>
</tbody>
</table>
Washington State Telehealth Collaborative

- **Established** in 2016 with passage of S. 5619
- **Mission**: to provide a forum to improve the health of Washington residents through the collaboration and sharing of knowledge and health resources statewide and increasing public awareness of telehealth as a delivery mechanism
- **Accomplishments**: inventory of telehealth providers and programs, provider training slide set, best practices related to consent and documentation, 5 bills passed and signed into law related to originating sites, proxy credentialing, Project ECHO funding

https://www.wsha.org/policy-advocacy/issues/telemedicine/washington-state-telemedicine-collaborative/
mHealth, Health Apps and AI
UW Developed Health Apps

BiliCam – Jim Stout, Shwetek Patel
mPOWEr – Heather Evans, Bill Lober

https://mpower.cirg.washington.edu/demo/users/login
UW Developed Medical Apps

Acoustic detection of middle ear fluid – J Chan, R Bly
FOCUS app (UW)

• Users track symptoms and receive targeted interventions based on responses to daily assessments

• Users can select domains to focus on including medication adherence, mood regulation, sleep, social functioning, and coping with auditory hallucinations

• Users can opt to transmit their data to servers for processing to display on a web-based dashboard and can grant dashboard access to their clinicians to support collaborative treatment

• Decreased psychotic symptoms, depression

• Improved recovery times after hospital discharge

• Comparable outcomes with in-person psychotherapy

Issues with Health Apps

• Reimbursement (would need to meet RPM requirements)
• FDA regulation
• Standard of care issues
  • Liability for the systems/apps themselves as well as care delivered via those systems/apps
• Documentation and data integration compliance
  • For reimbursement purposes
  • For standard of care (SOC) purposes
• HIPAA/privacy/security issues?
• Data “ownership”
  • Patient
  • Healthcare professional/system
  • Monitoring system/device manufacturer
Examples

saykara

JAMA | Original Investigation | INNOVATIONS IN HEALTH CARE DELIVERY
Development and Validation of a Deep Learning Algorithm for Detection of Diabetic Retinopathy in Retinal Fundus Photographs
Varun Gulshan, PhD; Lily Peng, MD, PhD; Marc Coram, PhD; Martin C. Stumpe, PhD; Derek Wu, BS; Arunachalam Narayanaswamy, PhD; Subhashini Venugopalan, MS; Kasumi Wdcher, MS; Tom Madams, MEIing; Jorge Cuadros, OD, PhD; Rajamony Kim, OD, DNB; Rajiv Raman, MS, DNB; Philip C. Nelson, BS; Jessica L. Mega, MD, MPH; Dale R. Webster, PhD

JAMA | Original Investigation
Babak Ehteshami Bejnordi, MS; Mitko Veta, PhD; Paul Johannes van Diest, MD, PhD; Bram van Ginneken, PhD; Nico Karssenmeijer, PhD; Geert Litjens, PhD; Jeroen A. W. M. van der Laak, PhD; and the CAMELION16 Consortium

98point6
What’s in the Black Box?
New Guidance Documents (Dec ’17)

• Software as a Medical Device (SAMD): Clinical Evaluation - Guidance
• Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act - Draft Guidance
• Clinical and Patient Decision Support Software - Draft Guidance
Whole Bunch of Legal Issues with AI!

• Corporate practice of medicine: States ban corporations from getting licensed, or non-licensees from owning equity in MD practice

• Negligence: concepts of duty, intended harm, standard of care, agency

• Conflicts of interest: pharma or device company influencing algorithm, decisions designed to steer more business to certain procedures

• Informed consent: disclose to patient that AI is involved in care?

• Is AI a service or a product? If latter, than subject product liability claims

• Privacy: California Consumer Protection Act of 2018 (CCPA): Consumers may seek categories of personal info collected, including inferred health data, and ask that personal information be deleted
## Resources

<table>
<thead>
<tr>
<th>ITEM</th>
<th>DESCRIPTION</th>
<th>SOURCE</th>
<th>WEBSITE</th>
<th>FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Telehealth Training</td>
<td>Northwest Regional Telehealth Resource Center</td>
<td><a href="http://nrtrc.dev.uen.org/education/training.shtml">http://nrtrc.dev.uen.org/education/training.shtml</a></td>
<td>No</td>
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<tr>
<td>4</td>
<td>Telehealth Training &amp; Certification</td>
<td>Arizona Telemedicine Program</td>
<td><a href="https://telemedicine.arizona.edu/training">https://telemedicine.arizona.edu/training</a></td>
<td>Yes (ATA Accredited)</td>
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<tr>
<td>5</td>
<td>Telehealth Coordinator, Staff Coordinator Training</td>
<td>California Telehealth Resource Center</td>
<td><a href="http://www.caltrc.org/knowledge-center/training/">http://www.caltrc.org/knowledge-center/training/</a></td>
<td>No</td>
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<tr>
<td>6</td>
<td>Learn Telehealth</td>
<td>South Central Telehealth Resource Center</td>
<td><a href="http://learntelehealth.org/courses/">http://learntelehealth.org/courses/</a></td>
<td>No</td>
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<tr>
<td>7</td>
<td>Telehealth Training</td>
<td>Center for Connected Health Policy</td>
<td><a href="http://www.cchpca.org/jurisdiction/washington">http://www.cchpca.org/jurisdiction/washington</a></td>
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<tr>
<td>8</td>
<td>Telehealth Training</td>
<td>American Telemedicine Association</td>
<td><a href="https://www.americantelemed.org/main/ata-accreditation/training-programs">https://www.americantelemed.org/main/ata-accreditation/training-programs</a></td>
<td>Yes (ATA Accredited)</td>
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<tr>
<td>10</td>
<td>Telehealth Resource Center Fact Sheets</td>
<td>National Consortium of Telehealth Resource Centers</td>
<td><a href="https://www.telehealthresourcecenter.org/fact-sheets/">https://www.telehealthresourcecenter.org/fact-sheets/</a></td>
<td>No</td>
</tr>
</tbody>
</table>
Summary

- Huge potential with telemedicine to improve access to care
- Significant barriers still exist: payment parity, interstate licensing, awareness, IT issues
- Please consider signing Interstate Compact!
- Collaborative structure is productive avenue for digging into issues and proposing solutions
- AI is coming! Much promise but also whole set of legal and policy issues
QUESTIONS?

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