# Telehealth
# White Paper

**wedi** ™  Partnering for Electronic Delivery of Information in Healthcare

# Telehealth Modalities

**March 13, 2018**

# CONTENT

**Disclaimer**

# Disclaimer

## I. Purpose

The purpose of this white paper is to provide information on the various modes of delivering patient care using telehealth services and technology, including virtual encounters, remote patient monitoring, wearable devices, and integrated care management.

### Introduction

There are numerous services provided under the umbrella of "telehealth[1]" and there are many methods through which to deliver those services. Virtual encounters, remote patient monitoring, wearable devices, and integrated care management are all examples of the more common telehealth modalities used today. Delivering health care services via telehealth can benefit the patient, provider, and payer by making care accessible and available in a more convenient, lower-cost setting, and reducing overhead and administrative expenses for the health care system. Further study, time, and uptake of telehealth services will allow more precise evaluation of the potential benefits and limitations of such transformative healthcare delivery. Each of these potential benefits is an area of increasing importance as providers and health systems move to adopt risk or performance-based reimbursement for care.

## II. Scope

The scope of this white paper is to provide information on various telehealth modalities that are currently in use. The modalities addressed in the white paper are not intended to be a complete list, as innovations in telehealth are happening continuously. Additionally, the white paper is not intended to evaluate the business case for or merits of each modality. Organizations and products included in the paper are for educational purposes only and are not endorsements by WEDI.

The content of the paper is primarily addressing structure, use, and payment for telehealth modalities among providers. The definition of providers encompasses physicians, physician groups, hospitals, and health systems as well as free-standing clinics, mid-level personnel, and other individuals alone or in group practice providing direct patient care.

## III. Telehealth Modalities

### Availability & Coverage

Telehealth is available in a wide variety of modalities and new uses are rapidly developing. In addition to the numerous telehealth services available, there are also a wide range of reimbursement structures and rules for telehealth that differ depending on the payer and location of the provider. Telehealth can be offered as a standalone service, as part of a continuum or risk-based structure of care, or as a complement to in-

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[1] Under current federal law for the Medicare program telehealth is defined as video- and audio-interactive, synchronous interactions. The Medicare program's current definition of telehealth does not include remote patient monitoring. As a result, the current Medicare statutory limitations on this narrowly defined "telehealth" services do not apply to remote patient monitoring. Many payers consider remote patient monitoring as a subset of telehealth—the Medicare program does not.

office services. The modality in which the telehealth service is deployed may affect the reimbursement structure for providers.

Prior to offering telehealth services, providers should start by understanding payers' reimbursement requirements for the care. The telehealth services covered by payers and the reimbursement structure for those services vary significantly. Currently, the Medicare Part B Fee-For-Service (FFS) telehealth requirements are considered by many to be the most restrictive reimbursement rules.[2] Medicare FFS beneficiaries are eligible for reimbursement of telehealth services only if these services are presented from an originating site[3] located in: a rural Health Professional Shortage Area (HPSA) located outside of a Metropolitan Statistical Area (MSA) or in a rural census tract or a county outside of an MSA.[4] Further restricting access is excluding the home as an originating site. Even those beneficiaries who are able to travel to an originating site are restricted to individuals residing in certain rural areas with a known health care shortage.

Federal legislation removing restrictions on how and where telehealth may be used is vital to extending coverage of telehealth services. Other Medicare programs, such as the Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs) waive restrictions for telehealth in limited circumstances and some Medicare Advantage plans offer telehealth services as a supplemental benefit. The restrictive nature of Medicare's Part B reimbursement may influence providers' interest in offering telehealth modalities.

The 2018 Medicare Physician Fee Schedule Final Rule finalized a number of proposed coverage expansions of telehealth and remote patient monitoring services. While Medicare will now cover a few additional telehealth services, these remain subject to originating site and geographic restrictions. Because remote patient monitoring is outside the scope of the Medicare statutory definition of telehealth, Medicare has expanded coverage of remote patient monitoring without restrictions  Current Procedural Terminology (CPT®) code 99091 (collection and interpretation of physiologic data) has been activated for coverage of remote patient monitoring services for separate payment under Medicare for 2018 as a short term measure until new CPT codes have been valued and considered as part of the 2019 Medicare Physician Fee Schedule. The American Medical Association's Digital Medicine Payment Advisory Group (DMPAG) is working on recommendations for the coding, valuation, and coverage for digital medicine services, which are then considered by the CPT Editorial Panel. Medicare added a number of additional coverage requirements including advance beneficiary consent, a face-to-face with the billing practitioner for new patients, and those who have not seen their practitioner one year prior to billing the code.

In addition, the support for digital medicine was recognized in the Centers for Medicare & Medicaid Services (CMS) Merit-based Incentive Payment System (MIPS). The

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[2] Social Security Act §1834. "Special Payment Rules for Particular Items and Services." https://www.ssa.gov/OP_Home/ssact/title18/1834.htm

[3] "Originating site" is a term used within the Medicare reimbursement framework to identify the location of the patient at the time the telehealth service is conducted.

[4] Department of Health and Human Services. Medicare Learning Network. "Telehealth Services." https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/TelehealthSrvcsfctsht.pdf

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Improvement Activity "Engage Patients and Families to Guide Improvement in the System of Care" now includes the use of patient generated health data and the activity was reweighted from medium to high to reflect the higher priority of this component of care.

Some delivery systems integrate the payer and providers into a single entity. These systems can create internal incentives to use telehealth in managing costs and outcomes under global capitation. The "closed loop" systems can internally arbitrage costs for telehealth services against savings in total costs of care.

The lack of a uniform definition of telehealth and telemedicine results in differences in clinical permissibility of telehealth services. All states allow physicians to treat patients via telehealth so long as the physician holds a license to practice medicine in the state where the patient is located, and therefore where the service is being delivered. In addition, some states have established special licensing mechanisms for physicians to provide telehealth services across state lines. At the time of this publication, medical boards in Alabama, Louisiana, Maine, Minnesota, New Mexico, Ohio, Oregon, Tennessee (osteopathic board only), and Texas issue special licenses or certificates related to telehealth. The licenses allow an out-of-state physician to treat patients via telemedicine in a state where the physician is not located, or allow a physician to provide services via telehealth in a state if certain conditions are met – such as agreeing not to open an office in the state.[5] For physicians, state medical boards should look to the Interstate Medical Licensure Compact[6] to facilitate more efficient multi-state licensure of physicians. Although the compact license was not created specifically for telehealth, it is being leveraged to accelerate adoption and use of telehealth services across state lines.

Privacy and Security Considerations

The use of any modality of telehealth should adhere to privacy and security policy requirements that safeguard patients' protected health information. The following is a set of principles that should be present when engaging in telehealth of any modality (as applicable).

- Ensure that all interactions are conducted through a secure transmission. Through the use of a telehealth service, the patient is 'opting in' to the secure transmission of their data.
- Privacy notices must be displayed or be easy to find on the modality site.
- Ensure compliance with state and federal regulations.

The following questions related to privacy and security should be considered depending on the type of modality being used.

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[5] Center for Connected Health Policy. State Telehealth Laws and Reimbursement Policies: A Comprehensive Scan of the 50 States and District of Columbia. April 2017. Available at www.cchpca.org/sites/default/files/resources/50%20STATE%20PDF%20FILE%20APRIL%202017%20FINAL%20PASSWORD%20PROTECT.pdf.
[6] Interstate Medical Licensure Compact, www.licenseportability.org.

**Table 1 – Privacy and Security Considerations**

| Questions | Considerations |
|---|---|
| Who will track the individual rights afforded to the members by HIPAA (confidential communications, restrictions, etc.)? | Ensure there is a policy that addresses and accounts for provider-to-provider disclosures vs. patient-to-provider treatment sessions. |
| Will data be stored and how will it be stored? | All data must be secured. Data architecture and operation must include a verification and authentication of identity and an authority process prior to disclosing and treating (this may be part of the log-in process). This may include verifying there is a one-to-one match from the person who logs into the data being retained to ensure it aligned with the correct individual. |
| What is the length of storage of the data and who has responsibility for securing the data? | Standards for data storage and retention should be established and monitored. Policies, procedures, and auditability for access, use, and transfer of information should be established and implemented. |
| How will breaches be handled? Who has responsibility/ownership for this process? | Define process for breaches, who will be notified, required timeframes, and types of potential notifications that may be required. Identify individuals that may need to be part of breach/incident response process (privacy, legal, information security, public affairs) and ensure they are aware of process and their roles/responsibilities in the case of a breach. |
| Are there published training, and privacy policies for the covered entity together with Business Associates (BA) reflecting structure for the service? | The Privacy Officer as oversight for the following. <br>• Alignment with HIPAA is required for all instances of data collection – Who, How, What, When, Where <br>• Transparency is imperative so patients, providers, the care team and family members understand the specific provisions for opt-in, opt-out, and access <br>• Patients or authorized representatives control access and disclosure <br>• Authorizations are set prior to initiating services with a minimum or calendar year review and potential for modification |
| Is the telehealth technology included in the HIPAA risk assessment? | Any technology, including equipment and software, used for providing telehealth services needs to be included in the HIPAA risk assessment. |

Regulatory and Reimbursement Considerations

State laws and medical board regulations also dictate the parameters and availability of telehealth. State laws and regulations govern licensure, requirements for establishing a valid patient-physician relationship, prescribing medication, and coverage of telehealth services. Issues include how a clinician-patient relationship is established, and

prescribing of medication. Providers looking to perform telehealth services should review any state and licensure requirements to which they are subject.

A related point is understanding how state coverage and price parity may vary by state and payer. Providers need to understand the regulatory requirements for payment in a state. One example is whether the state mandates parity for coverage or price or both for services in-person or using telehealth. An additional consideration is assessing how "parity" services are set within each state. Further considerations include what modalities are covered and which categories of health care providers are covered under state laws and regulations.

<u>Modalities and Examples of Care Delivery</u>

The following provides an overview of each modality and examples of how the care is delivered to patients.

**a. Virtual Encounters**

Virtual encounters are typically delivered via a camera-enabled device such as a computer, laptop or mobile device and have the ability to be delivered 24/7. The patient and provider interact in a real-time and two-way mode.

**i. Primary Care**

Primary care virtual encounters address and treat a variety of symptoms for a wide number of people. A benefit of primary care virtual encounters is the ability to treat routine conditions or focused problems in a lower-cost setting compared to a brick-and-mortar setting without barriers of time, distance, or geography. A 2014 paper[7] on the costs and benefits of telehealth services concluded that a patient would save $66 by using a telehealth service instead of going to an urgent care center. The same paper found that patient issues are able to be resolved 83 percent of the time during the initial telehealth visit, requiring no additional follow-up care, which reduced traffic at hospitals, emergency departments (ED), and doctors' offices.

<u>Example 1</u>

Mary is a 25-year-old generally healthy woman with no health care coverage who has come down with red, itchy eyes and the symptoms seem to be worsening. After a night of discomfort, she is not looking forward to a trip to urgent care for an evaluation and possibly a prescription. Not only is she quite uncomfortable, but the condition has also impaired her vision. Instead of driving to the local urgent care, Mary decides to connect with a doctor using her smartphone. She chooses her telehealth provider and is able to connect to a physician for a live, two-way video appointment. Her physician goes through a series of questions

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[7] Yamamoto, D. "Assessment of the Feasibility and Cost of Replacing In-Person Care with Acute Care Telehealth Services." December 2014. http://www.connectwithcare.org/wp-content/uploads/2014/12/Medicare-Acute-Care-Telehealth-Feasibility.pdf

and an examination to assess Mary's symptoms and condition and is able to provide a treatment plan and a prescription. The provider sends the prescription electronically to Mary's pharmacy and sends Mary a summary of the visit, diagnosis, and prescription along with additional symptoms of which she should be aware.

- Without health insurance, Mary is able to gain access to care at a cost much less than an urgent care visit.
- If she did have insurance coverage, the visit would likely be covered in the same manner as an in-office visit (subject to copay, coinsurance, and deductible).
- If Mary were covered under Medicare Part B, this type of virtual visit would not be covered. Instead, Mary would need to be located in an HPSA, travel to an approved originating site, and be assisted by a health care professional in order to contact a physician for telehealth services.

Example 2

A child who is sick at school must be picked up by their parent and is often taken to an urgent care for further evaluation and treatment. To expedite a child's care, two elementary schools in Georgia, working with the State Office of Rural Health, can now connect to a primary care provider via videoconference to assess a child's situation, recommend a remedy, and potentially prevent that visit to an urgent care setting.[8] Furthermore, Brigham Young University conducted a literature review of fifteen research studies and found that in schools where the school nurse employed telehealth it resulted in increased effectiveness of medical care, improved collaboration between the school and the student's primary care provider, reduced absenteeism, improved cost effectiveness, and improved convenience.[9]

Example 3

Bundled payment is increasingly a common option for reimbursement with total knee replacement (TKR) under Medicare, Medicaid, and commercial plans. The intent is aligning incentives for care and cost under the orthopedic surgeon. The approach creates a single point of accountability for all services delivered to each patient within a fixed period; that includes the surgery and set number of days for recovery.

Services included in the bundle encompass imaging, implant, and supplies, surgical care, fees for professional services, medications, and all follow-on care within the set 'after' period. This encompasses office visits, wound care, and physical therapy (PT).

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[8] Lampert, JG. "Local Examples: Innovations in Telehealth." *Third Way*. 30 Mar. 2015. http://www.thirdway.org/memo/local-examples-innovations-in-telehealth
[9] Reynolds, Cori A. and Maughan, Erin, "Telehealth in the School Setting: An Integrative Review" (2014). *All Student Publications.* Paper 7. http://scholarsarchive.byu.edu/studentpub/7

Managing 30-day readmissions is a primary measure for defining success with bundled payment contracts – particularly with the CMS-sponsored Comprehensive Joint Replacement (CJR) demonstration.

Experience is demonstrating telehealth as enabling enhanced interaction and follow-on with TKR patient during the 'after' period. These interactions include remote provider visits to assess overall status and wound care evaluation as well as review, planning, and execution for physical therapy. The latter interactions leverage telehealth to provide a remote visit with the Physical Therapist and enable in-home therapy using devices, such as the Nintendo Wii.

Effects of employing telehealth are embedded within the overall management structure for post-acute care (PAC) under TKR. Findings reported by Navathe and colleagues in JAMA Internal Medicine denote 49% of total savings to Medicare through bundles from including PAC.[10] Savings are linked to reduced use of institutional care post-discharge.

These results compare with findings using telehealth to support post-discharge care for TKR among patients at Bon Secours St. Mary's Hospital in Richmond, Virginia.[11]

Example 4

Sue is an elderly woman who was transferred to a skilled nursing facility following an inpatient hospitalization for pneumonia. In the middle of the night, Sue's breathing became labored and increased. The nurse called the physician and reported the symptoms. Using two-way video conferencing, the physician was able to evaluate Sue and determine that she needed to be readmitted to the hospital for more acute treatment and monitoring.

- Without the ability to use telehealth to evaluate the patient, the physician would have had to travel to the skilled nursing facility, which would have delayed the patient's transfer to the hospital and subsequent treatment.
- The use of telehealth in skilled nursing and other facilities offers the potential for additional opportunities for providers to monitor patients, which can decrease inpatient readmission rates.

**ii. Specialty Care**

Specialty care can also be delivered through virtual encounters. A wide range of specialty services can be delivered in hospitals, other facility settings, and offices using telehealth. The ability to conduct specialty care

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[10] Navathe AS, Troxel AB, Liao JM, Nan N, Zhu J, Zhong W, Emanuel EJ. Cost of Joint Replacement Using Bundled Payment Models. *JAMA Intern Med.* 2017;177(2):214–222. doi:10.1001/jamainternmed.2016.8263
[11] "VOX Telehealth Launches OrthoCare Program", Jan 12, 2015, http://www.voxtelehealth.com/vox-telehealth-launches-orthocare-program/

encounters virtually provides patients with care that may have been lacking or difficult to access in provider shortage areas.

Example 1

A study published in JAMA Neurology found that a Cleveland Clinic mobile stroke treatment unit (MSTU) was able to initiate treatment faster for its patients than those treated in the ED by consulting with specialists via telemedicine.[12] The Cleveland Clinic's telestroke network uses live-streaming video to assess a patient in an ambulance with a potential stroke, enhancing the ability to administer the proper remedy within half the time compared to waiting until arriving at the ED.

Example 2

Jane presents at a local ED complaining of a sudden onset of amnesia. The ED staff assesses her and determines that given the rare set of symptoms, a neurologic examination is needed. The local hospital is small and does not have a neurologist on staff 24/7, but they are able to conduct a live, two-way visit with a neurologist at another location. The staff is able to communicate the patient's condition and answer questions just as if the neurologist were on site while the neurologist is also able to observe and communicate with Jane.

- The use of telehealth in this situation gets the patient the specialist care they need in an emergency situation and helps the hospital reduce costs by reducing the need to retain unnecessary staff.

Example 3

John undergoes annual routine exams by his dermatologist. The dermatologist has taken pictures of several moles and large freckles that are being monitored. Several months after his annual visit, John notices one of the moles has developed a scab and has started to bleed when manipulated. He contacts his dermatologist and is able to set up a virtual appointment. Using two-way video conferencing, the dermatologist examines the mole and makes a determination for John to be seen in the office for removal of the mole.

- The use of telehealth in this situation shortened the time from identifying the problem with the mole to having it removed.

### iii. Behavioral Health

*Telehealth for Mental Health and Substance Use Disorders.* There have been numerous studies documenting the efficacy of telehealth services

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[12] Itrat A, Taqui A, Cerejo R, Briggs F, Cho S, Organek N, Reimer AP, Winners S, Rasmussen P, Hussain MS, Uchino K, for the Cleveland Pre-Hospital Acute Stroke Treatment (PHAST) Group. Telemedicine in Prehospital Stroke Evaluation and ThrombolysisTaking Stroke Treatment to the Doorstep. *JAMA Neurol.* 2016;73(2):162–168. doi:10.1001/jamaneurol.2015.3849

for treating mental health and substance use disorders (MH/SUD), including by the U.S. Department of Veterans Affairs[13] and in randomized control trials published by the American Psychiatric Association.[14] The latter study shows the same effectiveness in providing psychiatric care as in-person treatment. There is evidence of success using telehealth for treatment of many MH/SUD related conditions, including child psychiatry, depression, dementia, schizophrenia, suicide prevention, post-traumatic stress, panic disorder, substance abuse, eating disorders, and smoking prevention.[15]

*Reaching Additional Individuals.* Telehealth for MH/SUDs helps address the long-standing and critical behavioral health workforce shortage. There are significant gaps, particularly in rural areas in the behavioral workforce; from physicians to licensed psychologists or other mental health professionals. Telehealth can assist primary care practitioners, who are often left to support individuals with these conditions in reaching the expertise of a behavioral health clinician. Telehealth can also help individuals manage their MH/SUD conditions, which are chronic conditions, that require medication adjustments and other supports to maintain stability and avoid hospitalization to reach behavioral health clinicians easily on a routine basis.

*Barriers.* Providing telehealth for MH/SUDs is an important tool to help individuals get and stay well. A significant segment of individuals with MH/SUD are homeless or in other unstable situations where they cannot access computers or other mobile technology. In this situation, managed care organizations can struggle to reach and assist individuals in using these services. The other challenges in providing telehealth services for MH/SUDs are similar to those for physical health telehealth.

Telepyschiatry

The growing field of telepyschiatry allows providers to connect with patients without geographic barriers. Given the access issues surrounding psychiatry care, especially among specialists such as child-psychologists, patients are able to access more providers and have their health care needs met in a virtual environment. In addition to access issues and provider shortages, telepyschiatry is also able to assist patients who may be home-bound or lack adequate transportation.

Example 1

*Anthem's Mental Health/Substance Use Disorder (MH/SUD) Telehealth Efforts.* In January 2016, Anthem launched Live Health Online Psychology. Preliminary results show visits have grown steadily overtime and the majority of access is on evenings or weekends. In addition, data

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[13] Outcomes of 98,609 U.S. Department of Veterans Affairs Patients Enrolled in Telemental Health Services, 2006 – 2010, Psychiatric Services, April 2012
[14] Randomized Controlled Trial Shows Telepsychiatry Is As Effective as In-person Treatment, American Psychiatric Association, June 2007
[15] The Effectiveness of Telemental Health Applications: A Review, Canadian Journal of Psychiatry, Nov. 2008

indicates engagement is high with members returning on average six times to Live Health Online Psychology for on-line therapy.[16]

<u>Example 2</u>

Cherokee Health Systems in Tennessee utilizes a sophisticated model of telehealth to provide services to a number of outlying counties in very rural areas and in semi-urban areas that lack sufficient resources such as Child/Adolescent psychiatry. Through telepyschiatry, a child/adolescent psychiatrist who lives in Georgia is able to telecommute to East Tennessee to see patients daily.

<u>Example 3</u>

The first mobile medical application to treat substance use disorders received Food and Drug Administration (FDA) approval. Patients who used the app, which delivers cognitive behavioral therapy, with outpatient therapy were found to have a lower likelihood of relapse. The app is called "Reset" and is used to treat patients with addictions to alcohol, cocaine, marijuana, and stimulants. A similar app is under development for opioids. As with other medical apps, it provides clinicians with a tool to evaluate progress and treatment options. Integrating new digital health tools with traditional treatment protocols is just another aspect where telehealth technologies are expected to drive synergies within the health care system.[17]

**b. Care Across the Continuum**

The clinical and technical extension of leveraging digital modalities for care delivery is enabling continuous encounters. The examples noted for virtual encounters provide a sense for how telehealth can extend the scope as well as scale of care. Integrating digital monitoring with video and voice communication facilitates creating a platform that supports providing care whenever and where ever needed to optimize the quality outcomes and costs of treatment for each patient.

Deployment of remote patient monitor together with use of wearable technologies offer two examples for how integrating digital technologies can support delivering the scope of services at scale to meet the requirements of patients with multiple clinical needs. Flexibility in the design and deployment of digital platforms allows use in addressing the continuum of care for individuals with acute as well as chronic conditions. Health information technology developers are encouraged to work with providers on designing tools with technology and service combinations that will improve coordination of care and promote wellness.

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[16] Anthem subject matter expert interview, 02/03/.2017
[17] Sweeney, E. "After a 'game changing' FDA approval, a former HHS official says mobile apps will reshape addiction treatment." *Fierce Healthcare.* 21 Sept 2017. http://www.fiercehealthcare.com/mobile/after-a-game-changing-fda-approval-former-hhs-official-predicts-mobile-apps-will-reshape

Providing comprehensive care across the continuum also requires that patient generated data from the various sources be integrated into the patient's electronic health record (EHR). The integration of that data must be done in a manner that fits within the workflow of the physician or other health care provider who needs to review the data and make treatment decisions based on it. There is a need to strike a balance with the inclusion of this data with its quality – more data is not always meaningful. The goal is to capture and identify the actionable information for the patient and not just record volumes of data.

### i. Remote Patient Monitoring

Remote patient monitoring (RPM) technologies facilitate ongoing clinical observation of the patient by the clinician, which allows for more timely and effective management of chronic conditions. Some of the benefits of RPM include decreased health care costs and increased patient satisfaction, since the patient can be managed at home or in a lower acuity care setting.

RPM devices can collect a wide range of data from patients through various methods. Data that is able to be monitored and transmitted includes weight, blood pressure, blood oxygen levels, heart rate, blood glucose, and other clinical information. The use of RPM allows clinicians the ability to monitor physiological data on an ongoing basis and identify trends that signal a change in status, acute episode or other illness.

There are many clinical scenarios in which patients benefit from RPM. Cardiac patients can be sent home with a remote heart rate monitor to track potential arrhythmias instead of staying in the hospital. Patients with chronic respiratory diseases can have their status monitored for potential onset of an acute episode.

Example 1

RPM has shown significant promise in the Medicare population, which has a higher likelihood to be homebound and have difficulty traveling to a facility or office for in-person monitoring and follow up care. In studies of Medicare beneficiaries who have experienced heart failure, RPM has reduced hospital admissions and overall costs of treatment. An RPM program in Boston covering 1,200 patients since 2006 has seen readmission rates for heart failure patients plummet by half[18], while a similar program through the Veterans Health Administration reported similar results.

Example 2

The Cleveland Clinic Hypertension Program links RPM with care coaching to evaluate patients. Cleveland Clinic launched the chronic care

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[18] Broderick, A. "Partners HealthCare: Connecting Heart Failure Patients to Providers Through Remote Monitoring." The Commonwealth Fund. January 2013. http://www.commonwealthfund.org/~/media/files/publications/case-study/2013/jan/1656_broderick_telehealth_adoption_partners_case_study.pdf

and RPM pilot with an enhanced capacity to conduct video visits to hypertension patients. The pilot monitors blood pressure through a combination of consumer device data and the platform's integration with Apple HealthKit. Cleveland Clinic is planning to assess the results in the near future and begin the second phase to expand the pilot. Combining RPM and telehealth is a new dimension with the power to greatly impact patient outcomes.[19]

### ii. Wearable Devices

The 21st Century Cures Act, passed late in December 2016, clarified FDA's regulation of medical software (Sec. 3060), amending the definition of "device" in the Food, Drug and Cosmetic Act to exclude certain software functions. Commonly used consumer health and wellness trackers are explicitly excluded from this oversight, aligning with FDA's general wellness guidance from 2015.[20] However, of note, wellness products that specifically address a particular disease or condition would still be subject to FDA oversight.[21] Technology companies creating software functions and platforms designed for medical use may also be subject to FDA regulatory authority.[22]

Example 1

Proteus Discover encapsulates medications into a single pill with an ingestible sensor that can measure when a medication is taken and a patient's associated physiology. Information then transmits to an app on a mobile device, which the patient can monitor and share with a health care provider. If for any reason a patient forgets to take a prescription, they can be notified by a reminder sent to their mobile device. A study published last year in the Journal of the American College of Cardiology illustrated greater reductions in blood pressure and cholesterol in patients with uncontrolled hypertension and diabetes when using Proteus Discover than usual care.[23]

Example 2

The Mayo Clinic researchers tested a health program available online and through a smartphone app that provided information about healthy lifestyles and asked patients undergoing cardiac rehabilitation to chronicle dietary and exercise habits. When compared with a group of patients that

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[19] Cohen, Jessica Kim. "How Telehealth Has Enhanced Cleveland Clinic's Value-based Care Strategy." *Becker's Hospital Review*. Becker's Health IT & CIO Review, 24 Mar. 2017. Web. 20 July 2017.
[20] General Wellness: Policy for Low Risk Devices - Guidance for Industry and Food and Drug Administration Staff (2016). Print.
[21] Pavlovic, Yarmela, and Jennifer Henderson. "President Obama Signs 21st Century Cures Act into Law, Exempting Certain Types of Medical Software from FDA Regulation." *www.hoganlovells.com*. N.p., 16 Dec. 2016. Web. 06 July 2017.
[22] Mobile Medical Applications - Guidance for Industry and Food and Drug Administration Staff (2015). Print.
[23] Lars Osterberg, Naunihal Virdi, Yoona Kim, Praveen Raja, Miriam Cruz, George Savage, Jeffrey Unger, Marina Raikhel, and JuanFrias, "First Clinical Evaluation of a Digital Health Offering to Optimize Treatment in Patients with Uncontrolled Hypertension and Type 2 Diabetes," *Journal of the American College of Cardiology* Volume 67, Issue 13, Supplement. 2016: pg. 2028

had traditional care, those using the digital program improved lifestyle habits and had fewer cardio-related emergency department (ED) visits and re-hospitalizations.[24]

### iii. Integrated Care Management

Awareness, engagement, and empowerment are essential factors to meet clinical, financial, operational and quality goals for care. Often missing in treatment is a shared sense of these elements between a patient, their provider(s), and family or other individuals supporting treatment.

Digital platforms combining voice and video communication with sensor technology for self as well as remote monitoring create a unifying resource that facilitates achieving an enhanced level of understanding and participation in care by a patient. That increased sense of ownership serves to more directly link actions by providers and the individual in reinforcing actions that maximize the value of therapy. The result is integrating care both for and with each patient.

Example 1

Virta Health allows patients to video-chat with a remote Virta doctor, who consults with their primary care doctor, reviews their blood tests and medical history, and makes diet and drug recommendations. Initial results that examined the program's impact on 241 Type 2 diabetics, published in the journal JMIR Diabetes in March, found that 56 percent had lowered their blood sugar to nondiabetic levels after 10 weeks.[25] About 90 percent had reduced or stopped their use of insulin altogether, and three-quarters had lost at least 5 percent of their body weight. After six months, 90 percent remained on the Virta program, and most continued to lose weight and improve their blood sugar control.

Example 2

For a group of patients with a heart failure condition, the use of a telemonitoring system was shown to improve patient self-care by instructing the patients in real-time how to appropriately modify their lifestyle behaviors. Patients felt more aware of their heart failure condition, less anxiety, and more empowered.[26]

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[24] R. Jay Widmer, Thomas G. Allison, Ryan Lennon, Francisco Lopez-Jimenez, Lilach O. Lerman, and Amir Lerman, "Digital health intervention during cardiac rehabilitation: A randomized controlled trial." *American Heart Journal* Volume 188, 2017: pg. 65-72

[25] McKenzie, Amy L., Sarah J. Hallberg, Brent C. Creighton, Brittanie M. Volk, Theresa M. Link, Marcy K. Abner, Roberta M. Glon, James P. McCarter, and Jeff S. Volek, "A Novel Intervention Including Individualized Nutritional Recommendations Reduces Hemoglobin A1c Level, Medication Use, and Weight in Type 2 Diabetes," *Journal of Medical Internet Research Diabetes* 2(1) (2017): e5. Web

[26] Seto E, Leonard KJ, Cafazzo JA, Barnsley J, Masino C, Ross HJ, "Perceptions and Experiences of Heart Failure Patients and Clinicians on the Use of Mobile Phone-Based Telemonitoring," *Journal of Medical Internet Research* 14(1) (2012):e25.Web

Example 3

Various asthma mobile applications, most of which are free of charge, offer functions related to asthma education, self-monitoring of symptoms and consistent reviews of treatment. With the capacity for instant real-time notifications, analysis found these apps could empower behavioral change relevant for asthma self-management. Even still, advantages present within technology are not fully realized, and it is expected mobile smart phone sensors could permit automated tracking functions in the future.[27]

## IV. Conclusion

As the use of telehealth continues to gain traction, the modalities through which the health care services are delivered continue to evolve. While additional studies are needed to evaluate impacts on health care costs, this paper has provided an overview of the various telehealth modalities that exist today. It has also given numerous examples to demonstrate how the modality is used and the benefits seen by patients, providers, and payers. Organizations wishing to implement telehealth should further explore the different modalities to determine which ones will best meet their needs.

## V. Acknowledgements

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