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Telemedicine

Federal Agencies "ECHO" Call for Progress in Telehealth Policy



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By now "telehealth" is a common term and many have a basic understanding as to its meaning. "Telemedicine," as <u>defined</u> by the American Telemedicine Association, is "the use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status." The term originally was understood to simply mean communication between two providers. The term telehealth is often used interchangeably with telemedicine, as are "m-health" and "e-health." However, telehealth usually refers not only to telemedicine but also to patient/provider communication as well as electronic health management/data collection (e.g., via smartphone apps, health information trackers).

The health-care industry generally regards telehealth as highly beneficial from a clinical and patient satisfaction standpoint. However, despite its undeniably rapid growth as an industry overall, telemedicine has yet to be fully accepted and integrated within either the public or private health-care programs. This is due primarily to existing payment and regulatory obstacles imposed by the health-care programs themselves (e.g., Medicare and commercial plans) and state regulatory agencies (e.g., state medical boards). As discussed in this article, throughout 2016, new proposed legislation, regulations and government reports all continued to recognize current and potential benefits of telehealth, as well as the obstacles preventing significant expansion. In one way or another the governmental issuances all asserted that the telehealth growth called for should not be expected until greater evidence is cultivated that illustrates its benefits. It appears that only with such evidence will the stage be set for any significant loosening of the legal ties around telehealth. However, as discussed below, legislation passed at the end of 2016 holds some promise for providing such data and evidence.

CONNECT for Health Act

While Medicare currently covers and provides reimbursement for certain telehealth services, section <u>1834(m)</u> of the Social Security Act (<u>42 U.S.C. § 1395m</u>) imposes restrictions on the following: the type of service, the type of provider who may render the service from the "distant site" (i.e., where the provider is located); the type and geographic location of the "originating site" (i.e., where the telehealth patient is located); and the type of technologies that can be used to provide telehealth services. In the first quarter of 2016, bipartisan legislation was introduced that expanded the use of telehealth and remote patient monitoring (RPM) under Medicare. (Remote patient monitoring is the home use of mobile devices by patients to perform certain routine tests and send the results electronically to their treating practitioners. Examples of such tests include blood glucose testing for diabetic patients, heart or blood pressure monitoring for cardiac patients.) The "CONNECT for Health Act" (S. 2484) proposed to reduce or eliminate current Medicare restrictions found in SSA § 1834(m).

The CONNECT for Health Act proposed a bridge demonstration waiver for which providers could apply. Applicants would need to submit a proposal describing how they would furnish telehealth or remote patient monitoring in a manner consistent with the goals of the <u>Merit-based Incentive Payment System</u> or "MIPS" under the Medicare Access and CHIP Reauthorization Act (MACRA) (<u>Pub. L. No. 114-10</u>). If granted the waiver, providers may use telehealth within their practice free of the traditional and existing restrictions, including limitations on: the type of origination site, any geographic locations, the use of store-and-forward technologies or the type of health-care provider who may furnish the services. The use of telehealth must be budget neutral, and providers would be subject to certain reporting requirements related to utilization, expenditures and data regarding the achievement of certain quality measures consistent with the MACRA and MIPS. Further, waiver participants will be subject to audit.

The same waivers under the bridge demonstration are available to participants in MACRA's alternate payment models or "APMs" (See <u>42 U.S.C. § 1395I(z)</u>). Similarly, APM participants would be required to submit certain data reports to the Centers for Medicare & Medicaid Services on an annual basis.

RPM would have been specifically expanded for chronic care services. Individuals with two or more Medicare-covered chronic conditions who were hospitalized or visited an emergency room at least twice in the last year would be eligible to receive RPM for 90 days (with a possibility of renewal), and eligible providers would receive reimbursement. The proposed expansion of telehealth services for chronically ill, even if limited to RPM, echoes the proposals of a 2015 Senate Finance Committee Report.

The CONNECT for Health Act also proposed expanding the definition of an "originating site" to include: a dialysis facility at which an individual is located and receiving monthly end-stage renal disease (ESRD) visits via telehealth; any site where stroke evaluation or management services are provided via telehealth; and any facility of the Indian Health Service (IHS). However, stroke evaluation and management sites and IHS facility sites would not be eligible for the originating site facility fee. With respect to distant sites, eligible telehealth distant sites would be expanded to include federally qualified health centers and rural health clinics.

The CONNECT for Health Act also proposed changes for Medicare Advantage (MA) plans by allowing them to elect to use telehealth or RPM to provide benefits under original Medicare fee-for-service program options. MA plans which elect to provide these services must collect data from members on expenditures and utilization.

The last part of the CONNECT for Health Act clarified that, with respect to the prohibition on the payment of inducements in the form of "remuneration" to Medicare beneficiaries, 42 U.S.C. 1320a - 7a(a)(5), the provision of telehealth and RPM technologies would not be considered remuneration.

An <u>independent third-party study</u> of the bill suggests that it could generate \$1.8 million of savings. Notwithstanding, the Congressional Business Office would have (one of) the last word as to its cost savings and has been consistently skeptical, calling for additional evidence as to the cost savings. Skeptics and proponents alike agree that evidence of the benefits of expanded telehealth services (or lack thereof), such as through the CONNECT for Health Care's demonstration project, is needed. Despite this promise, the bill was sent to the Committee on Finance in early February 2016, and there was no further action.

2016 MedPAC Report

On March 3, 2016, the Medicare Payment Advisory Commission (MedPAC) held its second meeting on the topic of telehealth. The resulting report, "Telehealth Services and the Medicare Program," was issued with the commission's June 2016 "Report to the Congress on Medicare and the Health Care Delivery System." MedPAC does not make any express recommendations in its report but rather raises issues for policymakers to consider when addressing the question of expanding telehealth services under Medicare.

In its report, MedPAC recognized the broadening nature of telehealth by listing the six common categories in which telehealth services fall:

- · Consultations between a patient at home and a distant clinician;
- Consultations between a patient in the presence of a clinician and a distant clinician;
- · Consultation between two clinicians without the patient present;
- RPM of a patient in a hospital or other facility;
- RPM of a patient at home; and
- Asynchronous electronic transfer of patient information to a clinician (e.g., labs or images).

The report summarized the current status of Medicare Fee for Service (FFS) reimbursement and its limitations (i.e., those found in SSA § 1834(m) and discussed above), and makes an effort to note how MA plans have the ability to offer benefits beyond Medicare FFS, which some plans have already acted upon. However, MedPAC noted that these extra benefits may come at an extra cost to beneficiaries and/or the program. The MedPAC report also discussed the

availability of telehealth within the context of Medicare's bundled payment programs and certain ACO programs via waivers of traditional limitations, such as those applicable to the originating site. MedPAC's nod to these waivers seemingly implies that their inclusion in the bundled payment programs conveys an expectation that telehealth will facilitate such programs' goals of quality improvement and cost savings.

MedPAC did acknowledge the rapid growth of telehealth services in recent years and shared research as to characteristics of its usage. For example, the primary users of telehealth services are patients who are younger, disabled, dually eligible for Medicare and Medicaid and/or living in rural areas. The most common service rendered has been evaluation and management services (E&M) followed by psychiatric consultations. The most common type of provider of telehealth services, not surprisingly, is a physician, followed by outpatient hospital departments. MedPAC also noted the increased usage of telehealth in the private setting. Commercial insurers are including telehealth in their plans for member convenience and to increase access to primary care, while health systems have developed services in the inpatient and outpatient setting (tele-stroke, tele-ICU and tele-hospitalists). Employers increasingly offer telehealth services as a convenience to their workforce. Walmart, for example, built health clinics where employees can consult with a remote clinician. MedPAC also noted the Veterans Administration's robust program, aided in part by the health-care system's expansive integration and the fact that practitioners are permitted to practice across state lines.

Despite the undeniable growth of telehealth usage, MedPAC asserted there is still not enough evidence to make conclusions regarding the efficacy of telehealth. While MedPAC seems to agree that existing evidence suggests access and convenience is improved through telehealth, the case is less strong as it relates to improvements to quality or reductions of cost. MedPAC believes more research is needed on specific telehealth interventions for specific populations, suggesting that there may not be a one-size-fits-all telehealth policy for all its variations and modalities.

AMA Ethical Guidelines for Telemedicine

In June 2016, the American Medical Association (AMA) further affirmed its support for the use of telehealth technologies by adopting ethical guidelines for the use of telehealth within professional and ethical medical practice. The guidelines focused a good deal on the technology itself, noting that it must include privacy and confidentiality protections to prevent unauthorized access by others and that patients must be informed as to any technology limitations of which they may not be aware—e.g., the technology may not be best suited for use in an emergency or urgent situation. Physicians should also inform patients how to receive follow-up care, when needed.

The guidelines further addressed a physician's obligations regarding his/her fiduciary duties to the patient, noting that physicians must disclose any actual or potential conflicts of interests to the patient, such as interests or ownership in the telemedicine technology being used. The guidelines speak to how meeting the standard of care in the context of telehealth not only requires professionalism on the part of the physician but also his/her proficiency in the use of the technologies. Considering there is no in-person exam, the AMA asserts that physicians must ensure they are gathering as much information from the patient as possible and should be prudent when determining whether circumstances are appropriate for a telehealth consult. Any informed consents should address the features of telemedicine and its limitations. Physicians should support the continuum of care by exchanging information with the patient's primary care provider or

specialist involved in the patient's care, and recommend that the patient follow up with his/her primary care provider and specifically inform the provider of the telehealth consult.

In <u>announcing the new guidelines</u>, AMA Board Member Jack Resneck, MD, summarized their main goal, stating: " Physicians who provide clinical services through telemedicine must recognize the limitation of the relevant technologies and take appropriate steps to overcome those limitations." While the AMA clearly supports the use of innovative telehealth, these guidelines serve as a reminder of the traditional requirements of professional and ethical practice.

Department of Health and Human Services Report to Congress

In August 2016, the Department of Health and Human Services (HHS) issued, at Congress's request, a report on the department's progress and efforts in the telemedicine arena, "Report to Congress- E-health and Telemedicine ." The HHS report paints a picture of telehealth similar to that of the MedPAC report with regard to the current use and challenges of telehealth, as well as the potential for its expanded usage. The HHS report specifically highlights the benefit of telemedicine for the chronically ill and the "particular promise" held for chronic disease management, noting that telemedicine may cut down on frequent clinical visits that this population often requires and "avert costly emergency room visits and hospital stays." Again, bundled payment program waivers are acknowledged as is the government's rationale for including the waivers as a means to facilitate not only improved quality and/or patient satisfaction but for achieving cost savings as well.

Notwithstanding telehealth's promise, the HHS report highlights critical obstacles in the way of the industry's desired growth, which go beyond the Medicare reimbursement limitations already discussed, and include regulatory issues such as state licensure. Although the Federation of State Medical Boards has drafted <u>model legislation</u> for a streamlined licensure process allowing for physicians to more easily practice in multiple jurisdictions, only 18 state medical boards have enacted it to date. Other challenges relate to hospital credentialing and privileging requirements and processes. The most practical of the obstacles noted is the lack of Internet connectivity, which impacts the rural areas with the most need for, and patients who could most greatly benefit from, telehealth services and connectivity to remote providers.

The HHS report summarized current efforts, including grants and investments, by various federal agencies into the research and expanded use of telemedicine services within government programs and service offerings. A <u>cost benefit</u> <u>analysis</u> by the Agency for Healthcare Research and Quality (AHRQ) in 2016 found that, "almost universally," patients are pleased with the outcome of their telemedicine visit. The AHRQ overview cites telemedicine's "distinct promise" in behavioral health, dermatology, chronic disease management (as previously mentioned) and physical rehabilitation, as well as the potential for improved access or care in teleradiology, burn care and surgery support. Notwithstanding the cited benefits for telehealth, the AHRQ report again states that there is insufficient evidence to support the cost-effectiveness of telehealth.

2017 Physician Fee Schedule

In November 2016, CMS issued its final Physician Fee Schedule (PFS) for CY 2017. Each year CMS considers adding new CPT codes for covered telehealth services. CMS reviews requested codes and determines whether to add them based on their satisfaction of the criteria and characteristics of one of the two categories.

Category for New Medicare Telehealth Codes	Categorical Basis for Adding New Codes	
Category 1	Services that are similar to professional consultations, office visits and office psychiatry services that are currently on the list of telehealth services. CMS looks for similarities between the requested services/codes and existing telehealth services for the roles of, and interactions among the beneficiary, the physician (practitioner) at the distant site and, if necessary, the telepresenter (a practitioner who is present with the beneficiary at the originating site). CMS looks for similarities in the telecommunications system used to deliver the system such as interactive audio and video.	
Category 2	Services that are not similar to the current list of telehealth services. CMS reviews the request and assesses whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of the telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Evidence in support of the code should be submitted and include a description of clinical studies that demonstrates the telehealth service improves a beneficiary's diagnoses or treatment of an illness or injury or improves the function of a malformed body party. CMS does not consider minor or incidental benefits to be clinical benefit.	

In the 2017 PFS, CMS finalized its proposal to add new ESRD codes (90967, 90968, 90969 and 90970) (MedPAC has also recognized the benefit of telehealth in the context of ESRD services) and new advance care planning codes (99497 and 99498) on a Category 1 basis. CMS added the ESRD codes in response to requests to do so, but added the advance care planning codes without having received a request for them. CMS also finalized new G-Codes (G0508 and G0509) for intensive telehealth consultations, with the intention of addressing the additional resources and costs needed for remote consultations with critically ill patients, such as stroke patients. Although CMS received requests to add other codes, it declined to propose adding such codes for the following reasons:

Requested Code Services	Category 1 Basis for Denial	Category 2 Basis for Denial
Observation Care	CMS refers back to its denial in CY 2005.	CMS found no evidence of clinical benefit.
Emergency Department Visits	Contrary to requestor's position, CMS asserted these visits are different from outpatient physician office visits (which are on the current list of Medicare telehealth services). Per CMS, acuity of patients is generally more severe and emergency medicine often requires frequent and fast-paced re-assessments and interventions.	CMS found no evidence of clinical benefit.
Critical Care Evaluation	Due to acuity of critically ill patients, CMS does not believe these services are similar to any on the current list of Medicare telehealth services.	CMS found no evidence suggesting that telehealth is a reasonable surrogate for face-to-face delivery. (See above re: new G-Codes for consultations to the critically ill).
Psychological Testing	CMS asserted these are dissimilar to services on the current list of Medicare telehealth services due to the need for close observation of patient's response.	CMS found no evidence of clinical benefit.
Physical and Occupational Therapy and Speech Language Pathology	CMS noted that physical therapists, occupational therapists and speech-language pathologists are not authorized practitioners of telehealth under Medicare.	

CMS also finalized a new POS code for telehealth services to be used by the distant site (where the remote provider is located) to signal that the service was rendered via telehealth. The originating site (where the patient is located) would continue to use the POS code that applies to the type of facility. CMS asserted there would be no change in reimbursement for the distant site providers or to the facility fee for the originating site. The GT and GQ modifiers that certify that the service meets the applicable telehealth requirements continue to be required along with the new telehealth POS code. However, because the POS code would serve to identify telehealth services, CMS will revisit the idea of eliminating the GT and GQ modifier through future rulemaking.

The ECHO Act

On December 14, 2016, the President signed the Expanding Capacity for Health Outcomes (ECHO) Act (Pub. L. No. 114-270). It is the first stand-alone telemedicine bill to receive a vote on the Senate floor, as opposed to being wrapped up in a larger health bill. The ECHO Act was first introduced in the spring of 2016, not long after the CONNECT for Health Care Act was introduced. While the CONNECT for Health Care Act proposed changes to Medicare telehealth policies, the ECHO Act proposes the continuation of current private sector telehealth programs across the country. Specifically, the ECHO Act supports the expansion of Project ECHO to a national model for serving underserved rural areas. Project ECHO was first launched in 2003 at the University of New Mexico's academic medical center. It connects highly trained specialists at academic medical center "hubs" with primary care and other community-based providers in mostly rural areas—the "spokes"—for purposes of training. Through interactive videoconferencing, specialists and primary care providers participate in weekly tele-ECHO[™] clinics, which are like virtual grand rounds, combined with mentoring and patient case presentations.

Specialists serve as mentors and colleagues, sharing their medical knowledge and expertise with primary care clinicians. Essentially, Project ECHO creates ongoing learning communities in which primary care clinicians receive support and develop the skills they need to treat a particular condition. While Project ECHO first started with a focus on treating Hepatitis C patients, it has grown to address more than 40 health conditions. Further, the number of ECHO hubs and ECHO Superhubs, (locations other than the University of New Mexico qualified by Project Echo to train a hub) has expanded nationwide as well as around the world (currently in 10 countries). The touted result of Project ECHO is the ability for local providers to provide comprehensive, best-practice care to patients with complex health conditions, right where they live.



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Sponsors of the bill, Senators Brian Schatz and Orrin Hatch, assert that only about 10 percent of the nation's physicians practice in rural areas, which are home to almost 25 percent of the population. Schatz and Hatch maintain these areas have difficulty recruiting health-care providers as professional development opportunities are slim compared to more

populated urban areas. (See <u>114 Cong. Rec. H7198</u>, <u>H7199 (Dec. 6, 2016)</u>). Further, rural populations tend to have higher rates of chronic diseases and practice challenges that hinder access to health care, such as lack of transportation, connectivity and isolation. According to Congressman Burgess, a supporter of the legislation, "[the Echo Act] offers a means by which to evaluate successful models in the private sector and opportunities to build upon them and adopt them if successful." (See id.)

The ECHO Act requires HHS to examine the models' impact on the following: (1) addressing mental health and substance abuse disorders, chronic disease and conditions, prenatal and maternal health, pediatric care, pain management and palliative care; (2) addressing provider capacity and workforce issues; (3) implementation of public health programs; and (4) the delivery of health-care services in rural areas and other shortage or underserved areas (HPSAs and MUAs). HHS must issue a report on its findings within two years. The report must contain an analysis of:

- · Providers' use of the models,
- · Impact of the models on provider retention,
- · Impact of the models on the quality of and access to care for patients located where the model is already in operation,
- Barriers faced by health-care providers, states and communities in adopting the models and

• The impact of such models on the ability of local health-care providers and specialists to practice to the full extent of their capacity (education, training, licensure, etc.)—including patient wait time for specialty care.

The report must also contain: (1) a current list of the Project Echo models in place during the five years preceding the report; (2) recommendations to reduce barriers for using the models and opportunities for expanding use of the models; and (3) recommendations regarding the role of these models in providers' continuing medical education and lifelong learning.

Concluding Thoughts

Telehealth continues to be recognized in the health-care industry as a highly beneficial means to provide patient care in terms of both clinical results and patient satisfaction. Even so, federal agencies, task forces and government agency leaders, as evidenced in the several publications discussed here, continue to cite the need for more research and evidence on the benefits of telemedicine. The ECHO Act (and Project ECHO on a national scale) may be the much needed impetus that generates the evidentiary support being called for to justify the expansion of telehealth in federal programs, by private insurers and elsewhere. As data is generated and made available with the expansion of Project ECHO, it will be interesting to see what changes and expansions to telehealth are proposed and how quickly those changes take shape.