

LEGAL AND REIMBURSEMENT ISSUES FOR HOME TELEHEALTH©

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Despite robust predictions of growth in e-Health and personal electronic health records, the initiatives for home-delivered telehealth and remote monitoring of the chronically ill have failed to move forward with the rapidity predicted five years ago. This trend persists despite vast unmet need in the care of the chronically ill². Disease management researchers have attempted to demonstrate credible data showing improved outcomes and cost efficiencies to a still skeptical Department of Health and Human Services and other payers.

Chronic illness and disease management are the subjects of increasing numbers of scholarly papers and research endeavors. Nationally, and internationally, the perceptions are that the prevalence of chronic illness within the swelling ranks of the aging may cause catastrophic costs to the health services delivery systems of nations, as well as to States within the US or Provinces within other countries which are also responsible for funding care. Much of the recent disease management research focuses upon the possibility of eHealth and in particular, remote monitoring, to avert the tipping of a patient's chronic illness into acute mode. The instability of the chronically ill person may necessitate emergent and costly interventions, may threaten his or her wellbeing and perhaps survival, and may result in care delivery at institutional facilities rather than the home where the patient prefers. The maintenance of a patient at home, and an increased ability to function in and ambulate from such a base with electronic health data transmissions [through telephone/POTs, broadband, cell phone and sensor technologies], are proposed as keys to maintaining cost efficiencies in chronic care coordination³.

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² A National Study of Chronic Disease Prevalence and Access to Care in Uninsured U.S. Adults, Wilper, A. et al, *Annals of Internal Medicine* 2008; 149:170-176.

³ For a comprehensive review of the early published studies, see P. Whitten et al, "Systematic Review of Cost Effectiveness Studies of Telemedicine Interventions", *BMJ* 2002; 324; 1434-7, BMJ.com.

Five years ago, many community-based care providers were inclined to try or recommend eHealth and remote monitoring to help sustain persons in homecare, but these providers lacked clear reimbursement sources. The first home electronic technologies were ones focused on safety in the home, alerting care providers and emergency systems in the event of a sudden acute symptom or a fall. These “home alert” systems were used by a variety of aged or frail individuals including those with coronary disease, serious pulmonary problems, and vascular and neurological disorders. Although privately paid, such devices were accepted by patients and families as reasonable costs to make personal residences safer for frail individuals. The second early device developed for at-home chronic disease management was blood glucose monitors. By 2003, these were well accepted by patients, and in a manual version (that is, without electronic data transmission) have been reimbursed as durable medical equipment under the Medicare Part B program, the Medicaid programs of most states and by many private third party insurers. However, more than five years later, remote chronic disease monitoring is still funded largely by demonstration grants and pilot programs, although some State Medicaid programs will fund televisits in the home setting. Medicare policy offices remain hostile to inclusion of telehealth in long term care settings of all kinds. Consequently, some homecare providers have given up attempts to implement it.

Most experts in the telehealth field would likely agree that at least five legal, regulatory and political factors are slowing telehealth growth for home care: (1) the persistence of acute medical models and tightened payment methodologies for Medicare homecare, with resultant diminished dollars for agencies’ hardware and software deployment; (2) the problems of inter-state licensure for healthcare professionals; (3) risk management and privacy challenges in implementing home telehealth; (4) the Congressional focus on *rural* health funding; and (5) the alarm within the Department of Health and Human Services [HHS] about the recent and dramatic durable medical equipment [DME] and home health agency fraud scandals.

Reimbursement and the Acute Medical Model for Home care

There has been little movement away from an acute homecare model in the federal Medicare program. Despite the alteration of the Medicare Part A reimbursement methodology to an episodic prospective

payment in fiscal year 2000, and indications from the Centers for Medicare and Medicaid Service [CMS] that Medicare home health agencies were allowed flexibility to design visits and clinical disciplines as well as home health aide support services, the industry response has been fewer services to homecare patients, shorter lengths of stay overall [thus, little opportunity for any chronic care management other than brief teaching] and a much more “acute” Medicare benefit than before. This repositioning of home health back to an acute care model was one of the CMS goals during 2001-8 Bush administration, and it has succeeded. Unfortunately, the Administration’s additional stated goal of increasing home and community based services under Medicaid received little targeted funding for telehealth and care coordination. While there are increased numbers of studies demonstrating reduced hospitalizations and emergency room visits for chronically ill persons with CHF, home care lacks studies showing substituted remote monitoring nursing plus fewer nursing visits is equivalent to in-home visits of greater frequency for an acute medical model.

In contrast, the British Health System has identified telehealth as an important link between chronic illness and health maintenance. Health and social care services are developing the telehealth and telecare services to cope with an aging population through the NHS Connecting for Health “Whole System Demonstrator Project” with 400 participants each in three of the country’s geographic regions. More than 31 million British pounds have been funded to the project. Individual projects aimed at chronic illnesses such as chronic pulmonary obstructive disease [COPD] have been launched at individual primary care trusts. Other ambitious home telecare programs are up and functioning in Scotland and Northern Ireland. The efforts at reforming the American health funding and delivery system initially proposed by President Obama includes a medical home model incorporating remote monitoring and health information technology so there may be some new approaches to the rigidity of the Medicare homecare delivery service for the elderly.

CMS has changed the Medicare homecare reimbursement methodology three times in a decade⁴. Cost-based reimbursement changed in 2000 to a prospective payment system with home health reimbursement groups [HHRGs] founded on diagnosis, history of services and levels of self-care impediments. When the

⁴ See, Randall, Deborah, “Home Health and Hospice Legal Issues, Reimbursement Changes, Growth and Quality Changes”, Chapter Ten, Health Law Handbook, 2008.

ten-visit therapy threshold changed to three levels affecting reimbursement, home care providers lost some of their monetary flexibility to utilize aggregated reimbursement from all patient care --the “profit” so to speak ---for creative deployment of otherwise uncompensated care, such as telehealth equipment, to parts of their patient populations. Now, there seem to be no “extra” dollars in home health. Reimbursement of Medicare-eligible, chronically ill individuals may be paid at the lower end of the Part A HHRG, so home health agencies may be less willing to accept these admissions, even though these patients could be among the best candidates for remote monitoring of diabetes, hypertension, CHF, COPD and other conditions. The tele-monitored visit still does not count as a Medicare visit to the home health agency;the remote nurse monitoring the care, the equipment and the infrastructure costs must be borne by the home health agency.

Interestingly, when the Office of the Inspector General [OIG] of the Department of Health and Human Services considered the developing landscape of Medicare home telehealth in 2003, it noted:

The Centers for Medicare and Medicaid Services (CMS) – construing congressional intent in 42 U.S.C. 1395fff(e)(1) – has provided that, as part of the benefits for which payment may be made by Medicare, a home health agency “may adopt telehealth technologies that it believes promote efficiencies or improve quality of care,” HIM 201.13, although the use of such technologies may not substitute for services ordered by a physician. By ensuring prompt emergency assistance and potentially forestalling the need for more expensive care and services, the provision of the [electronic home alert system] is reasonably related to the delivery of home health services and to the fostering of efficiency and quality of care. Given *CMS’ express encouragement of innovative telehealth technologies* in the delivery of home health care, we conclude that the provision of the [electronic home alert system]....in the context of home health services would not beimpermissible....”⁵

⁵ Office of the Inspector General, Department of Health and Human Services, Advisory Opinion 03-4, February 2, 2003, emphasis added.

By tightening reimbursement, CMS has adversely affected the provision of “innovative telehealth technologies” funded through the home health global payment. MedPac has now issued a January 2010 opinion advising Congress to increase the freeze home health reimbursement rates in 2011 and beyond. Both these developments are hindering growth of home telehealth.

Problems with Inter-State Telehealth Professional Services and Licensure

The barriers to telemedicine practice throughout the United States have increased rather than receded in recent years with regard to licensure requirements for physicians and allied health professionals. This is due to physician resistance to out of state physician consultations, both on quality of care and professional competitiveness grounds. Typical state licensure demands include the necessity of a physician’s performing a physical examination of a patient, the requirement that a physician patient relationship be established prior to prescribing medications, and the review of documents and a thorough history prior to making a diagnosis and beginning treatment.

There are now several States which also have licensure requirements for the companies which are providing telehealth services. The likelihood is that a legal standard of telehealth care will be developed through regulatory procedures, integrating the concepts of quality of care with patients’ rights, consumer protection and professional discipline for companies and managers who fail to ensure appropriate outcomes for persons treated with distanced health services. Home care companies face significant regulatory burdens already, and they currently may be reluctant to add the costs and procedures in preparing for and maintaining the additional status of an approved telehealth provider.

Risk Management, Liability and Privacy

Health care providers who offer distanced health services including remote monitoring should get expert advice on how to assess, respond to and protect against the increased liabilities which telehealth services may entail. The vendors of equipment, software, programmatic disease management and trending products

will want to shift most responsibilities for proper patient identification, education, assessment and triage for emergencies onto the health providers themselves. Home care company executives and clinical managers do not always appreciate how important it is to balance those risks taken and those risks for which indemnifications may be available. Proper policies, the adequacy of patients' consents, avoidance of kick-back referral arrangement and the training of staff are four essential areas where important protections are needed. Weaknesses in any of these will determine the amount of risk home telehealth adds to the corporation and its managers. Home care companies seeking liability insurance for their added telehealth services may find insurance companies are not knowledgeable about, or agreeable to, insuring additional risk, because the telehealth field is so new. There are few if any cases in the tort law field that deal with telehealth equipment or personnel treating patients in their homes.

The protection of patient privacy and records' security have also become major health provider issues, generally, and are more complicated because of the changes in the HIPAA laws enacted during 2009. Many of the federal regulations covering this area of concern are still being finalized. Increased law enforcement resources have been added to the Office of Civil Rights within HHS, and the States' Attorneys General are now empowered to enforce HIPAA locally. States such as California have additional, more stringent requirements about privacy and patient notifications of breaches.

Home care companies must now have robust information protection policies under all circumstances of their businesses. These companies may hesitate to initiate telehealth services when the privacy exposure implicit in telehealth equipment information exchanges are added to the possible triangulating of data transmission to physicians' offices, web-based data repositories and lay family members who wish to access health care information. Those hospitals, physician practices and regional health information exchanges which will be receiving funding under the ARRA grants and incentive payments that begin in 2011, will be expected to ensure that receipt and transmission of health data are secure. Community providers of care in the home will want to partner in the future with these organizations and practices. An experience legal expert can assist health providers' careful mapping out of how these activities and the privacy laws will intersect.

Telehealth Focus Limited to Rural Providers

Another area which has not seen much positive development in recent years is any loosening of Congress's funding constraints on the federal Office for the Advancement of Telehealth [OAT] to largely focus on **rural** providers. While the history of the Congress's legislation and preferences for rural health provider funding are beyond the scope of this article, it is noteworthy that in January 2010, the Health Resources and Services Administration [HRSA] of federal Department of Health and Human Services reorganized portions of its Rural Health division. At a time when draft health reform legislation was considering an office for health innovation, HRSA continued to place substantial responsibilities of health information technology and grant making ---and the monies attached---firmly within a rural health emphasis.

In fact, large clusters of chronically ill individuals reside in major urban areas, and are un-served or underserved. The fiscal prohibitions to companies' funding home care nursing adequately, or to finding home care nurses who are willing to work in urban areas, are as monumental as those in many rural or "professionally underserved" areas. In many urban areas with high costs of living, it is enormously difficult to attract and retain staff because they must live at such distances to the urban centers where rental and home ownership is too costly. If the reality is that Congress has favored rural telehealth in the telemedicine context for diagnostic and consultative **physician to physician** services, another and different look should be given to **telehealth** remote monitoring, which may be more **nursing**-driven or coordinated, and where urban centers are just as needy as remote rural locales⁶. And perhaps the rural health focus of Congress is largely a matter of political history-- with those of the greatest seniority on the Congress's funding Committees coming from highly rural states. Advocates for eHealth technologies and remote monitoring may need to press for reformed health delivery based on demographic needs of the chronically ill regardless of geography.

⁶ OAT in the past indicated that it would welcome funding from Congress to enable more home telemonitoring grants in urban areas. With the reorganization of the health IT functions which OAT once performed, it has been firmly reconnected to the rural health policy area.

Fraud in the Medical Equipment and Home Health Industries

A final and serious barrier to the advancement of home telehealth may result from the last five years' surge in cases involving fraudulent conduct by certain durable medical equipment and home health companies funded by Medicare, Medicaid or both. Multi-million dollar fraud cases ensued from "Operation Wheeler Dealer", an OIG and Department of Justice major investigation focused on abusive sales of power wheelchairs and scooters, among the most expensive equipment available for home use under the state and federal programs. Many of the investigations have resulted in large fines and jail sentences in Florida and Texas; the common theme is patients in their homes are exploited with equipment they did not need, or billed for a higher grade than was delivered. While a power wheelchair is not equivalent to remote electronic transmission of blood pressure and glucose measurements⁷, the common site of the home as a private, largely unsupervised, and "unseen" environment where a service or item is delivered has always caused a degree of concern among the investigative committees of Congress and the fraud and abuse enforcement divisions of HHS and the States.

The equipment fraud cases, a new crop of home health fraud cases in 2009 involving billing for services not rendered, as well as OIG's long-standing concerns about relationships between homecare providers and their referral sources, could provoke additional government questions about whether remote monitoring leads to under-service to homecare patients. Generalized concern about home health 'fraud' certainly could increase HHS hesitation about coverage expansion and the direct payment of home-based remote monitoring. This integrity concern will likely be combined with the long-standing and familiar "woodwork" arguments (that is, a new benefit such as telemonitoring would draw in countless new users and thus increase costs).

The home delivered services industries--which include homehealth, hospice and personal care---are in great need of a strong public effort to create pro-active, solution-driven compliance approaches, including Codes

⁷ The Suppliers of items of durable medical equipment such as wheelchairs and the monitors, are subject to the CMS Standards for DMEPOS, 42 CFR 424.57. In the past these were loosely monitored, but standards were tightened with amendments published in 2008. Department of Justice attorneys are investigating and using failures of these standards as grounds to bring False Claims Act lawsuits.

of Conduct such as AdvaMed and PharMa have instituted. Specific provisions of such a Code should address how telehealth services can be maintained and billed with integrity, and be patient-protective. The Code should also indicate what role should be played by disease management companies, health IT equipment vendors, researchers and software developers. Representatives from these interests groups should begin discussions now about what parameters would be for a cross-industry compliance program in telehealth. If this were undertaken, the barriers of negative perception might be reduced, and home telehealth might begin to expand to better fill the existing need to recognize the limited amount of in-person professional resources available and to provide services to the huge future constituency of the chronically ill living at home.

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