

HEALTH CARE LAW | A SPECIAL REPORT

With the fate of the Affordable Care Act in the Supreme Court's hands, we consider this week some other aspects of health care practice—regulatory hurdles to the use of remote diagnostic and treatment technologies that would allow elderly people to remain in their homes longer; a new complication for the defense side in whistleblower cases; and the targeting of the life-sciences industry by patent assertion entities.



The Cyber Future of Long-Term Care: Applying Health Care Laws to “Aging in Place” Technologies

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With baby boomers entering retirement, the United States faces an aging boom that will have dramatic financial implications for national health care spending. According to the U.S. Department of Health and Human Services' Administration on Aging, between 2000 and 2020 the number of Americans older than 65 will grow by more than 50 percent, from 35 million to 55 million. This number is expected reach 89 million by 2050.

Many seniors will at some point require long-term care. In 2012, spending on long-term care totaled \$220 billion, about 9.3 percent of the nation's personal health care spending and 1.4 percent of the gross domestic product. See National Health Policy Forum, *The Basics: National Spending for Long-Term Services and Supports (LTSS)*, 2012 (2014). The Medicaid program is the biggest payor of long-term care services, covering approximately two-thirds of such expenditures, including for services that are institutional (e.g., nursing home), community (e.g., adult day care) and home-based (e.g., personal care). See Steve Eiken et al., *Centers for Medicare and Medicaid Services (CMS), Medicaid Expenditures for Long-Term Services and Supports in FFY 2012* (2014).

“Home telehealth” technology promises to be a critical component of providing quality care to the growing number of Americans who need long-term services and supports to “age in place” at home. Home telehealth and related technology can make it cheaper, easier and more comfortable for seniors to remain at home and avoid nursing facility placement.

Providers, developers and patients seeking to use home telehealth face a complex and



DOCTOR ROBOT: Technology like this RP-VITA device at Mercy San Juan Hospital in Carmichael, Calif., lets doctors beam themselves to remote patient bedsides, but government rules need to catch up.

evolving reimbursement and regulatory landscape, however. Not only does Medicaid reimbursement policy vary by state, but state licensing rules, Medicare reimbursement rules, U.S. Food and Drug Administration (FDA) regulations, and the Health Insurance Portability and Accountability Act (HIPAA) and related state privacy laws further complicate efforts to expand the use of home telehealth technology.

Telehealth and Home- and Community-Based Long-Term Care

We are already starting to see remote, 24-hours-a-day “telemonitoring” of patients living in their homes. Today, providers can use Internet-based technology to remotely track blood pressure, heart rate, weight, glucose levels, temperature, oxygen

saturation and other important health indicators. See, e.g., Laurie M. Orlov, *Aging in Place Technology Watch February 2013 Newsletter* (Feb. 28, 2013). Wearable technology, live-stream video and sensors can provide other types of monitoring. For example, sensors can alert a provider or family member when the patient has left the home or failed to open a pill box by a certain time. See, e.g., Heather Kelly, *Sensors Let Alzheimer's Patients Stay at Home, Safely*, CNN.com, Oct. 12, 2014. Developers have created tools to analyze data from these technologies and identify in real time patient deterioration or other developments that might otherwise go undetected. See, e.g., id. These technologies are replacing a less efficient system of monitoring that relied on trips to a physician's office, visits from a nurse

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or home health aide, observations of family members and personal care workers, and personal emergency response system devices that call for emergency help.

Telehealth technology can also allow elderly patients to interact with their medical and behavioral service providers from their homes, without the challenges and stresses associated with transporting a frail individual. Primary care providers can use programs similar to Skype or FaceTime for remote face-to-face consultations with patients and to monitor their health status. In addition, patients can use mobile applications to contact health care providers, send them photographs and other information, and have prescription drugs delivered to their door.

Some long-term care recipients require personal care assistance, which includes help with eating, bathing, toileting, personal hygiene and grocery shopping. Services like Instacart, Uber and Amazon allow individuals to have groceries and other necessities delivered to their doors within hours. Other Internet-based programs allow users to hire independent contractors to help with chores around the house and transportation to appointments. Developers have already produced similar mobile applications and programs designed specifically for elderly users, and someday soon we may see similar services that can connect seniors to vetted attendants who are trained to help with bathing, toileting and personal hygiene.

Navigating the Reimbursement and Regulatory Landscape for Home Telehealth Services

Regulators, payors and providers need to keep pace with the rapid evolution of telemedicine and telehealth technology.

Medicare generally does not cover long-term care services, but its reimbursement policies tend to set standards for private insurance, and it is often the payor for medical services for individuals receiving long-term services in their homes. While Medicare has been expanding its use of telemedicine, such as through accountable care organizations, see 79 Fed. Reg. 72760, 72863 (Dec. 8, 2014), Medicare Part B's reimbursement policies remain tied to geographic location and they have not evolved to help individuals age in place.

Medicare will reimburse for telemedicine services only when the originating site (where the patient is located) is in a "Health Professional Shortage Area" or in a county that is outside of any metropolitan statistical

area or within a rural census tract. And this originating site must be a medical facility (e.g., another practitioner's office) and not the patient's home. With limited exceptions, a consultation must be "face-to-face" by video. See Social Security Act 1834(m), 42 U.S.C. 1395m(m); 42 C.F.R. 410.78.

Medicaid, by far the largest payor for long-term care services, has reimbursement policies for home telehealth that vary by state. As a result, providers and developers seeking reimbursement for technologies used nationwide must navigate 50 different sets of rules and requirements (plus the District of Columbia and the territories). In addition, Medicaid regulations require all providers to practice within the scope of their state practice act, which may require different state licenses depending on where patients are located.

States have generally embraced telehealth as a cost-effective way to deliver Medicaid services. At least 46 state Medicaid programs reimburse for some form of telehealth. Center for Connected Health Policy, *State Telehealth Policies and Reimbursement Schedules* (2014). However, reimbursement is generally limited to services that treat certain conditions or to certain types of providers. Even when Medicaid reimburses for the underlying telehealth service, it may not reimburse for the necessary hardware or software. And many states followed Medicare's lead and require that patients be at a medical facility and/or require a trained staff person be present with the patient. See generally *id.*

While almost all state Medicaid programs reimburse for some form of telehealth, far fewer provide reimbursement for remote patient monitoring. See *id.*; American Telemedicine Ass'n, *State Medicaid Best Practice: Remote Patient Monitoring and Home Video Visits* (2013). Telemonitoring is not a recognized state plan service, although states may be able to cover it as a home health service or incorporate it as part of a physician's service.

More likely, it would be covered through "Section 1915 waivers," which allow states to provide home- and community-based services to a targeted population (e.g., seniors, individuals with developmental disabilities) as an alternative to institutional care. See, e.g., Kansas Home and Community Based Services for the Frail Elderly, Application for 1915(c) Home and Community-Based Waiver (effective Jan. 1, 2010). Section 1915 waivers give states greater flexibility in the benefits that can be provided, but they

require a special approval process through the Centers for Medicare & Medicaid Services and a separate application process for consumers.

In addition to Medicare and Medicaid reimbursement, additional regulatory issues face home telehealth services. State licensing rules can be a significant obstacle. Health care practitioners are generally limited to delivering services to patients in states in which they are licensed, although this is changing. See Mei W. Kwong et al., *Interstate Licensure for Telemedicine: The Time Has Come*, 16 Am. Med. Ass'n J. of Ethics 1010 (Dec. 2014); CCHP, *Common Legal Barriers*, <http://cchpca.org/common-legal-barriers> (last visited Feb. 25, 2015). Furthermore, the FDA regulates a relatively narrow subset of mobile apps that might be used in home telehealth. Specifically, the FDA actively regulates "mobile medical apps" as medical devices, which the FDA defines as apps that meet the statutory definition of medical device and either are intended to be "used as an accessory to a regulated medical device" or "transform a mobile platform into a regulated medical device." FDA, *Mobile Medical Applications, Guidance for Industry and FDA Staff* (Feb. 9, 2015). Finally, telehealth services and programs often face complex privacy and security issues under HIPAA and state privacy laws.

Although the industry faces major reimbursement and regulatory challenges, we anticipate that the home telehealth industry will flourish. We foresee that baby boomers aging in place will rely heavily on Internet-based remote monitoring, video conferencing and other telehealth technology. But, at least until government payors and regulators catch up with the technology, the patchwork of laws that govern in this area needs to be navigated carefully.

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