



HEALTH CARE INNOVATIONS

Telemedicine and Telehealth

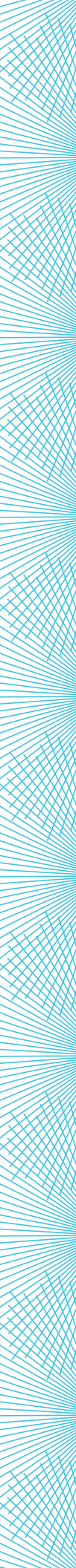


TABLE OF CONTENTS

<i>Introduction</i>	1
<i>A Context for Success</i>	2
<i>Telemedicine & Telehealth Markets</i>	7
<i>Health Care Communications Applications</i>	13
<i>Distribution, Payment and Reimbursement</i>	23
<i>Demonstrating Value: Selected Studies</i>	25
<i>Additional Regulatory Considerations</i>	27
<i>Conclusion</i>	31

ABOUT VITA ADVISORS, LLC

VITA Advisors is a research-based merger & acquisition and strategic advisory firm serving the health care industry. The VITA founders have significant industry experience and relationships and have earned reputations for success with integrity.

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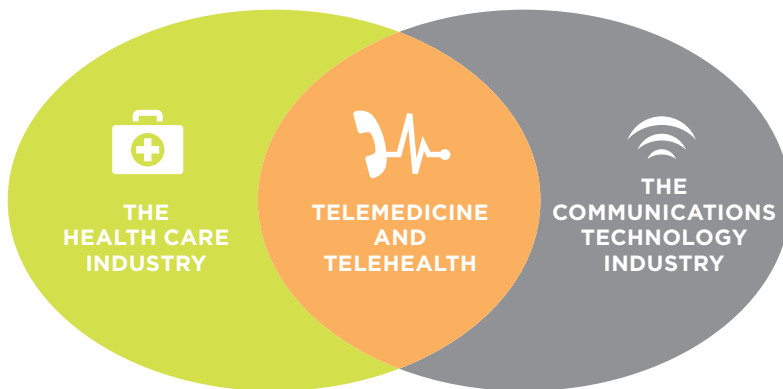
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INTRODUCTION

The American health care system is beset with problems: spending seems impossible to control; treatment quality is inconsistent; and many people do not have insurance or receive even basic medical care. The wrenching effort to overhaul the health care system has heightened public awareness of these concerns and led to extensive debate about the right solutions. Whether the final legislation does or doesn't improve access and quality or reduce costs, the process of getting to an enacted bill has focused attention on these issues. While the reform debate has had center stage, private innovation in health care products and services has continued to occur; innovation that improves access and quality, often while lowering health spending. Creative use of emerging communications technology has been at the forefront of this health care innovation.

The application of communications technology to health care has spawned a plethora of labels: telemedicine, telehealth, e-Health, telepresence, e-Visits, e-Consults, e-Care, mHealth, and others. These terms are often assigned different meanings by different users. We utilize the broad definition of the Institute of Medicine that describes telemedicine and telehealth as the “use of electronic information and telecommunications technologies to provide and support health care when distance separates the participants”. We use “telemedicine” and “telehealth” to refer to all the terms listed above.

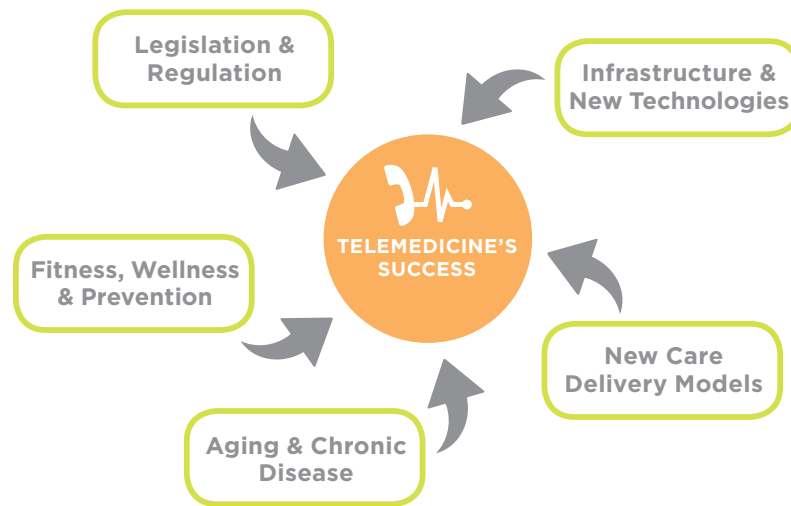


Providing solutions to the three core health care problems—quality, access and cost—is the critical driver for telemedicine and telehealth products and services. Access may be improved by distributing relatively scarce expertise to areas which lack the necessary resources to match patient demand, often rural or inner city geographies; the cost of delivering health care services is lowered by reducing transportation, minimizing facility capacity and avoiding precautionary emergency room admissions; and quality is improved by creating constant, consistent, real-time access to patient-specific information for purposes of disease and care management and increasing patient engagement in their health and health care, including self-care and wellness program participation. A key attribute of these telemedicine solutions is the ability to collect and share information between patients, providers, payers and intermediaries. Perhaps the most significant value is better coordination and organization of care among the patient, multiple health care professionals and many sites of care.

This Report examines today's telemedicine and telehealth markets, products and factors influencing the opportunity for success.

A CONTEXT FOR SUCCESS

A variety of factors influence the development of and market for telemedicine and telehealth products and services. Those factors create opportunities and momentum for vendors. Some relate to trends in health care utilization and cost, which are reflected in population market segments with rapid growth. Some relate to broad changes in the organization and delivery of health care, such as movements toward wellness and away from acute care or realignments of reimbursement like the medical home or accountable care organizations (“ACO”). Others involve legislative and regulatory changes which facilitate and even create market demand. And others relate to the infrastructure and technical applications that allow the development of innovative solutions. Many times new and innovative solutions are stifled because the time is “not right”; therefore it is essential to the commercial growth of new communication technology applications that there is an appropriate context that is conducive to their success. In many ways the external environment for these innovations is extremely positive, though there are obstacles and roadblocks that must be overcome.



FEDERAL LEGISLATION AND REGULATION: The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (collectively “Reform Legislation”), if fully implemented, will bring about significant changes to the American health care system. In addition to the Reform Legislation’s core expansion of coverage provisions, it contains initiatives to encourage wider use of prevention, wellness and care management programs, to further fund comparative effectiveness research and the development of evidence-based medicine and to implement new payment and care delivery models, such as the medical home and ACO’s. Many of these provisions will create stronger market opportunities for telemedicine and telehealth products. Even before the Reform Legislation was passed, the 2009 American Resource and Recovery Act (“ARRA”) provided substantial funding to accelerate the adoption of electronic health records and the creation of a health information exchange infrastructure and directed the Federal Communications Commission (“FCC”) to revamp broadband and wireless communications with an eye toward health care uses. These two initiatives help provide critical infrastructure for using telemedicine and telehealth. The Center for Medicare and Medicaid Services’ (“CMS”) Physician Quality and Reporting Initiative and the pending hospital readmission penalties create individual and organizational accountability for the quality of care; an accountability which telemedicine and telehealth can assist in fulfilling.

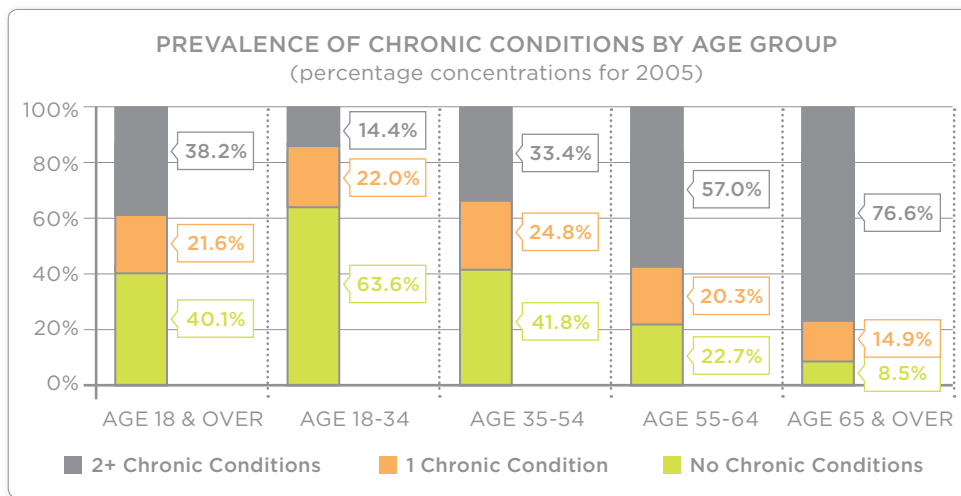


The Reform Legislation and ARRA will dramatically change the business of health care in the years ahead. Much of the impact is work-in-progress as the responsible regulatory bodies develop the guidelines and standards required by these laws.

Most aspects of health care are very highly regulated and telemedicine and telehealth are covered by a variety of complex regulatory schemes. Many regulators have just begun to consider the potential value of telemedicine and telehealth use and the issues related to how that technology affects patients and providers. While some agencies, such as the FCC, have taken steps to facilitate the spread of these technologies, others, such as CMS, appear disinclined to be helpful, or in the case of some state licensing authorities, to be obstructive in the interest of local provider protection.

In addition to the FCC and CMS, the Food & Drug Administration (“FDA”) will undoubtedly play a key role in new technologies. Companies introducing or planning to introduce new communication technology solutions need to be mindful of the potential FDA regulatory framework to which they may be subject. A more in-depth discussion of the regulatory considerations is presented in a later section of this report.

AGING AND CHRONIC DISEASE: The American population is aging and developing more chronic disease, which is the major driver of health spending. Over this past decade, the number of Americans aged 45-64 increased by 31%, the number of those 65 and over will reach 55 million in 2020 and the number of those 85 and older will reach 6.6 million. Not only are there significant issues about where the elderly will be able to live, but the incidence of high-cost chronic disease care increases dramatically with age. Presented in the graph below is AHRQ data for 2005 that show the percentage of each age group with chronic illness. While approximately 60% of all adults had one or more chronic condition, more than 90% of those over 65 had these conditions.



The impact of aging and chronic disease on spending creates substantial opportunities to apply communication technologies to both enhance the safety and quality of daily living and better manage health conditions.

FITNESS, WELLNESS AND PREVENTION: Well over 80% of national health expenditure is related to chronic, and to some extent preventable, conditions such as diabetes and heart disease.¹ A good example is obesity, which has gotten additional visibility recently through the efforts of the First Lady. Obesity is a contributing factor to diabetes, heart disease, several types of cancer and other diseases and now accounts for 9.1% of all medical spending, or about \$147 billion, half of which is paid for by taxpayers through Medicare and Medicaid. About 34% of American adults, or more than 72 million, are



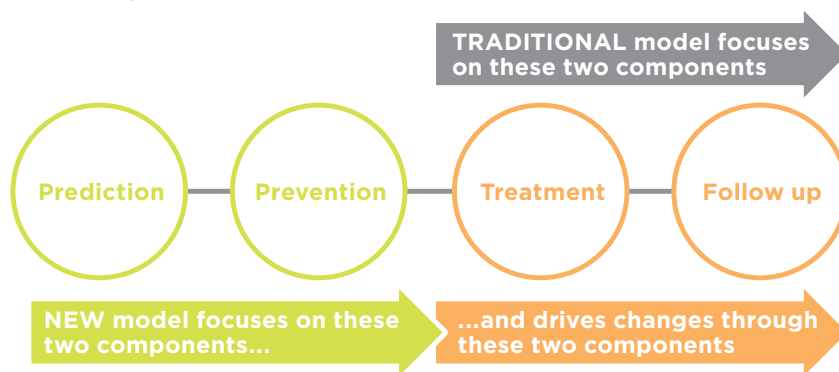
Innovative solutions that facilitate aging in place and home management of chronic illness can provide dramatically greater convenience and significant savings for the aging and chronically ill.

obese, up from 23% in 1994. Obese people spent 42% more than people of normal weight on medical costs in 2006, a difference of \$1,429.^{2,3} Consequently, preventing obesity could create large health spending savings.

In addition, many Americans have one or more other unhealthy (and preventable) lifestyle risk factors, such as smoking, lack of exercise, and excess stress, all of which add significantly to total health spending. The workplace, which still provides health coverage for over 60% of most Americans, has been a natural setting for the introduction of many programs offered through the health benefit design. These programs, including health risk assessments, biometric and other screenings, health education and coaching, various wellness programs and disease management programs, are often combined with financial incentives to facilitate a recognition and call to action to employees who may have underlying untreated conditions or who can benefit from certain lifestyle changes which would enhance health and reduce the risk of disease onset.⁴

Bringing prevention approaches to these populations could similarly produce significant benefits. The illustration below, derived from PriceWaterhouseCoopers' March 2010 Health Research Institute HealthCast, highlights the role that prediction and prevention play in reducing disease onset.

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Smoking, stress, obesity and other behaviors are risk factors for disease. If unhealthy lifestyles can be modified, the onset of disease states can be avoided. Wellness programs are common in the workplace and increasingly becoming part of the community at large.



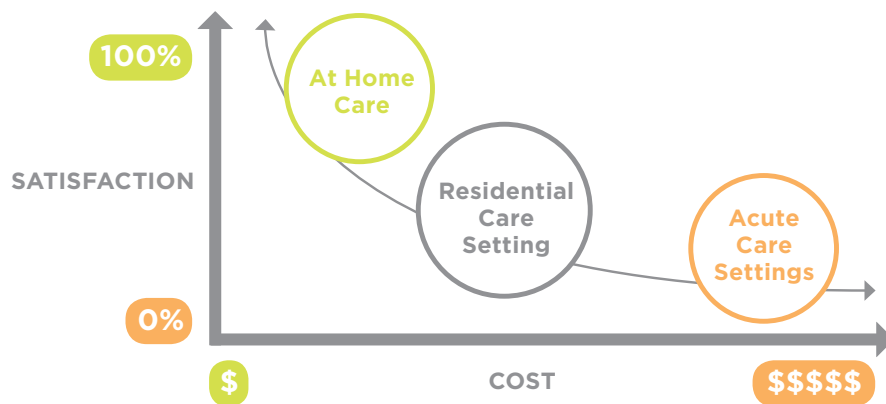
Finally, there is a large segment of the population that is healthy and wants to stay that way as long as they can. This fitness-oriented group seeks to understand diet and nutrition, they exercise regularly, and they track and measure and share their activities as well as their questions about fitness and lifestyle. This is a segment that is the Nike pedometer generation who will spend money on personal measurement systems of all kinds. This segment is motivated by a fear of what lies ahead in the aging process and they want to forego it for as long as possible.

NEW CARE DELIVERY AND REIMBURSEMENT MODELS: The continued rise of health care spending puts pressure on providers and payers to lower the cost of care while improving quality; a difficult task. These financial pressures are serving to birth several new collaborative approaches for the care of patients and payments for that care. These models include the patient centered medical home (“PCMH”) and the ACO model. The principle of each of these is to enable better coordination of care through enhanced continuity and to lower spending by giving providers a stake in the total cost of care.

In the case of the PCMH, a key tenet is that the physician will proactively oversee and manage all aspects of the patient’s care, emphasizing wellness, and patients will actively participate in managing health and avoiding disease states. Coordination models, like

the PCMH, are intended to improve health and lower cost through early identification of risk factors and prevention of disease.

The objective of the ACO is similarly to increase provider responsibility for overall patient care, in this case by aligning reimbursement to encourage providers and facilities to work together without incentives for over-treatment, and to reward the organization for providing high quality outcomes. Many believe one way to realize significant savings in these models is through greater use of the home as a non-institutional health care setting. This concept of moving care from hospital to outpatient settings or the home is expected to result in cost-reduction and improved quality of life. Research also indicates that patients are more satisfied with home care, as illustrated in the graph below.



The need for information tracking and analysis tools to facilitate this trend is obvious and telemedicine and telehealth are the source of that capability, linking patients and providers to shared data collection devices and data repositories. Personal health communication systems, including remote patient monitoring and management, are also recognized as having the potential to help address access and resource challenges.

INFRASTRUCTURE AND NEW TECHNOLOGIES: There are four critical infrastructure components for use of communications technology in health care: the physical transmission networks; devices to send and receive over the networks; standards for both the methods of transmission and the substance of what is transmitted; and underlying health information systems which collect, store and facilitate use of medical data. Most adults now have access to a phone and the majority to a cell phone, and the internet, again most with broadband connection. Health care providers and facilities also have very high device and communication network access.

The FCC has recently published the National Broadband Plan (“NBP”), which builds on previous efforts to expand the number of homes and businesses with access to high-speed internet, particularly in rural or other underserved areas. Much of the perceived need for this capability to be universal relates to health uses and there is a specific chapter of the plan regarding health care. While consumers and providers are generally well connected to basic telecommunications networks, there are concerns about whether there is sufficient access to the high-speed, high capability connections that are necessary to facilitate many health care uses, particularly those involving images or video. There is a high awareness of this issue, as reflected in the NBP, and it is likely that as health care use of telecommunications capacity grows, that capacity will be sufficient to meet the demands placed upon it.



The new reimbursement models of shared risk will compel providers to use communication technologies that can facilitate collaboration of the entire care team.



EMR's, HIE's and commitments to broadband will create the infrastructure by which the vast amount of available information can make its way to those who need it to manage health and health care.

Any products or services which rely on data communication or interchange, or which collect data for analysis, need standards to maximize efficient use of the product or service. Lack of standards may provide some competitive advantage to vendors with proprietary solutions and having standards may remove one opportunity for differentiation. In the case of health care, however, with its multiplicity of patients, health care providers and suppliers, payers, regulators and various intermediaries and its ubiquity of data collection and exchange, not having standards lowers the overall market opportunity drastically by limiting the value of products and services to customers. Absence of standards also raises costs significantly to both customers and vendors. In connection with the ARRA Health Information Technology for Economic and Clinical Health (“HITECH”) provisions to encourage broader use of health information technology in health care, the federal Department of Health and Human Services (“DHHS”) has issued an Interim Final Rule which included standards to ensure interoperability, that is, the ability of various systems to share information electronically⁵. While there have been private and governmental efforts to develop standards for health information in the past, the new HITECH provisions should ensure greater interoperability.

HITECH, if effective, will cause the great majority of providers to be using electronic medical records (“EMR”) in a few years. Many administrative uses are heavily automated today, for example claims submission, eligibility and benefit checks and health plan enrollment. The entire prescription drug supply chain is almost entirely electronic on the administrative side and the use of electronic prescribing is growing rapidly⁶. While it will be several years before EMRs are pervasive, creating a greater ability to share information across providers and among providers, patients and payers, progress is being made on a regular basis. As necessary as the underlying systems to collect the information created by patients, providers, monitoring devices and other sources, is the research to identify how that data can best be used to improve patient care and health outcomes. The results of this research can then be embedded in updated versions of health records to facilitate the delivery of optimal health care. This research and the resulting guidelines for effective information use are critical to ensuring value is obtained from implementation of health information technology.

There is significant progress being made on interoperability of devices of all kinds, increasing their ability to transmit, accept and understand data from a variety of sources, regardless of manufacturer. The collaboration on communication standards has been led by organizations like the Continua Health Alliance, whose mission is to create a system of interoperable personal health solutions that can extend into the home in order to foster independence, empower individuals and provide the opportunity for truly individualized health and wellness management. As an organization, the Alliance attempts to unite smart technology and medical devices to allow patients to exchange vital information and increase their engagement in maintaining good health. Other organizations with similar missions include the Center for Connected Health, the Home Care Technology Association and The Aging Technology Alliance.

In addition to consumer and provider-oriented connectivity devices, almost any piece of equipment can now have a wireless transmitter and/or receiver embedded in it, including implanted medical devices such as pacemakers, and stick-on or wearable monitors for glucose levels, blood pressure, pulse, respiration, heart activity or other clinical measures. There is even technology to put a transmitter in a pill to indicate when it has actually

been taken. These capabilities are relatively inexpensive, as are the hubs to collect and relay such information.

There are more than 200 “vertical” local and statewide telehealth/telemedicine networks in the United States, which are operated by leading medical centers. These networks connect more than 2,000 existing health and medical centers, including major medical centers, rural hospitals and other facilities such as clinics and schools. The typical network consists of a consultative resource located at a hub site such as a VA hospital, an academic medical center, a military health facility or a comprehensive community hospital that provides consultative and educational resources via telecommunications infrastructure to a group of outlying health facilities, inner city clinics or remote military bases. A typical telemedicine program uses the system for such medical services as pathology, pulmonary/critical care, dermatology, teleradiology and neurology. Many use these networks to provide infectious disease diagnostic services. Some integrate the provision of emergency medical services through linkages with EMT personnel serving as first responders.

TELEMEDICINE & TELEHEALTH MARKETS

The health care markets are complex in part because those that pay for health care often are different from those who use and benefit from health care. Telemedicine and telehealth solutions usually directly impact patients and consumers but are frequently paid for by some other third party, creating a “dual customer” dynamic and begging the question: how do you define the market? While it may be clear that the user clinically benefits from a telemedicine or telehealth solution, the one who pays has a different perspective for determining value. The focus of this section is defining larger subpopulations with a significant health-related need which might be met by telemedicine and telehealth. A later section of this report will discuss the determination of value for the payer constituent.

Specific populations that can benefit from telemedicine and telehealth applications can be defined by needs that can be addressed with these technologies. We have defined 5 segments in the table below that represent different market opportunities. The five segments include the underserved; the elderly population, who do not have significant health issues but wish to live at home safely; all individuals with chronic conditions; employees and their families; and healthy, fitness-oriented adults.

MARKET	NEEDS	BENEFITS
The Underserved	Lack access to medical care, either by virtue of geography, mobility or cost	Improve access without the cost of travel
Elderly and Caregivers	Desire for independent living	Improve safety for elderly and convenience and peace of mind for care givers
Persons with Chronic Disease	Gaps in care result in acute events	Better care coordination, avoid hospital and re-hospitalization
Employees and Dependents	Convenient and low cost access to care, improving health status	Improved workforce productivity, lower cost
Fitness-Oriented	Monitor and measure themselves and share through social media	Enforces behavior change through enhanced engagement



Access is a persistent issue for a large segment of the population. For many without easy access, a primary cause is the ratio of physicians in a geographical region to the population of that region. Certain remote presence communication solutions can effectively bridge these gaps by bringing physicians to patients electronically.

THE UNDERSERVED: The underserved segment consists of persons who do not have close physical access to needed medical care resources. This population might include residents in either rural or poor urban settings, workers in remote locations such as oil rigs or on ships, as well as prisoners. In these instances, telemedicine and telehealth bring clinical care to remote centers, significantly enhancing access and quality for this group.

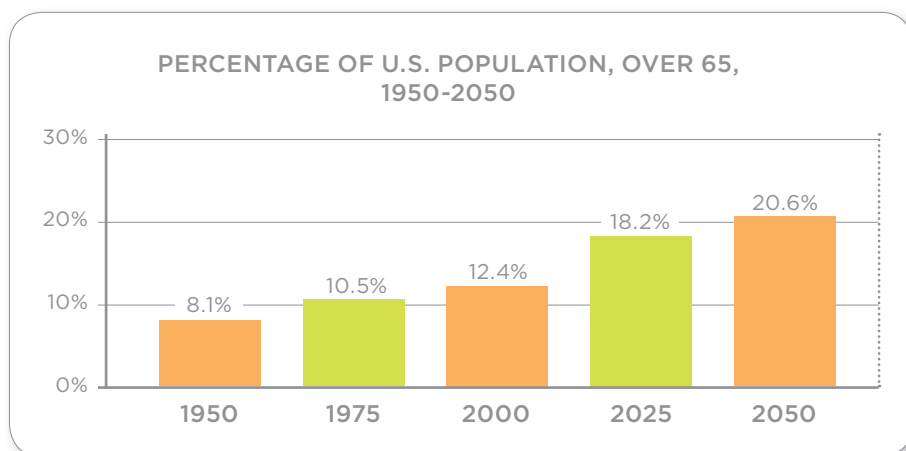
A very large portion of the population lives in areas in which the supply of primary care physicians is inadequate. The DHHS' Health Resources and Services Administration ("HRSA") designates a county as a Health Professional Shortage Area ("HPSA") when it has a population-to-primary care physician ratio of more than 3,500-to-1. HRSA also created similar but separate designations for dentists and mental health professionals. The designation may apply to a geographic area (usually a county), specific population groups (such as low-income individuals) or facilities (such as prisons). As of September 30, 2009, the HRSA data indicated there were:

- 6,204 Primary Care HPSAs with 65 million people living in them.
- 4,230 Dental HPSAs with 49 million people living in them.
- 3,291 Mental Health HPSAs with 80 million people living in them.

Within the 2.3 million people incarcerated in the United States, approximately 200,000 were in federal prisons, 1.3 million were in state prisons and 800,000 were in local jails.⁷ Although the rate of growth has slowed, the number of prisoners continues to increase. According to one publicly-traded correction health care company, the aggregate correction facility health care market is approximately \$10 billion annually, about 40% of which is outsourced to third-party health care providers, largely prison management companies or university-based systems.

Good estimates of remote laborers are not easily available. However, one anecdotal account of the benefits of telemedicine for this population is that the vast majority of offshore oil rig evacuations are for unnecessary and costly medical reasons and increase the risks associated with offshore operations. While the use of telemedicine services may not eliminate helicopter evacuations altogether, it can help reduce them.

THE ELDERLY AND CARE-GIVERS: Elderly persons who are relatively healthy usually want to continue to reside at home and conduct their lives independently. But they and care-givers recognize the potential risks associated with home living, as well as the prob-

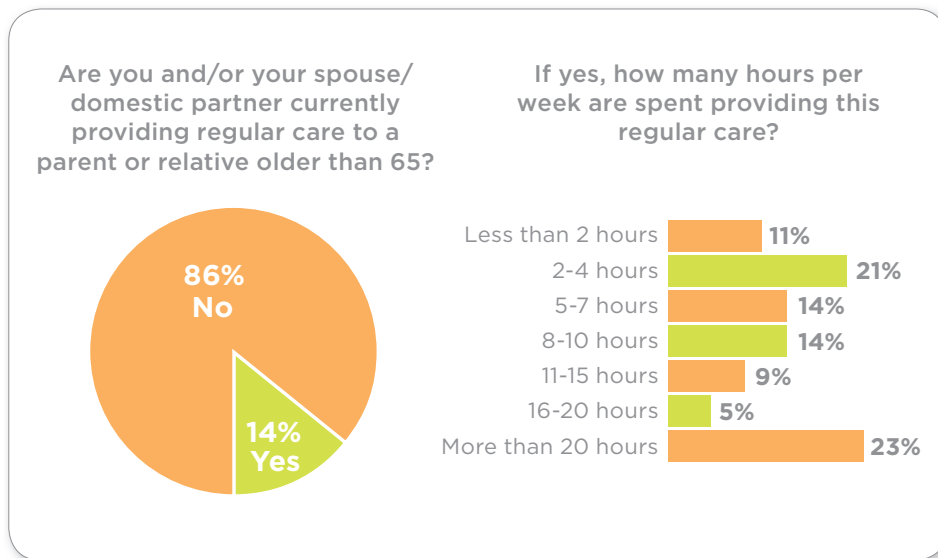


able eventual deterioration of cognitive and physical capabilities, which can result in significant health problems. Personal emergency response (“PERS”) technologies, new sensor technologies that passively detect motion-related risks, and monitoring technologies to facilitate medication or other regimen compliance can safely extend the ability to continue living at home for older Americans. This segment of the population will be growing very rapidly over the next 40 years, placing a further burden on the children or other care-givers who are concerned with their safety and health.

Highlights from the DHHS Administration on Aging’s latest statistics as of 2009 include:

- The number of Americans ages 45-64 will increase by 31% during this decade;
- Over one in every eight persons, or 12.4% of the population, is an older American;
- Persons reaching age 65 have an average life expectancy of an additional 18.6 years;
- About 31% (11.2 million) of older persons live alone;
- The population 65+ increasing from 40 million in 2010 to 55 million in 2020;
- The population 85+ increasing from 5.7 million in 2010 to 6.6 million in 2020.

The need for enhanced solutions is bolstered by the responsibility for care of the elderly shared by informed care-givers. A study conducted by The MetLife Mature Market Institute (“MMMI”) looked at the issue of care-giver responsibility. It found that one-third of people from 55 to 65 years old (approximate 36.7 million people) have at least one parent living. Of those with at least one parent alive, one in seven is providing regular care to the parent or another relative, spending an average of 11 hours per week on these tasks and almost one-quarter are spending more than 20 hours a week doing so. Selected data from this study is presented below.

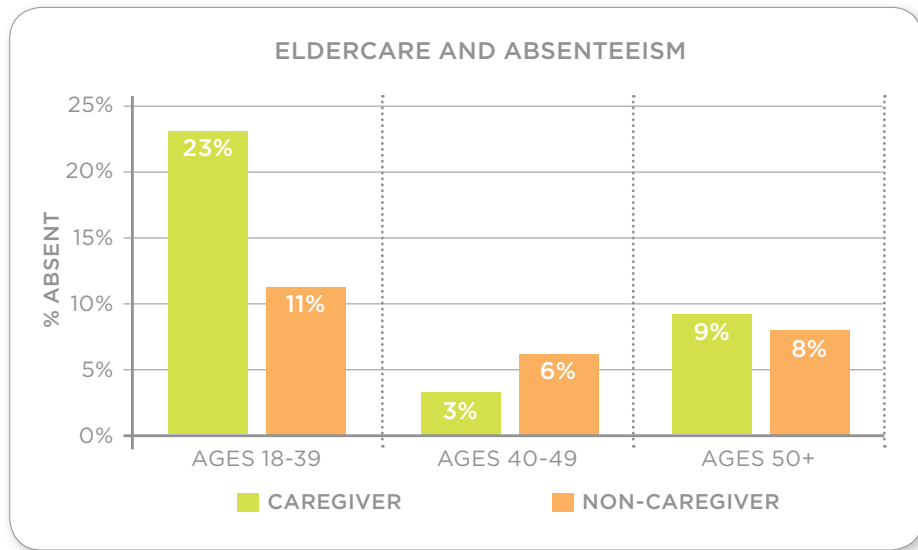


The care-giving burden is not limited to older people caring for elderly parents or spouses. A similar MMMI study found that employees with eldercare responsibilities were more likely to report missed days of work than those without such responsibilities. This was captured in the study results that showed a much higher level of absenteeism among care-giving employees ages 18 to 39. Within this group, 23% missed work over the study period as compared to 11% of non-care-givers. Telemedicine and telehealth

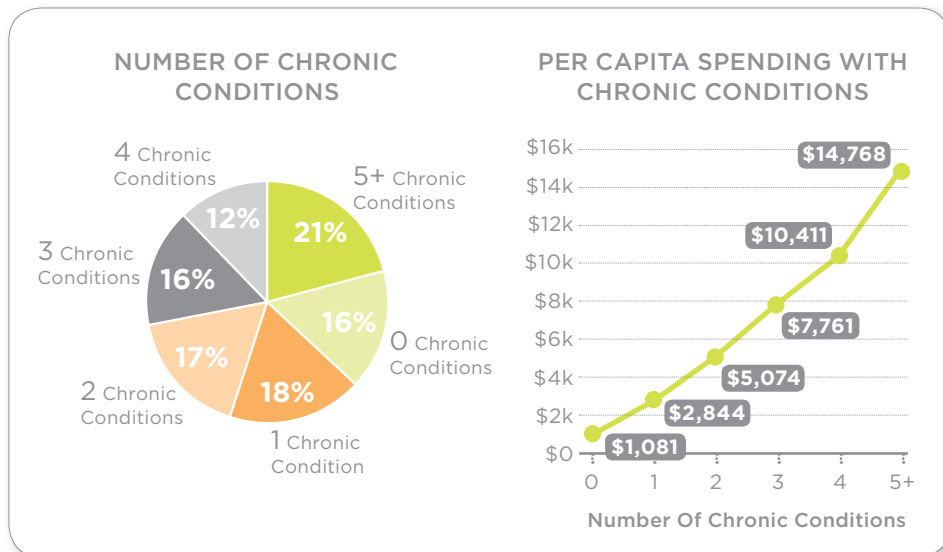


The elderly population has a strong desire to age at home while spouses, children and other caregivers help manage the burden of their care. New technological solutions are needed to facilitate the safety and monitoring of the older population and provide remote solutions for the convenience of caregivers.

services have enormous capability to lessen the burden on these care-givers, while providing greater safety and better health care for the ill relative or friend.

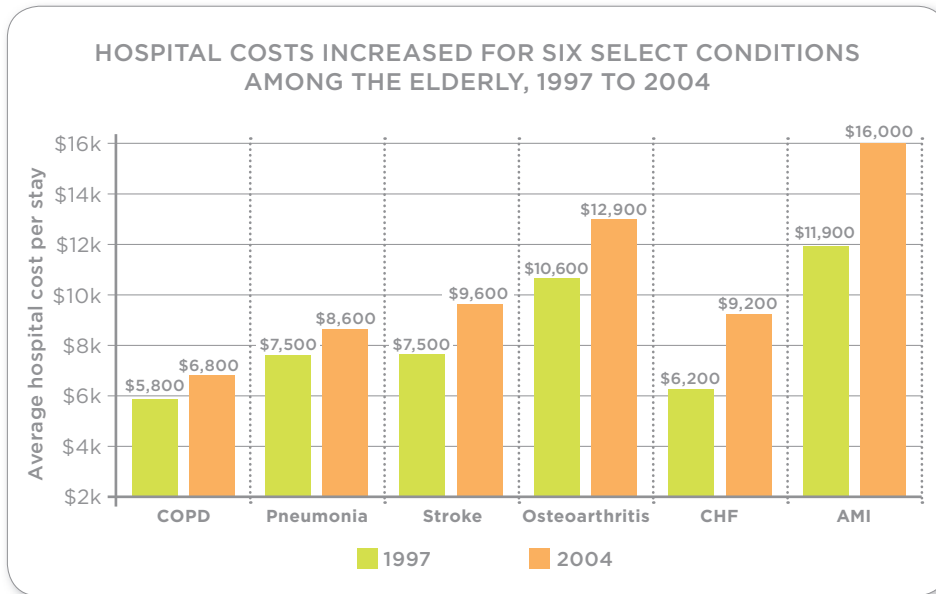


PERSONS WITH CHRONIC DISEASE: The treatment of chronic diseases accounts for the majority of health expense in the United States. This population incurs significantly higher cost than those without chronic disease. According to data from the Medical Expenditure Survey (“MEPS”) for 2006, people with chronic conditions account for 84% of all health care spending. This expense goes up significantly in correlation to the number of chronic conditions, with 66% being spent on those with multiple conditions. The individual average expense ranged from \$2,844 per capita for individuals with one chronic condition to \$14,768 per capita for individuals with 5 or more chronic conditions. A distribution of the total costs and the per capita costs by the number of chronic conditions is presented in the pie chart and line graph below.



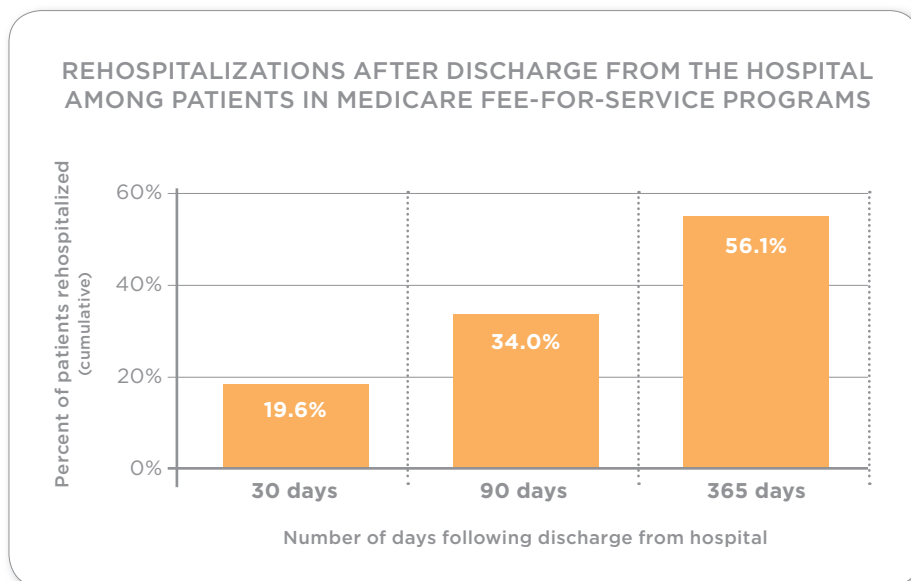
The concentration of chronic conditions and costs is especially high among the elderly. Estimates indicate that 96% of all Medicare spending is consumed by individuals with one or more chronic conditions.

Much of this chronic disease cost is for hospitalization. AHRQ has detailed the top six conditions leading to hospitalization among the elderly and the average cost per stay for each condition. The chart below displays the relative growth in average hospital cost per day by condition from 1997 to 2004. While the elderly population represented just over 12% of the population in 2004, this age group accounted for 34% of all hospitalizations. Of significant note is that more than 57% of these hospital stays were admitted through the emergency room.



Chronic disease prevalence is spiraling out of control and accounts for over 90% of all health expenditures, primarily because of acute events. Communication technologies that facilitate anticipatory care management are essential to avoiding the onset of an acute event.

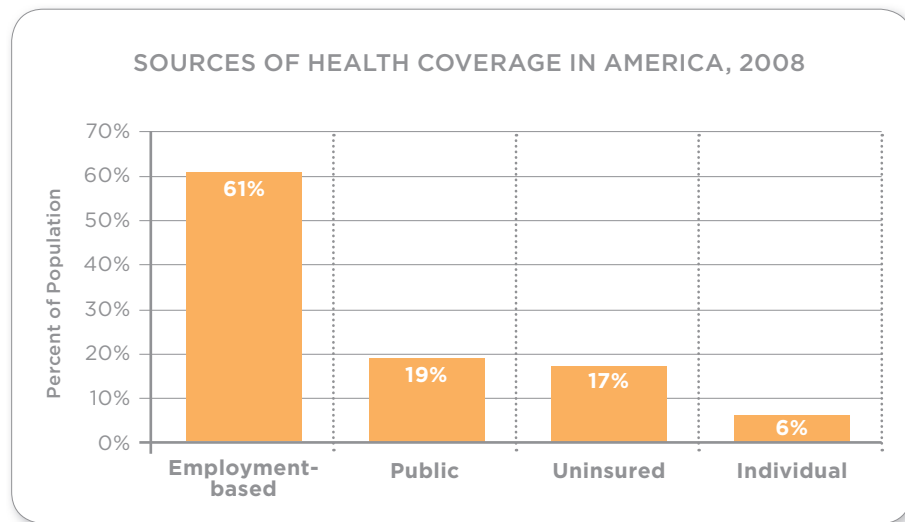
Many of the hospital admissions are re-admissions, many of which may be preventable. Medicare studies have shown that 19.6% of the Medicare beneficiaries discharged from a hospital were re-hospitalized within 30 days and 34% within 90 days of discharge. Needless to say, the use of telehealth capabilities to reduce both unplanned admissions through the emergency room and re-hospitalization soon after discharge by improving transitional care, as well as managing ongoing chronic disease more effectively, could provide significant savings.





Convenient care for employees and dependents is essential for a productive workforce. More companies are investing in technologies which can facilitate access to care from a work-site location.

EMPLOYEES AND DEPENDENTS: Most Americans obtain their health coverage from an employer health plan. The graph below presents data from the Employee Benefit Research Institute that estimates the sources of health coverage in the U.S. in 2008, showing over 180 million people still get coverage through their employer. Employers need their employees healthy and at work. It is of vital importance to the employers that they design benefit plans and utilize technology that can facilitate wellness among this group. Convenience for the employee is a key attribute of solutions that the employer may provide. Hence, we have seen a continuing interest in onsite clinics. In addition, some employers are introducing technology stations and kiosks that allow the employee to regularly measure specific health parameters and engage interactively with remote clinicians. Telehealth techniques are also increasingly a part of wellness programs; from use of the internet to obtain health information to online health education and health improvement programs to text messaging and emails for diet, exercise and other reminders.



Many people are intent on avoiding chronic disease or aggressively managing a chronic condition. They measure their activities, re-search health issues and seek out communities of people with similar concerns.

FITNESS-ORIENTED: This group consists of working individuals who are physically active, strive to lead healthy lifestyles and will actively and aggressively manage a chronic condition. The fitness-oriented are on the lookout for any signs of a rise in their own risk factors. This segment is very familiar with value of data and comfortable measuring and collecting personal health and fitness-related information, taking these measurements pro-actively and regularly. People in this group tend to have sufficient disposable income and are willing to pay for the various measurement devices out-of-pocket.

This segment also is typically very technologically astute and uses the internet regularly to find information on health, nutrition, fitness and lifestyle as well as providers, procedures and facilities. They are extremely familiar and comfortable with sharing their information through social networks and look to these networks as a place for new ideas or approaches on managing their lifestyles. Many companies are building businesses that tap into the power and influence that these self-defining communities have to support behavior change and positively impact health and wellness.

HEALTH CARE COMMUNICATIONS APPLICATIONS

The principle markets for telemedicine and telehealth relate to delivering health information and health care through the use of telecommunication technologies. This may include transmitting x-rays from a patient at a rural clinic to a radiologist in an urban hospital, providing clinical services to and communication with patients at a distance, or monitoring a patient's vital signs from a remote health care facility. It may also involve providing care-related alerts, reminders or notifications to patients by phone, email or text message.

These applications of telecommunications do not create new or different health care services. Rather, they provide innovative and improved methods to deliver existing services. Telemedicine bridges the distance between patient and physician, allowing patients to remain in their workplaces, homes and communities. Telemedicine also limits gaps in care by utilizing monitoring technologies that make patient information available to physicians and care-givers more frequently and consistently. As the use of telehealth grows, more people will have monitoring devices in their homes or connected through mobile technologies.

Another market for telehealth, which is gaining momentum, includes people who are concerned or thoughtful about their state of health but who may not necessarily be diagnosed with a condition. These consumer applications will include extensions of the current home-use medical device market, with manufacturers offering additional internet-based services to people that purchase their monitoring equipment. These services include simple analysis of readings and some level of generalized feedback that may include dietary and nutritional advice, as well as a host of specialized software applications which provide more detailed guidance on specific health issues. Consumer-oriented telehealth services could prove to be a major force which moves health care professionals and policymakers to provide greater support for telehealth.

We believe there are five primary telemedicine and telehealth solution models that address the needs of market segments described in the preceding section.

These primary solution models include:

- **Electronic patient visits** typically occur between a patient and a health professional for purposes of diagnosis or treatment. The interaction is usually with a primary care physician, but may be with a specialist, such as a dermatologist, ophthalmologist or even psychiatrist. These would most often be synchronous delivery models, but occasionally a store and forward model might be used, such as email.
- **Professional-to-professional consultations** occur when specialized expertise is sought, for example, to assist a general practitioner in rendering a diagnosis. The transmission of diagnostic images and information and/or video along with other patient data is typically part of these consultations, which most often use an asynchronous mode but may be real-time.
- **Remote monitoring and management** uses devices to collect data at the patient's location, often the home, but it can be wherever the patient is, and transmit



There are five primary telemedicine and telehealth solution models addressing the needs of the market segments.

that data directly, or indirectly through intermediate hubs, to a centralized information repository where it may then be made immediately available to the monitoring personnel or may be stored and analyzed at a later time. The information might include all manner of biometric and clinical measurements, self-reported patient outcomes, or even the location or activity level of an individual.

- **Alerts and notifications** include messaging intended for a patient to influence his or her behavior. The behavior desired is typically compliance with a treatment regimen such as taking medication or exercising, or measurement and submission of vital signs or other biometric data.
- **Social networks and health information** give people an opportunity to ask about health and find others with similar conditions or issues. Using internet and social media technologies, consumers and patients can learn about health problems and treatments, compare health providers and insurers on price and quality, and engage in peer interactions for support and experience sharing.

The intersection of the population markets and the solution models provides a construct to help define and distinguish the solution technologies and applications. As described earlier, there are several population groups that represent markets for various telemedicine and telehealth solutions. These markets include the underserved, the elderly and their care-givers, persons with chronic disease, employees and their dependents, and the fitness-oriented. The Chart below summarizes the intersection of market segments and solution models which define the potential for specific telemedicine and telehealth applications. The shaded circles are intended to estimate the potential value from applying a specific solution to the population-based market.

<i>Population-Based Market</i>	<i>Solution Models</i>				
	<i>Patient-Physician Communication</i>	<i>Professional Consultations</i>	<i>Remote Monitoring & Management</i>	<i>Alerts & Notifications</i>	<i>Social Networks & Health Information</i>
The Underserved	●	◐	○	●	○
Elderly and Caregivers	●	◐	●	●	●
Persons with Chronic Diseases	●	◐	●	●	●
Employees and Dependents	●	◐	○	◐	◐
Fitness-Oriented	○	○	◐	○	●

○ Low Potential ◐ Medium Potential ● High Potential

ELECTRONIC PATIENT COMMUNICATIONS: There are several business models and communication technologies that enable routine as well as acute encounters between clinicians and patients. These range from remote presence solutions that utilize sophisticated video conferencing and incorporate multiple medical devices to an email exchange with a primary care physician.

PATIENT-PHYSICIAN COMMUNICATION				
The Underserved	Elderly and Caregivers	Persons with Chronic Diseases	Employees and Dependents	Fitness-Oriented
●	●	●	●	○

These applications are potentially relevant to all of the population markets. For rural residents, electronic patient visits may be the only practical method to get access to needed care. It is not only practical but potentially life-saving for remote workers to have electronic access to physicians. Such encounters could be a routine check-up with a primary care physician or a real-time evaluation with a neurologist following a work-related head injury. Similarly, chronically ill patients can benefit significantly if they have ready access to clinicians in the event that their condition deteriorates. To a lesser degree, and largely for geographical convenience, the elderly and many employees are able to communicate with physicians from their home or workplace in order to discuss an otherwise non-acute health concern. The fitness-oriented are less likely to need or benefit from remote patient-physician communications, simply because they have fewer health needs.

At one end of the spectrum are the hospital “cart” solutions, which facilitate a wide range of remote clinical encounters. Generally, these cart solutions enable a physician to gather diagnostic information and move, see, hear and talk as though they were actually with the patient. Health care professionals can consult with hospital-based patients and hospital staff more rapidly and efficiently, thereby improving hospital throughput, physician productivity and quality of care. And hospital-based physicians may be able to use the same equipment to help conduct an electronic visit with a patient far from the hospital.

Oftentimes the suppliers of these solutions integrate best of breed technologies from manufacturers, many of whom are very large companies and have international operations. For instance, some large companies like Polycom, Sony, Lifesize and Tandberg provide the base video conferencing capabilities of many systems. Similarly, other components, such as cameras, audio, video capture and computer processing will be incorporated into the final solution by the system integrator. These integrators compete in the market on the features and functionality of their own proprietary configured solutions, like a medical or exam “cart”. These carts are often designed to be mobile but can have stationary configurations. An example of a stationary configuration may be a pathology viewing station.

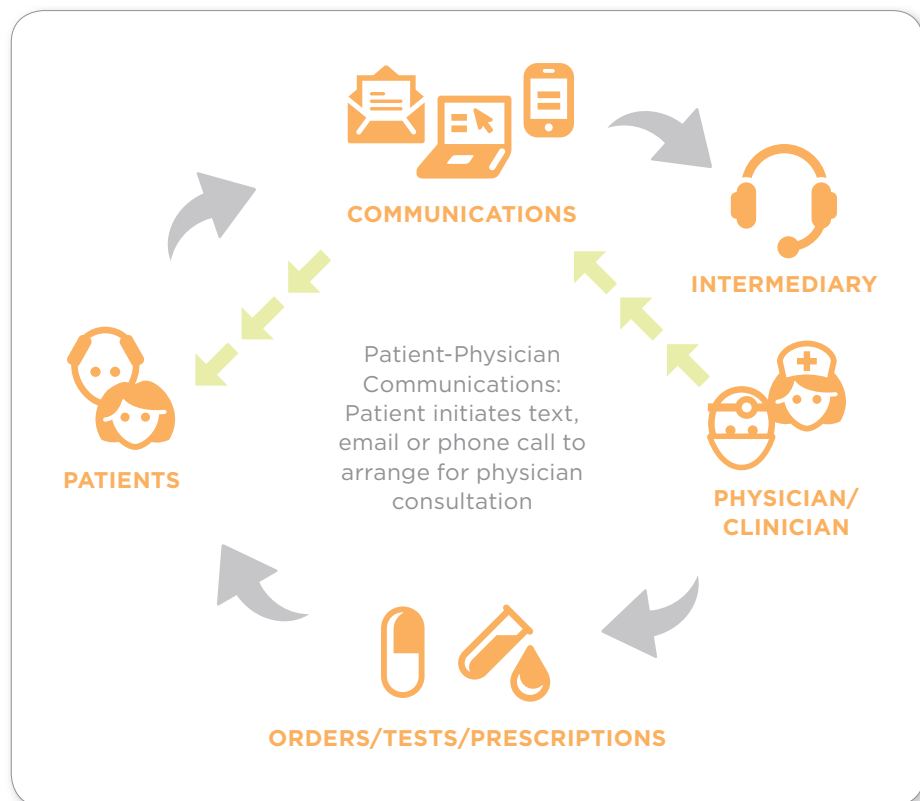
Other patient-physician communication solutions are designed to be used in a workplace or clinic setting. A good example of a relatively new entrant is Cisco and its HealthPresence Pilot that combines the Cisco TelePresence with a variety of medical



New models for interaction and communication between patient and physician hold tremendous promise. A key is to successfully address the need for the physician to be appropriately compensated.

devices that enable health care professionals and patients who are in separate locations to conduct an electronic visit. The equipment to facilitate these visits is often deployed by large employers at the workplace in order to make it easier for employees, and sometimes dependents, to access health care, which may lower costs and reduce absenteeism and improve presenteeism. A different technology in the same solution category is a fixed base health kiosk. These will often incorporate audio and video capabilities as well as allow for a variety of devices to be connected, such as stethoscopes, blood pressure cuffs and weight scales. Several station-based kiosk solutions are targeted at individuals of all ages and locations, and may be found in retail locations or public places as well as in the workplace. These solutions are becoming more flexible and robust in terms of both the data they can collect and store and the interactions they enable between provider and patient. Two of the more established companies in this market include Computerized Screening, Inc. and Lifeclinic International.

Finally, there are emerging capabilities that are less equipment intensive and use common communication technology but nonetheless allow for convenient, timely and valuable interactions between patients and physicians. These solutions rely on text messaging, email, telephone conversations and video conference calls. The systems that are being marketed to facilitate these communications will generally provide one or more of these communication modes. They are differentiated from one another by patient access options, physician administration tools and payment models. In all cases, they require the use of an electronic record for the patient. One of the better known suppliers for this capability is McKesson's RelayHealth, but several other exciting business models are gaining momentum.

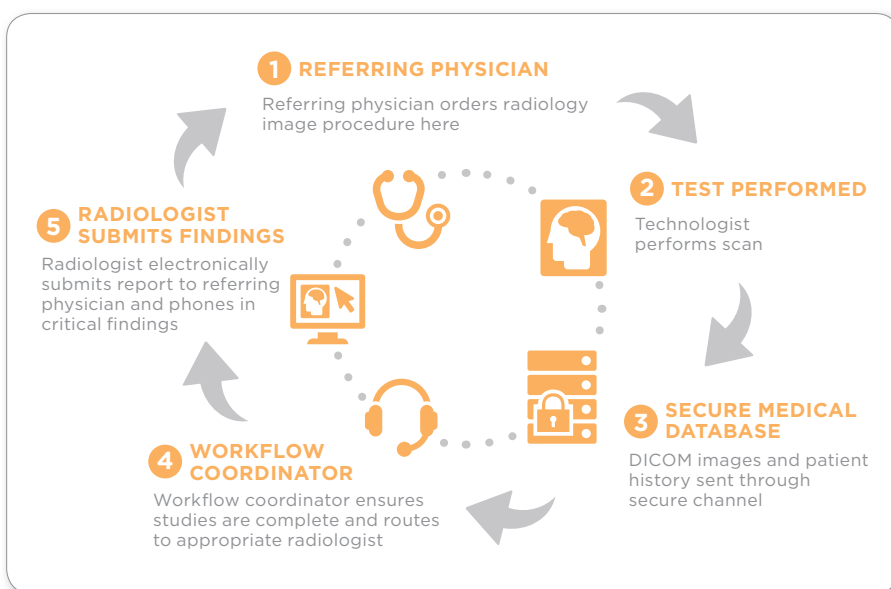


PROFESSIONAL CONSULTATIONS: In many cases physicians and other health care providers have a need to consult other professionals with a specific or higher level of expertise in regard to a health problem. Telemedicine, through the electronic exchange of diagnostic information, enables remote or small health care facilities to improve clinical quality by accessing the diagnostic expertise of specialists in a timely and efficient process.

PROFESSIONAL CONSULTATIONS				
The Underserved	Elderly and Caregivers	Persons with Chronic Diseases	Employees and Dependents	Fitness-Oriented
●	●	●	●	○

This solution model can serve the needs of most of the population markets defined above. Any patient’s diagnostic test which is ordered as part of a routine examination may be evaluated by a specialist who receives the diagnostic data at a remote location. This model is often employed to balance workflow and allow a specialist to batch process diagnostic tests and is an efficient way for smaller facilities to access specialists without bearing the fixed burden of full-time staff. There may also be a need to utilize an outside specialist in acute situations where the evaluation must be performed real-time, such as for a suspected stroke. These real-time consultations often use the remote telepresence technologies discussed in the prior section.

One early example of the Professional Consultation model was teleradiology. Teleradiology, as a practical and affordable solution, was facilitated by major advances in the past 10–12 years in lower-cost communications systems, improvements in price versus performance for computers, and wide adoption of picture archiving and communications systems by radiology practices. In the same time frame, medical imaging underwent a transformation from film to direct digital capture and computer workstation, and even mobile phone, viewing of images from all modalities. Together, these advances have provided a practical and affordable platform for implementing teleradiology. Below is a schematic describing the workflow that presents information to the radiologist for evaluation.



Accessing limited or remote expertise has tremendous value to rural and underserved communities. The ability to appropriately triage neonatal or ICU patients can eliminate much unnecessary and costly precautionary travel.

The use of teleradiology for interpretation of images from off-hours examinations has continued to increase, due in part to the activities of a number of commercial enterprises founded specifically to provide outsourced off-hours coverage for radiology practices but also as some academic and private practices that have begun offering substantially similar services. Now some hospitals are beginning to use teleradiology vendors as the primary source of all imaging services. Some large players in the teleradiology sector include Virtual Radiology and NightHawk Radiology.

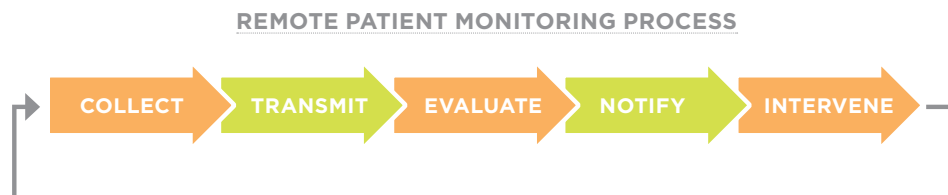
Other applications of Professional Consultations have emerged utilizing the off-hour or overflow remote specialist model. These emerging teleradiology specialties include pathology, ophthalmology, and dermatology.

REMOTE MONITORING AND MANAGEMENT: Remote patient monitoring and management refers to a wide variety of technologies and services designed to collect and transmit patient information for evaluation and intervention or ensuring safety. Patients have highly varied needs for remote monitoring technologies. Some patients want a simple, inexpensive, portable technology while others may require an expensive, integrated, home-based technology. Remote patient monitoring and management technologies are particularly useful for the chronically ill and the elderly.

>
Remote monitoring technologies increasingly will provide solutions that permit more active management of patients with chronic disease as well as allow the elderly to age at home safely.

REMOTE MONITORING AND MANAGEMENT				
The Underserved	Elderly and Caregivers	Persons with Chronic Diseases	Employees and Dependents	Fitness-Oriented
○	●	●	○	Ⓜ

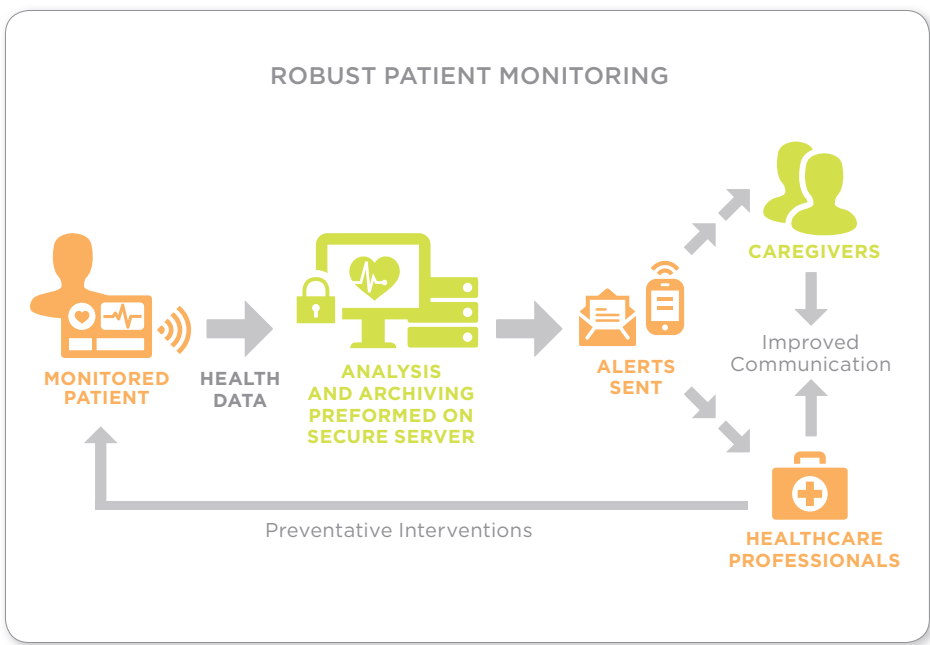
For the chronically ill, remote patient monitoring technologies provide essential support for the coordination of care, behavior change, and evidence-based decision support. Much of the care that chronically-ill patients receive is episodic, discontinuous and inefficiently delivered. Remote monitoring solutions allow for much better coordination of care, in a relatively inexpensive manner, primarily because critical information is collected regularly and transmitted to one location, where it can then be acted upon. Through daily automated, but personalized, patient communication, care providers can optimize the patient's medication and treatment and more efficiently manage a larger group of chronic disease patients⁸. An overview of the remote patient monitoring process, as outlined by the Center for Technology and Aging, is presented in the flow chart below.



Monitoring devices, such as weight scales, glucometers, implantable cardioverter-defibrillators, and blood pressure monitors may individually collect and forward health data. They may also become part of a fully integrated health data collection, analysis, and re-

porting system that communicates to multiple nodes of the health system. Such integrated systems provide alerts when health conditions decline, allowing patients, care-givers, and clinicians to intervene and modify treatment plans as needed.

Many people have the potential to live long, active lives despite the presence of a chronic health condition. Remote patient monitoring has been shown to increase these patients' role in the management of their own health, improve chronic disease management and reduce acute episodes. Because of the significant opportunity to maintain independence, prevent health complications and reduce expenditures, chronic disease management has been the focus of many recent telehealth and home care innovations. A robust example incorporating the full scope of the remote monitoring process is Bosch's Health Buddy System. Health Buddy has received National Committee for Quality Assurance certification for ten programs: asthma, cancer, coronary artery disease, congestive heart failure, chronic obstructive pulmonary disease, chronic pain, depression, diabetes, hypertension, and pediatric asthma. A schematic diagramming of the components of this system is provided below.



Another well-known provider of a large integrated device system is Philips' Telestation.

While there are an increasing number of integrated devices, many remote patient monitoring devices effectively function independently. Standalone monitoring capability is found in cardiac devices, such as pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization therapy devices. These devices can provide continuous, real-time tracking and analysis of patients' heart rhythms as well as device components, such as batteries and leads. Cardiac monitoring devices have demonstrated many benefits, including reduced in-person clinic visits, early detection of implanted device or health problems, increased patient satisfaction, and potential cost savings.

Most large cardiac monitoring device manufacturers use radio-frequency identification to wirelessly transmit data from the device to a base station, which can be stationary or

mobile. Such transmissions are either manually requested by a patient using a wand tool, or automatically uploaded to the base station without patient involvement. Base stations then transmit data via an analog phone line or GSM or cellular phone networks to the clinician. Transmission to the clinician can occur daily or on a scheduled basis. Acute events, like shock administration by the device, trigger an alert to the clinician, either by text messaging, e-mail, fax or phone. Clinicians can then investigate patient data to decide whether the patient should come into the hospital or stay at home. The principle players in this market are Medtronic, Biotronik, Boston Scientific and St. Jude.

Solutions for the elderly include fall detection, fall prevention, and location tracking technologies. Such devices allow care-givers and other parties to assess patient mobility and safety. Fall detection technologies actively or passively evaluate whether a fall has taken place and alert others that an individual has fallen. Fall detection technologies include personal emergency response systems and passive sensors. Fall prevention technologies measure gait and balance in order to predict the likelihood of falls. New technologies are currently in the developmental stage and utilize pressure and other types of sensors embedded in the user's shoe, cane or other assistive technology. Location equipment enables care-givers and others to locate older adults that are prone to wandering. Location tracking technologies employ numerous tracking approaches, including Wi-Fi, GPS, cellular networks, and radio frequency located in a device worn or occupied by the user. Tracking devices vary by tracking technique, signal activation, involvement of third parties, and level of acuity for device activation. The keys to success for these safety technologies are the patient-specific alert mechanisms and support services. Selected large vendors in this market include Philips' Lifeline, GE's QuietCare and LoJack's SafetyNet.

ALERTS AND NOTIFICATIONS: One common feature of many wellness and prevention, disease management and other health improvement programs is use of frequent messaging to influence patient behavior. This messaging commonly takes the form of alerts, notifications and reminders and is accomplished through multiple modalities, such as email, text messages or voicemails, which may be received by computer, cell phone or landline. The ubiquity of the computer and cell phone allow this messaging to very inexpensively and effectively reach large segments of the population. This capability for messaging could prove to be the most valuable near-term health application of cell phone technology.

ALERTS & NOTIFICATIONS				
The Underserved	Elderly and Caregivers	Persons with Chronic Diseases	Employees and Dependents	Fitness-Oriented
●	●	●	◐	○

Although those with chronic illness and the elderly can benefit greatly from alerts and reminders, most individuals within the market population segments have cell phones which can receive phone calls, text messages and e-mails for appointment reminders, past-due balance alerts, disease management initiatives, and other compliance-driven campaigns. Well-designed applications and programs can help identify, manage and

reduce costs and enhance the health and well-being of patients by engaging, educating and motivating.

John Hopkins Children’s Center has conducted several studies on the use of outbound messaging in a medical context, to understand the benefits this medium can provide. Sending a text to a patient’s cell phone about an upcoming appointment or a test or simply to remind them to take medications are examples of how these basic communication techniques can positively influence behavior that results in better care and lower administrative costs.

A vendor’s short messaging service platform enabled Kaiser Permanente to create and facilitate appointment reminders, treatment reminders and alerts that lab results are available. The vendor also outfitted the service with a short code “KAISER” to help recipients recognize and validate the sending organization and thereby increase the attention the recipients would give the message. The text messaging platform was integrated into Kaiser’s automated appointment reminder system and reminders were sent to those patients who opted-in a day before the appointment.

Another recent example is a new and highly visible service called Text4Baby, announced by U.S. Chief Technology Officer Aneesh Chopra, that aims to use text messaging to promote maternal and child health. The information provided through Text4Baby provides timely and expert health advice to pregnant women and new moms through their babies’ first year.

SOCIAL NETWORKS AND HEALTH INFORMATION: The internet has created a massive channel for finding and sharing health information. The core use of the internet for health care has been passive gathering of data on health conditions, treatments, providers and insurers. Now, however, social media uses are exploding. Social networking in health care makes data about your health freely available to family, friends and doctors in order to enhance the quality of care and promote collaboration between patients and providers. Although there are many web sites that provide health information, social media communities allow for sharing of user-generated data and experiences.

SOCIAL NETWORKS & HEALTH INFORMATION				
The Underserved	Elderly and Caregivers	Persons with Chronic Diseases	Employees and Dependents	Fitness-Oriented
○	●	●	ⓘ	●

People may be comfortable discussing common illnesses in public internet spaces like blogs and Facebook, but for more complex conditions, patients prefer private e-mail lists or discussion forums where they feel more secure in revealing details. Some patients may get very specific in public forums in discussing how a particular treatment or medication could help them with their symptoms and seeking feedback. Some patients also choose to utilize online diaries that contain detailed data about their treatment.

The use of the internet to access and share health content underlies many of the developments in assisting consumers and patients to understand health issues, track their



Compliance may well be the greatest potential application for cell phone use within health care. Simple outbound automated rule-based messaging services can effectively nudge an individual to action.

health status, communicate with an extended community, and participate in efforts to improve their health. Users may include the employed and their families who are participating in a company-sponsored online health risk assessment or who may be looking for information about their own health condition or a child's illness. Other users may include persons with or concerned about chronic disease who participate in social websites that link individuals with the same disease to share experiences and discuss treatment options.

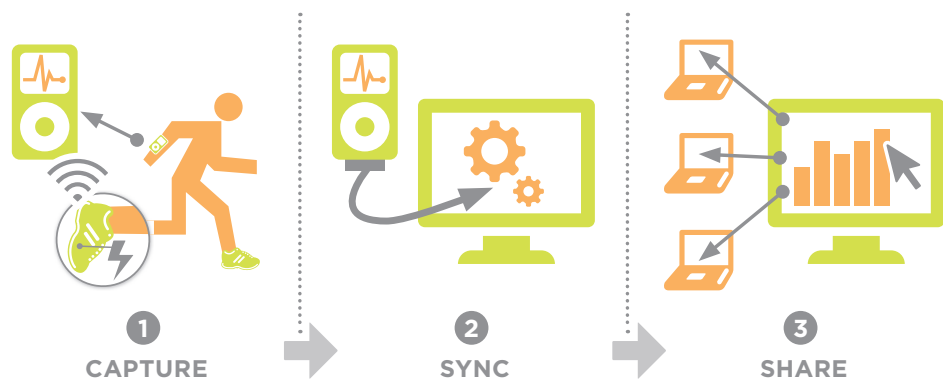


The marriage of lifestyle and technology provide new opportunities to understand and effect health-related behavior.

The elderly and aging are emerging users of social networks. Because successful aging depends on the psychological as well as physical health of an older person, technologies that provide social connectedness are an important component of any home-based care system. These technologies might include software designed to assess cognitive decline or help older users enhance memory, entertainment systems that offer both physical and mental stimulation and complex systems that provide important reminders to older people with memory loss. In addition, cell phones, video telephones and communications software can be adapted for older people, to encourage use and reduce isolation among this population.

Social networking also includes sites that allow the fitness-oriented to share information about themselves with others engaged in similar lifestyle activities. Technology savvy adults who are fitness-oriented are passionate about tracking their exercise activity, diet and other health-related activities. Once tracked, they will often share and compare that information with other similarly-situated persons.

The marriage of lifestyle and technology provides a new capacity for understanding the effects of how we live our lives with more clarity than ever before. Personal metric solutions provide transparent and meaningful feedback about the effects of actions, allowing users to improve by thoughtfully changing habits and behavior.



This group represents a large retail market for personal monitoring technologies similar to that used in the Nike running shoe pedometer. This specific technology allows users to track miles run via a pedometer in the running shoe, and then capture the information in their iPod and subsequently post it to the web and share a log of this weekly with a community of friends.

DISTRIBUTION, PAYMENT AND REIMBURSEMENT

A telemedicine vendor may sell its services or products to other telemedicine companies as components for their telemedicine services. It may also sell to providers or third-party payers, such as hospitals, the Veterans Administration or health plans, who use telemedicine or telehealth products and services as part of their operations or resell or make them available to employers or patients. Vendors may sell to service companies, such as home health agencies or disease management companies, that utilize the technology to provide their services. Finally, sales may be made directly to consumers and patients.

Generally, selling to health care providers or third-party payers is notoriously difficult as many have cumbersome purchasing processes and/or capital constraints. Selling directly to patients, care-givers or consumers often involves appealing more to emotional factors than developing a return-on-investment or clinical benefit case. By virtue of the fact that some purchasers, like hospitals, home health agencies or disease management companies, incorporate these technologies as part of the cost of operations, they need to be convinced that the product will produce sufficient revenue to justify the price or actually reduce costs, in other words, provide a return on investment.

For example, to induce a hospital to purchase video, voice and remote diagnostic equipment in order to perform telemedicine consultations, the vendor must persuade the hospital that it can bill for the consultations and be paid enough to cover the cost of the equipment and the physicians and realize some margin. Another example would be the use of remote patient monitoring equipment by a disease management firm that sells its services to employers or health plans. The disease management company charges a per member per month fee that must cover the cost of operations, and the company must believe that it can realize cost savings, or health spending reductions, in order to justify purchasing the equipment. The same would be true of a home health agency utilizing similar equipment for Medicare patients. An employer purchasing a telemedicine kiosk and associated service would need to realize enough health cost savings or productivity increases to justify that expenditure.

When the product directly or indirectly is dependent on reimbursement from private or public payers, often a provider must be persuaded that payers will provide reimbursement and the payers convinced to cover the product or service, followed by negotiating what amount will be paid. For almost any product or service to be approved for reimbursement by these payers, it must be ordered or approved by a physician. That means that the vendor must have a method for persuading the physician to write the order or deliver the service, which in turn has implications for selling costs.

Because of Medicare's size, its policies in regard to reimbursement are often followed by private insurers. CMS, which oversees the Medicare and Medicaid programs, has not been overly eager to pay for telemedicine and telehealth. When Medicare does agree to pay for innovative solutions, it often provides a very low reimbursement rate which does not allow for a sufficient margin to generate a return on capital. Medicare will pay for traditional telemedicine services, including a visit with a health professional, under certain limited conditions.⁹ The patient must live in a rural area and the visit must be conducted with real-time, interactive audio and video equipment. The

originating site, where the patient is during the encounter, must be a physician's office, a hospital, a rural health clinic, a skilled nursing facility or a few other locations. The services can include a traditional office visit, individual psychotherapy, drug management and a few other minor service categories. Medicare also covers some telemedicine consultations between licensed health professionals. Subject to state law limitations, physicians, nurse practitioners, physician assistants, clinical psychologists and some other health professionals can bill Medicare for covered telemedicine services within their scope of practice. Medicare pays the distant provider the regular fee schedule amount for the service and pays the originating site a modest fee. In total, Medicare reimbursements for telemedicine are miniscule.

To date, CMS has not been willing to extend telemedicine coverage to group treatment or education modalities nor to situations where it believes a face-to-face encounter provides superior information, such as evaluation of the condition of a nursing home resident or critical care patient. CMS' hesitation to embrace traditional telemedicine stems in part from a concern about undermining the viability of those providers who are located in rural areas. Medicare has reimbursed for some other forms of telehealth, such as remote cardiac telemetry, which is treated as an independent diagnostic testing facility service and must therefore meet all the conditions for that category of provider and service. As an example of the dangers of relying on government payment, in 2009 Medicare reduced the amount it pays for this telemetry service by over 30%. A number of other telehealth device and equipment manufacturers have sought Medicare reimbursement with limited results. And CMS has done almost nothing in regard to using telemedicine and telehealth in connection with wellness or care management programs. In keeping with its general approach, CMS is cautious about extending coverage or payment to new technologies and typically does so only in relatively limited circumstances.

While their licensing laws are often a hindrance to delivery of telemedicine and telehealth, a number of states have facilitated telemedicine by providing or requiring reimbursement. Most states pay for communications technology-assisted patient-provider interactions and provider-to-provider consultations in their Medicaid programs and some will pay for other uses of telehealth, such as remote patient monitoring.¹⁰ Innovative Medicaid chronic disease management efforts have utilized a variety of telehealth technologies to improve care and lower costs. A significant minority of states have laws mandating that private insurers pay for traditional telemedicine services.¹¹

Many commercial health plans, however, on their own initiative have been forward-looking in evaluating whether to pay for telemedicine and telehealth.¹² Most of the large carriers have projects under way to encourage use of traditional telemedicine for underserved populations.¹³ Some will pay for email or internet physician consultations.¹⁴ Most also offer some form of an electronic personal health record to members, which may include mobile capabilities, and many are testing social networking tools. The private insurers also will offer or pay for a variety of wellness and care management programs which utilize telehealth technologies, including phone or internet-based health education and coaching, text messaging for medication and other reminders and remote monitoring for chronic disease patients.

In sum, reimbursement by third-party payers is currently a mixed opportunity for providers and for telemedicine and telehealth companies. Current policies do not cover

a large number of the potential applications, but particularly among private insurers, there is a willingness to explore the value that can be delivered by telehealth solutions. CMS needs a change of attitude in order for Medicare reimbursement to expand, and this is the primary reimbursement issue for many vendors, since Medicare pays for such a large percentage of total health spending and many Medicare beneficiaries are users or potential users of telemedicine and telehealth products or services.

DEMONSTRATING VALUE: SELECTED STUDIES

As noted above, telemedicine and telehealth products and services are sold directly to consumers and to providers or payers to use in connection with patient care. Value must be demonstrated to induce the purchase. Categories of value include: a demonstration that the proposed use of a telemedicine or telehealth product or service is a feasible substitute to current alternatives; patient acceptance and satisfaction with the product or service; lower cost for the service or product than current alternatives; an ability to enhance revenues in the case of providers; demonstrating that the product or service results in lower overall health spending; or health status or outcomes improvement.

Sales directly to consumers or patients may not rely as much on research-validated health and cost outcomes as those to providers or for which reimbursement will ultimately be sought from third-party payers. The focus of this discussion is on the evidence for value needed to persuade third-party payers to provide reimbursement for a product or service. The types of value which are typically requested by these payers include health and cost outcomes. The following discussion is not intended to be comprehensive and focuses on relatively recent research publications to give a sampling of findings in regard to value.¹⁵

A number of meta-studies or meta-reviews have been published regarding various aspects of telemedicine and telehealth value. As is the case with most areas of health care, a consistent finding is that there is a lack of what experts would consider rigorous research, which does not mean the value does not exist, just that it hasn't been proven through methods like randomized clinical trials. The widespread acceptance and use of traditional telemedicine such as patient visits, physician consultations, store and forward applications such as teleradiology and teledermatology and remote patient monitoring and management, itself suggests that these techniques do have value and benefit for providers, patients and payers. Definitive proof is not always easily obtained. It should be noted that almost every study regarding the feasibility and acceptability of health communication technology, across a very wide range of specialties and uses, has been positive. The complaint regarding lack of rigorous evidence is largely limited to health and cost outcomes.

One of the earlier meta-reviews published in the British Medical Journal is typical in finding little conclusive evidence of proven value.¹⁶ The authors noted that most studies showed positive outcomes; their objections were to the quality and nature of the studies and their methodological shortcomings. In a more-recent meta-review, the Agency for Healthcare Research and Quality ("AHRQ") published an updated evidence review regarding the clinical efficacy of telemedicine in 2006.¹⁷ The AHRQ work looked primarily at store and forward uses, such as teleradiology; home-based telemedicine,

such as remote patient monitoring; and electronic patient/physician interactions or e-visits. AHRQ noted methodological deficits in much of the research and was unable to definitively state that clinical efficacy existed across the board; nonetheless, it found many studies supporting the feasibility of telemedicine and its ability to match or improve clinical outcomes. Another meta-review of home-based telehealth found overall positive effects of telehealth on clinical outcomes of care.¹⁸

The Veterans Health Administration has been a long-time user of traditional telemedicine and of health care technology for monitoring and management of patients with chronic diseases. A study of the VHA's Care Coordination/Home Telehealth initiative found that it was well-accepted by patients and there were high levels of satisfaction with the program.¹⁹ There appeared to be a significant reduction in both hospital admissions and bed days. The cost of the program per patient was far less than usual home care or nursing home residency. Based on its early success, the VHA is greatly expanding use of this approach.

Phillips has reported on the use of home monitoring compared to usual care and nurse telephone support in a randomized trial.²⁰ The trial showed better survival rates, a reduction of hospital days and an overall reduction in spending compared to usual or nurse support care. The finding in this particular trial is supported by a meta-analysis of remote monitoring of heart failure patients.²¹ Compared to usual care, remote monitoring appeared to lead to fewer deaths and hospitalizations. Another use of telemedicine, in this case to manage the care of patients with diabetes, was studied for a five-year period.²² Compared to patients with usual care, telephonic case management resulted in significantly better clinical outcomes—better blood sugar control, lower cholesterol and lower blood pressure. The length and rigor of this study make the results particularly compelling. A companion study, however, found no cost savings, primarily because of the cost of the intervention, which by the end of the trial was using clearly outdated and more expensive equipment.²³ A systematic simulation of nationwide implementation of traditional telemedicine patient visits and store and forward uses in emergency rooms, prisons, nursing homes and physician offices, based on evidence from the literature, found that several billion dollars a year would be saved.²⁴

While economic considerations such as lowering the cost of service or reducing overall health spending are important, vendors and purchasers can learn from the disease management industry's experience and focus more on improvement in health outcomes. Trials to demonstrate economic value are difficult, expensive and unpredictable. Two examples illustrate this. While the use of telemedicine to facilitate rural patients' access to physicians may impose a lower overall economic burden than having either the physician or patient travel for a face-to-face encounter, the actual cost of the service, with two sites involved and some equipment expense, may be higher. In addition, the ability to create such interactions may lead to health care being delivered that otherwise would be skipped because of the inconvenience. The physician interaction may lead to diagnostic testing or referral to other services. So overall costs, at least in the short run, may increase but the patient is clearly getting better care and is likely in better health as a result of the electronic interaction. Similarly, remotely monitoring the condition of chronically ill patients in their homes has been repeatedly demonstrated to improve their satisfaction, quality of life and clinical

outcomes, including lower mortality. But it may increase costs because the monitoring allows for early detection of problems and that detection may lead to patients being directed to come in for an office visit, go to the emergency room or even to the hospital. In an extreme case, in the absence of real-time monitoring the patient might die before the problem became apparent, which likely would result in lower health costs but certainly not a better outcome for the patient. Telemedicine and telehealth may actually increase costs in the short term because they facilitate the identification and fulfillment of needed and appropriate care which otherwise might be foregone. The existing evidence base, however, already provides strong support for better clinical outcomes and the overall goal of our health system should be to improve health at a reasonable cost. Telemedicine and telehealth can be a significant factor supporting achievement of that goal.

ADDITIONAL REGULATORY CONSIDERATIONS

As noted earlier, most aspects of health care are very highly regulated and telemedicine and telehealth are no different. Below is a brief description of some primary regulatory bodies and activities affecting telehealth.

FDA. The FDA's regulation of telemedicine and telehealth products springs chiefly from its medical device provisions. A medical device is:

“an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

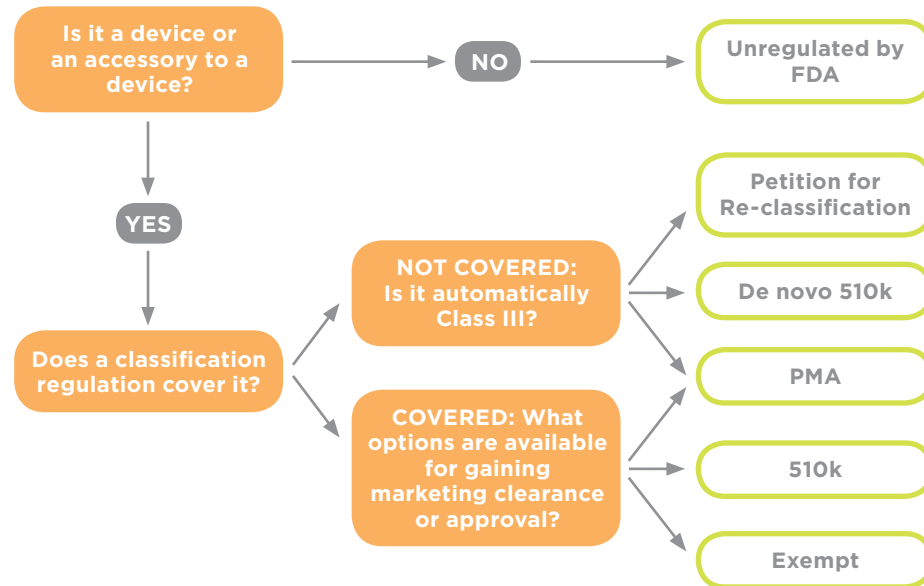
- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them;
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.²⁵”

The important aspect of the definition for telehealth is the intention to use the device for prevention, diagnosis or treatment. The marketing claims made for a product may determine its regulatory status, although disclaiming any health-related use may not avoid FDA regulation, if it is clear that the manufacturer knows how its product will be used and has encouraged that use in any manner. Software is treated as a medical device if it is written in computer media and otherwise meets the conditions of the definition above, so almost any product using communication technology will likely meet this rudimentary definition.

Once there is a possibility that a product is a device, there are several further steps necessary to ascertain the level of regulation applicable to the device. The FDA has

established several levels which correspond to the perceived risk of the product.²⁶ The chart below sets out several pathways through the FDA process. Class I devices have minimal risk and may not require any filing. Class II devices have some risk, but generally can be approved for marketing by a 510(k) process which requires a filing which the FDA must respond to in a short period of time. Class III devices are those with serious potential risks and usually require pre-marketing approval, which is a lengthy process involving submission of clinical trial data.

SOME MAJOR PATHWAYS TO MARKET FOR IT DEVICES



Another classification issue is determining if your device is a parent or finished device, or is an accessory or component. A finished device is one ready for use and intended for sale to an end user. A component is a device which is sold to the manufacturer of a finished device for use in or with that finished device. An accessory is a device used in or with a medical device and intended for use by an end user. The same device could be an accessory and/or a component depending on who buys or uses. The regulation would be different, however, as a component is basically exempt from FDA clearance and good practice requirements. The finished device manufacturer is responsible for compliance in regard to all parts of its device. That manufacturer, however, will likely require that the component maker show that its device will be acceptable to the FDA. Accessories generally must meet the same requirements as finished devices.

The FDA has also tried to put all devices into one of a limited number of therapeutic categories and then has created sub-categories under those. There are about 1700 of these specific device classifications with directly applicable requirements for each. Whichever existing category your device is in will likely aid in determining whether it is Class I, II or III and what kind of special rules may be applicable to the product. If the product is similar to another device, referred to as a “predicate” device, already

approved by the FDA, the 510(k) process can generally be used, so most telemedicine and telehealth product vendors try to identify a predicate device they can piggyback on. Upon receipt of a letter from the FDA acknowledging that the device is substantially equivalent, the maker is “cleared” to begin marketing. Aside from whether or not FDA clearance or approval is needed, other FDA regulations applicable to almost all devices include labeling, adverse event incident reporting and quality systems.

The FDA has been and is under significant pressure to improve its review of drugs and devices, primarily to assure that adverse events are unlikely. Because of the intense criticism, the agency is conducting a comprehensive review of its 510(k) process, which likely will result in significant changes. The outcome of this review, and other reform efforts, probably means longer review times and more expense in producing the data desired by the FDA. This may deter development of some products, add to their cost, result in limits on their use and slow innovation in health care. Vendors developing products now need to consider the regulatory environment at the time they anticipate being ready to market and create the necessary data to meet those future requirements. Recent action by the FDA in regard to smartphone apps²⁷ and the safety of home medical equipment²⁸ should alert vendors to the need to carefully consider how FDA regulation might be applied to their products. There is often a level of complacency which is not justified, and may lead to problems at the worst time—after the product is already being marketed. Any telemedicine or telehealth company should perform a careful review of its products’ FDA compliance and be proactive in avoiding situations which could lead to adverse publicity and harm to sales and marketing efforts.

FCC. The FCC role in regard to telemedicine and telehealth primarily relates to allocation and regulation of frequency use. Some rudimentary telemedicine, for example a phone-based call center, is relatively unaffected. But more advanced uses, either data-intensive ones such as teleradiology or those using wireless technologies, are affected by how much frequency is available for particular uses or users and whether or not certain users may get preferential access to the frequency. The FCC has attempted to facilitate rural telemedicine and has also provided specific wireless spectrum for medical purposes.²⁹ FCC’s Rural Health Care Pilot Program has spent approximately \$417 million in funds for 65 telemedicine projects.³⁰

Proposed “net neutrality” rules may affect the ability of internet service providers to facilitate data-intensive medical uses. Those rules have been temporarily derailed by a Federal Appeals Court decision.³¹ High intensity medical uses, such as transmission of complex imaging scans, may need to have priority in sending to ensure the most accurate and quickest receipt by the health professional. As the various modes of health communications technology use expand, particularly internet and wireless communications, the FCC may be an important regulatory facilitator to ensure that growth is not stunted by lack of frequency, bandwidth or access. Under the stimulus bill, FCC is charged with developing a National Broadband Plan, a draft of which was released in March 2010. Chapter 10 of that plan was devoted to promotion of health uses, and while containing useful recommendations, lacked detail on specific actions.

Other Federal Agencies. A number of other federal agencies have been involved in the use of telemedicine and telehealth and may be a source of revenue for vendors,

as well as facilitators of infrastructure requirements. The Department of Health & Human Services, in its Health Resources and Services Administration, has an Office for the Advancement of Telehealth.³² This Office coordinates federal activities in regard to telemedicine and provides grants to support its development. The Department of Agriculture has had a surprising effect on telemedicine through its ability to fund rural development, in particular through encouragement of better health service availability in non-urban areas. The agency's Distance Learning and Telemedicine Program provides funding for growth of rural telemedicine facilities and programs.³³ The Department of Defense has an obvious need for remote access to health care expertise and therefore each branch of the military has a number of telemedicine and remote health record access projects.³⁴ The Veterans Administration has been an extensive early adopter of telemedicine and telehealth in its health programs and has an office devoted to evaluation and expansion of those efforts.³⁵

State Regulation & Accreditation Organizations. The states also have a significant regulatory impact on use of communications technology in health care, particularly through their licensing laws.³⁶ Any time a health professional in one jurisdiction renders services to a patient in another, there will likely be issues about whether the health professional needs to be specifically licensed in the patient's locale. Spurred by local state medical societies, many licensing boards have been vigilant and protective in insisting that any professional interacting with a patient be licensed in that state, which adds significant time and expense to a telemedicine effort.³⁷ In addition to licensure, there may also be accreditation and privileging requirements for distant site professionals delivering service to a patient at a particular facility.³⁸ The Joint Commission on Accreditation of Healthcare Organizations has had policies which facilitated telemedicine by allowing the originating site to rely on the distant site's privileging of the professional in most circumstances. CMS has worsened this problem recently by not accepting the Joint Commission approach in the Medicare conditions of participation for facilities.³⁹ While this may ultimately be resolved by CMS, it reflects how a seemingly minor requirement can have a substantial effect on a telemedicine business, in this case by substantially raising compliance costs and probably limiting the ability to transfer expert resources across state lines or even within a state's borders.

CONCLUSION

There is a significant opportunity to apply communications technologies to improve quality and access to care while reducing costs. These technologies enable the elderly to live at home safely and ease the stress of the family caregivers who assist them as they age. They leverage the availability of primary care to underserved populations as well as increase access to specialists for consultations. They provide continuous monitoring of patients with chronic disease and apply rules to alert caregivers for early intervention if conditions deteriorate. New technologies allow providers to arrange care in a more integrated and seamless manner, as well as foster greater engagement of patients in their health and care. New social networking applications enable young and old patients and consumers to create communities of shared health concerns that provide support and encouragement in dealing with health problems and meeting health goals.

At the same time the context for the successful utilization of these kinds of communication solutions is positive and has good momentum. Several factors are contributing to the demand for improved solutions as well facilitating the development and introduction of innovative technologies. Examples of demand pressure include the 2010 Reform Legislation, which will provide coverage to millions of previously uninsured patients under Medicaid or through the exchanges; the aging population and the number of persons with chronic illness that continues to grow dramatically; and the youth's alarming incidence of obesity and diabetes. These factors alone will put significant pressure on the capacity of the provider system to arrange access to care as well as manage the associated costs if care continues to be delivered and paid for in its current manner. Examples of factors facilitating innovative solutions include the HITECH provisions of ARRA that promote the adoption of electronic health records and the creation of a health information exchange infrastructure; the ARRA provisions directing the FCC to develop the National Broadband Plan with an eye toward health care uses; and the substantive collaboration on communication standards for interoperability and wireless connectivity in the private sector. These factors will create opportunities to introduce technological solutions that can capitalize on the communication infrastructure and its ability to share data.

The telemedicine and telehealth products and services discussed in this report can be a very significant contributor of solutions to the health system's needs, particularly if reimbursement and regulatory barriers are removed. But like all things in health care, change will not come overnight. The health care system has significant inertia that resists change. Although government sticks and carrots will bring about delivery system modifications and incremental technology applications that facilitate efficiencies will find markets, bending the cost curve will continue to be an elusive goal. Similar to the manner in which a true stock market bottom is marked by "capitulation", real change in health care may only be brought about when the issues of cost reach crisis proportions. •

END NOTES

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- ³⁷ See generally <http://www.telehealthlawcenter.org/?c=118> For a specific example of the potential problems awaiting the unwary provider, see the story at <http://www.citizen-times.com/article/20100405/NEWS/304050018>
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