Gary & Mary West Wireless Health Institute

October 29, 2009

Dr. Mohit Kaushal
Healthcare Director, Omnibus Broadband Initiative
Office of Strategic Planning and Policy
Federal Communications Commission

Re: Remote Monitoring Adoption Rates

Dear Dr. Kaushal:

The West Wireless Health Institute is today submitting the accompanying response to questions regarding remote monitoring adoption rates, per an email request distributed to us on October 21, 2009.

Respectfully submitted,

/s/ Jennifer A. Temple

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Summary

The West Wireless Health Institute (the "Institute") respectfully submits the following information in response to the Commission's recent inquiry into 1) the current adoption rates of wireless monitoring and diagnostic devices both within hospitals and for patients and physician use outside of hospitals; 2) the demonstrated value of adoption in those settings, both in terms of superior and lower costs; and, 3) barriers to adoption and what can be done to break through them.

The Institute commends the Commission for seeking information to accelerate the adoption of wireless health technologies to improve the effectiveness, cost, and availability of health care in this nation. As one of the world's first medical research organizations dedicated to advancing health and wellbeing through the use of wireless technologies, the Institute looks forward to working together with the Commission, other governmental agencies, private parties, and all stakeholders to improve health care for all Americans and to drive down the cost of providing such care through the use of innovative wireless technologies.

I. Background

On September 30, 2009, the Institute submitted Comments in response to the Commission's Notice of Inquiry, "Fostering Innovation and Investment in the Wireless Communications Market," GN-Docket No. 09-157 and GN-Docket No. 09-51. As noted in those Comments, realizing the enormous potential of wireless health will require significant investment in new technologies, as well as documentation that wireless health applications – including those for monitoring and diagnostics – produce better and more cost-effective health outcomes.

In response to these challenges, the West Wireless Health Institute was launched earlier this year. The Institute is a 501c3 nonprofit medical research organization—one of the few medical research organizations in the world supporting the exploration, validation and application of wireless technologies to advance human health and wellbeing. Established with a $45 million grant from the Gary and Mary West Foundation, the Institute is based in San Diego, California, which is home to one of the nation's largest clusters of life science and wireless companies.

The Institute's goal is to move emerging wireless health technologies into the hands of doctors, health care organizations and consumers – ensuring along the way that life-enhancing and lifesaving devices and products are safe, efficacious, secure, reliable and cost-effective.

The Institute is also building its capacity to become a worldwide resource for wireless health education and a clearinghouse for information about the emerging field. As such, we welcome the opportunity to provide the Commission with the following data requested on October 21, 2009.

II. Current adoption rates of wireless monitoring and diagnostic devices within hospitals and for patients and physician use outside of hospitals.[1]

While many advances have been made over the last few years, wireless health is still an emerging field of medical practice. Wireless medical devices have not yet been widely adopted in the home or in healthcare settings, although more devices and products are in development,

[1] The data presented in this submission represent current information on adoption rates and demonstrated outcomes. An excellent list of additional sources, compiled by the Northeast Telehealth Resource Center and updated in April 2009, can be found at www.northeasttrc.org/content/4009/Webliography/. Moreover, a comprehensive summary of outcomes to date can be found in Litan's Vital Signs Via Broadband, 2008, Pgs. 38-42: www.betterhealthcaretogether.org/Library/Documents/VITAL%20SIGNS%20via%20BROADBAND%20FINAL%20with%20FOREWORD%20and%20TITLE%20pp%2010%2022.pdf.

from wearable sensors to "end-to-end" systems powered by advanced chipsets with integrated support for differing technologies and devices and for wide area and local area communications. Moreover, traditional medical device companies are increasingly seeking to add wireless digital functionalities to their products, whether it is for licensed wide areas or unlicensed local areas.

Growing evidence that wireless health devices will transform healthcare delivery has attracted a dynamic range of players into the space, from small start-up ventures, to Fortune 500 companies, global health organizations, and leading universities and major foundations. Last month, for example, Intel and GE announced a $250 million partnership to demonstrate the efficiency and value of remote monitoring and other innovative offerings.[2]

Pilot and demonstration projects are taking place across the country. Since 1999, for example, the American Hospital Association has conducted an annual benchmarking survey that examines the use of information technology at the nation's 5,000 hospitals and identifies the "Most Wired Hospitals" – ranking the 'top 100' that have adopted new technologies, including wireless devices and services to improve patient outcomes and quality healthcare delivery. The 2009 survey, published in July, found that among their top ranked hospitals, about 20 percent are piloting the use of wireless monitoring with heart patients.[3]

A. Healthcare Settings

A September 2009 research report from Berg Insight highlights some progress in the adoption of wireless technology among manufacturers of medical monitoring equipment, but

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[2] See: www.intel.com/pressroom/archive/releases/20090402corp.htm.

[3]See:www.hhnmostwired.com/hhnmostwired_app/jsp/articledisplay.jsp?dcrpath=HHNMOSTWIRED/PubsNewsArticleMostWired/data/07Summer/07SUM_MW_DataSet&domain=HHNMOSTWIRED.

finds there is still a long way to go before remote monitoring becomes standard in the healthcare sector. The same widely cited study found that the market for remote monitoring was worth approximately $11 billion in 2008 and is growing about 10 percent annually. Berg estimates that 300 million people in the U.S. and in Europe suffer from one or more chronic diseases; among those, 25 percent would benefit from existing wireless monitoring solutions and another 50 percent would benefit from handset integration of existing medical devices.[4]

In a seminal 2008 study, Litan found that home care providers have taken the initial lead among healthcare providers in adopting remote monitoring (with the exception of the Veteran's Health Administration).[5] Research conducted in 2007 by the National Association for Home Care and Hospice (NAHCH), which reviewed remote monitoring among more than 17,600 establishments, found that 17.1 percent of the sampled agencies use some form of telemedicine, but adoption is uneven. Agencies with Medicare budgets below $1 million have only a 9 percent adoption rate compared to a 32 percent adoption rate for agencies with Medicare budgets above $6 million.

Litan found that the state of adoption in hospital and nursing home settings is less clear. One of the most comprehensive findings is from a 2008 report to Congress by the Joint Advisory Committee on Communications Capabilities of Emergency and Public Health Care facilities

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[4] See: www.berginsight.com/ReportPDF/ProductSheet/bi-mhealth-ps.pdf.

[5] Litan, R. Vital Signs Via Broadband: Remote Health Monitoring Transmits Savings, Enhances Lives, October 2008.

(JAC); as of the beginning of 2008, there were over 200 currently operating telemedicine networks in the US, connecting over 3,000 health facilities ranging from hospitals to prisons.[6]

However, as is broadly recognized throughout the sector, one of the greatest impediments to the widespread adoption of wireless healthcare is current Medicare and insurance reimbursement policies.

B. Patients, Consumers and Physicians

As previously noted, wireless health monitoring and diagnostic technologies are experiencing rapid development, but are not widely deployed at this time. Medicare and most insurers will only reimburse patients or caregivers under very narrow and limited circumstances. This may be a reason there is at present limited research into the effectiveness of remote monitoring technologies. While there have been positive study results published within the last year, studies directly focused on costs savings are sparse.

That said, the following industry examples are demonstrative of the tremendous momentum wireless health is gaining among patients and providers.

CardioNet's Mobile Cardiac Outpatient Telemetry™ (MCOT™) offers an integrated technology and service to detect heart arrhythmic events by a monitor that transmits EGG data to a monitoring center utilizing a 3G cellular modem. This system enables continuous round-the-clock heartbeat-by-heartbeat, ECG monitoring, analysis and response, at home or away. The device is enabled with 3G CDMA2000 mobile technology and wireless networking services to

[6] See: http://energycommerce.house.gov/Press_110/JAC.Report_FINAL%20Jan.3.2008.pdf for more details.

help physicians diagnose and treat patients with arrhythmias where time is of the essence and delays can lead to increased morbidity and mortality.

The company received FDA market clearance in 2002 and began serving patients through its first monitoring center. In its initial year of operation, the CardioNet Center monitored nearly 3,000 patients. More than 80 percent of the cardiologists and electrophysiologists in the service area became regular prescribers. Today, CardioNet monitors more than 200,000 patients, and service has expanded throughout the United States.[7]

AirStrip Technologies has also demonstrated quick success with one of its initial offerings, AirStripOB, which provides obstetricians and nurses with real-time, remote access to fetal and maternal waveform data such as fetal heart rate and maternal contractions. The information can be accessed on mobile devices using cell phone connections, such as a BlackBerry, iPhone and a variety of Windows Mobile smart phones. The solution also provides hospital staff with the latest nursing notes, vital signs, order results and a host of other critical data from the hospital labor and delivery unit.

AirStrip OB is being used at more than 100 hospitals across the country, including the Cleveland Clinic and Texas Health Resources. Key advantages that have driven the deployment of AirStrip OB include its ability to increase patient safety, reduce risks, improve communication among caregivers, generate return on investment and improve the quality of life for obstetricians and nurses. Users of AirStrip OB are able to view OB patient data anywhere they have a cell phone connection and can therefore reactively respond to a nursing question or patient concern, as well as proactively check in on what is occurring in the labor and delivery unit. The Premier

[7] See: www.cardionet.com/media/pdf/Fact%20Sheet%20-%20CardioNet%20Company.pdf

Healthcare Alliance recently contracted with AirStrip Technologies to offer its 2,200 hospital members mobile healthcare information technology to boost obstetrical care.[8]

In July 2009, **Intel's** HomeHealth Guide became available commercially after receiving FDA approval in 2008. The Health Guide uses a simple interface with audio prompts and a touch screen to walk users through regular checks of their blood pressure, weight and other vital signs using peripherals from third parties connected via USB or Bluetooth. The data is stored and analyzed on the system and transmitted to health care providers. The product uses a broadband connection in the patient's home to enable communications with healthcare professionals and back-end data hosting.

Intel is collaborating with health care industry leaders to validate the clinical benefits of the Health Guide for a wide range of chronic disease conditions and health and wellness applications. These first studies focus on demonstrating improved health outcomes for conditions such as heart failure, diabetes, hypertension and chronic obstructive pulmonary disease.

The company has launched pilot studies in the U.S. with health-care organizations including Aetna, Erickson Retirement Communities, and Providence Medical Group in Oregon. The pilots will examine whether Intel's tools deliver better results for treating home-care patients with chronic conditions. Scan Health Plan, a large Medicare administrator, is one of the healthcare providers piloting the product. If found to work effectively, Scan plans to roll out the device to its entire network of 105,000 members in 2010.[9]

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[8] See: www.healthcareitnews.com/news/hospital-alliance-aims-boost-obstetrics-care-mobile-technology

[9] See: www.intel.com/pressroom/archive/releases/20081110corp.htm

A national survey conducted in October 2009 also indicates a growing awareness and strong demand for wireless health services among consumers and providers.[10] Released by Harris Interactive, in conjunction with the CTIA Wireless Association, findings include:

- About 30 percent of adults and more than half of physicians have heard of wireless / mobile healthcare. Among the chronically ill, almost 40 percent were aware of wireless health offerings.
- 80 percent of doctors and 90 percent of specialists support investments to drive mobile healthcare. They see broad value, especially for people with chronic diseases, people living in rural areas, and for caregivers.
- Almost 70 percent of consumers believed wireless mobility would enhance remote care, citing attributes such as peace of mind and the ability to manage their own health.

III. Demonstrated value of adoption in those settings, both in terms of superior health and lower costs

The value of remote patient monitoring has been demonstrated by numerous studies, the largest of which was conducted by the Veterans Administration (VA) between 2003 and 2007. The VA's national home telehealth program, Care Coordination/Home Telehealth (CCHT), involves the implementation of health informatics, home telehealth and disease management technologies, helping veteran patients with chronic conditions remain at home. The VA demonstration showed dramatic results among 17,000 patients, including a 19 percent reduction

[10] Harris Interactive, Taking America's Pulse on Mobile Healthcare: Consumers and Physicians Rate a Range of Concepts, October 2009.

in the number of hospital admissions and a 25 percent reduction in bed days of care. The costs of caring for patients with remote monitoring averaged 87 percent less than the VA's home-based primary care services.[11]

Additional findings released by the VA in 2008 found that remote patient monitoring decreased hospital visits significantly—for instance, 20% for diabetes patients and 56% for patients with depression. The technology cost $1,600 per patient per year on average, the VA reported, as opposed to $77,745 for nursing home care.

Another program reviewed by the American Hospital Association's annual benchmarking study noted supra, at the Mountain States Health Alliance in Tennessee, demonstrated significant results in 2009. Their Congestive Heart Failure (CHF) Disease Management Program combines wireless remote monitoring, home health, call centers and other related infrastructure. In three years, the program showed significant value for patients, employers and payers, including:

- a 68% drop in hospital admissions for heart-failure related reasons
- a 30% drop in admissions for all other reasons
- a 63% reduction in inpatient days

In addition, 88 % of patients report the program improved their quality of life, as defined as the ability to do normal or daily recreational activities.

[11] A Darkins, et al. Care Coordination/Home Telehealth: The Systematic Implementation of Health Informatics, Home Telehealth, and Disease Management to Support the Care of Veteran Patients with Chronic Conditions. Telemedicine and e-Health, December 2008.

Outcomes from additional pilot studies were cited in the September 2009 edition of *Managed Healthcare Executive:*[12]

- A remote monitoring program developed for home healthcare agency Bayada Nurses, Inc., reduced hospitalizations for congestive heart failure and hypertensive patients by 40 percent to 60 percent. The resulting cost savings were substantial; avoiding a single hospitalization can save a health plan as much as $30,000.
- Hospital re-admission rates for CHF patients enrolled in another remote monitoring program dropped 57 percent when participants used a Bluetooth-enabled scale to monitor weight fluctuations. The savings achieved by avoiding expensive hospitalizations delivered a 7-to-1 return on investment for the program's sponsor.

Finally, in a widely cited 2002 study by Meyer, Kobb and Ryan, the combination of remote monitoring and coordinated care resulted in substantial improvements in health outcomes among a group of elderly veterans with a variety of chronic diseases. The gains included a 40 percent reduction in emergency room visits, a 53 percent reduction in hospital admissions, and a 60 percent reduction in hospital bed days of care, along with similar reductions in nursing home care.[13] These types of outcomes also deliver significant savings to the health care system, particularly for the chronic illnesses that account for roughly 80 percent of increases in Medicare costs.

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[12] See: http://managedhealthcareexecutive.modernmedicine.com/mhe/Exclusives/Use-of-telehealth-could-save-billions/ArticleStandard/Article/detail/622624

[13] Meyer M, Kobb R, Ryan P. Virtually Healthy: Chronic disease management in the home. DiseaseManagement 5(2), 2002.

Another important consideration to note is extensively cited projections for wireless health cost savings. Litan estimates that remote monitoring alone could reduce health care expenditures by a net of $197 billion (in 2008 dollars) over the next 25 years, with the adoption of policies that reduce barriers and accelerate the use of remote monitoring technologies.[14]

Findings by Adler in 2007 also determined that if patients suffering from chronic conditions such as congestive heart failure, diabetes or chronic obstructive pulmonary disease agreed to have their doctor monitor them remotely via wireless mobile applications, the savings would amount to $21 billion per year by reducing emergency care, hospitalization and nursing home costs. In addition, wireless health would allow millions Americans living in rural areas to "visit" the best doctors in the country, eliminating healthcare disparities based on geographic location and economic differences.[15]

To demonstrate such impact, the Institute teamed with Corventis Inc. in June 2009 for its first multicenter, randomized clinical trial. The collaboration will test remote wireless monitoring to prevent hospital readmissions for heart failure patients, with a study group of 1,200 patients. Corventis is a developer of wireless cardiovascular solutions designed to enable early detection, prevention and treatment of cardiovascular conditions.

Congestive heart failure is one of the 'top ten targets' for wireless health, given the tremendous cost of care (estimated at $10 billion a year according the Agency for Healthcare Research and Quality), as well as the promise to save lives and reduce costs via remote monitoring. It was recently shown that 26.9 percent of heart failure patients in the Medicare

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[14] Litan, 2008.
[15] Adler, R. Healthcare Unplugged: The Evolving Role of Wireless Technology, November 2007.

cohort are re-hospitalized within 30 days. With the newfound ability to monitor multiple highly relevant physiologic parameters on a continuous 24 hour/7 day basis — such as heart rhythm, fluid status and respiratory rate — there is the potential to markedly reduce the need for hospital readmissions among patients with heart failure.

The Corventis remote monitoring wireless system was approved by the FDA in February, 2009. The technology is designed to deliver focused visibility into the cardiac health status of patients by combining patient-friendly wearable sensors with advanced computational algorithms, global wide area wireless communications capabilities and a comprehensive web-based infrastructure. Heart failure is prototypic for remote wireless monitoring. Through innovative wireless sensor technologies that use smartphones and wireless broadband communication, the capability of early and rapid detection of key parameters with simple disposable smart band aid's can relay the data on a continuous basis through the Internet. The trial is designed to clinically validate remote wireless monitoring technology while proactively managing heart failure patients with the goal of reducing hospital readmissions.

IV. Barriers to adoption and what can be done to break through them

A broad coalition of stakeholders, including the Institute, the Continua Health Alliance, the CTIA Wireless Association, and the American Telemedicine Association, have identified reimbursement for wireless health services, as well as universal broadband access, as instrumental drivers for widespread adoption.

A. Reimbursement

The realignment of reimbursement policies to include wireless health is among the most critical elements to speed the acceptance and penetration of wireless remote monitoring and diagnostics. In a statement released in June 2009, the CTIA Wireless Association stated that federal healthcare reforms to encourage the implementation of wireless health solutions and make them available to millions of Americans are critical to the medical and wireless industry's efforts to deliver better healthcare.[16]

Currently, wireless health and telehealth services are seldom covered by private and public insurance plans. A main reason are the policies implemented by the Center for Medicare and Medicaid Services (CMS) related to reimbursement for "Medicare telehealth services" that include incredibly restrictive requirements, such as originating sites of care which must be: the office of a physician or practitioner; a hospital; a critical access hospital (CAH); a rural health clinic; a federally qualified health center; a hospital-based or CAH-based renal dialysis facility including satellites; a skilled nursing facility (SNF); or, a community mental health center (CMHC).

Entities must be located in specific geographic areas such as rural health professional shortage areas (HPSA) or counties not classified as a metropolitan statistical area (MSA); and, services must provide interactive audio and video telecommunications permitting real-time communication between the distant site physician or practitioner and the Medicare beneficiary. As a condition of payment, the patient must be present and participating in the telehealth visit with the only exception to the interactive telecommunications requirement (i.e., asynchronous

[16] See: http://www.ctia.org/media/press/body.cfm/prid/1830.

"store and forward" technologies are allowed) being in the case of Federal telemedicine demonstration programs conducted in Alaska or Hawaii.

Thus, physicians are not reimbursed for collecting and later examining remotely monitored data as a preventive measure. In essence, physicians are dissuaded from authorizing 24/7 care when not physically present in a clinic, office or other defined site of care. Patients who live in metropolitan areas with life threatening diseases or conditions are denied the use of remote monitoring or wireless health technologies. Policy changes are desperately needed to change these restrictive, inefficient models of healthcare delivery. Institutions and providers should be incentivized to invest and adopt wireless health medical sensors, devices, and systems.

Moreover, current Medicare law provides for payments to physicians and healthcare facilities for some "telehealth services," as defined above, but the definition of telehealth services is not broad enough to include wireless healthcare services. Accordingly, "wireless healthcare services" should be accurately defined and added to the Medicare definition of covered services. The Institute and others are encouraging legislative healthcare reforms to redress this situation.

Additionally, the Institute supports amending relevant federal rules to provide expressly for payment for wireless healthcare services once the service or services have been accepted by CMS. The Institute also believes more federal funding should be made available for the development of wireless technologies to assist with the diagnosis, monitoring or treatment of disease at a cost less than existing technologies and with equal or greater efficacy and safety. If such technologies are proven to be safe, effective and cost-effective in comparison to existing

technology, CMS should allow for their payment and those services derived from the use of such technologies by Medicare.

B. Broadband Access

As the Commission itself found in May of this year, 95.6% of the US population is covered by at least one mobile broadband network (defined as a network based on EV-DO or WCDMA/HSPA), and 99% of the non-rural US population and 82.8% of the rural US population is so covered.[17] Achieving 100% mobile broadband coverage as quickly as possible—certainly within the next few years— is vital for the rapid proliferation of wireless health solutions. Just as vital is the continued expansion of the already vast mobile broadband eco-system driven by constant upgrades to air interfaces, increased efficiencies in the utilization of licensed spectrum, network capacity enhancements, new chipsets that power devices to offer a plethora of bands and technologies (licensed for wide area networks and unlicensed for local area networks), and a constantly expanding number of mobile broadband devices and mobile applications with rich content and varied operating systems.

The Institute urges the Commission to set a national goal of universal mobile broadband coverage. No single step that the Commission could take would do more to facilitate innovation in wireless health. Patients, doctors, and hospitals all need ubiquitous mobile broadband coverage if wireless health is to deliver on its potential.

In addition, the Institute recommends that the Commission consider providing funds, by refocusing the existing rural healthcare program or from other sources for commercial mobile

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[17] See Bringing Broadband to Rural America, Report on a Rural Broadband Strategy, released May 22, 2009, at Pgs. 12-13.

broadband access, devices, and applications. The use of commercially available devices on commercially available mobile broadband networks will ensure the widest possible broadband access and coverage at the lowest possible costs.

Finally, wireless health initiatives rely on real-time transmissions to ensure steady data flow and online delivery of the highest quality medical imagery. Policies must permit and encourage investments by telecommunications providers in networks that provide the needed capacity for live video and continuous monitoring, with quality of service features to enable doctors to treat their patients without interruption.

The continued enhancement of broadband capabilities by the injection of increasingly intelligent technologies can assure uninterrupted transmission of information that cannot tolerate the delays that might otherwise result during periods of congestion on the Internet. Smart networks and effective management also supports heightened security to protect the confidentiality of patient information, which is vital important for the expanded use of wireless health.[18]

The Institute looks forward to working with the Commission as it prepares the National Broadband Plan and as it continues its laudable efforts to facilitate innovation in wireless health.

[18] Litan, 2008.