m•Health's
Enabling Role in
Healthcare Reform

Moving from **Volume Based Care** to **Value Based Care**

In 2010, the Life365 team (formerly MedApps) was asked to prepare a white paper for Federal CTO, Aneesh Chopra.

The paper highlighted the role that mobile health technology, becoming known as mHealth, could have in enabling the goals of the new healthcare reform legislation.

Life365

IB

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111TH CONGRESS
1ST SESSION

H. R. 3200

[Report No. 111–299, Parts I, II, and III]

To provide affordable, quality health care for all Americans and reduce
the growth in health care spending, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 14, 2009

Mr. DINGELL (for himself, Mr. RANGEL, Mr. WAXMAN, Mr. GEORGE MILLER
of California, Mr. STARK, Mr. PALLONE, and Mr. ANDREWS) introduced
the following bill; which was referred to the Committee on Energy and
Commerce, and in addition to the Committees on Ways and Means, Edu-
cation and Labor, Oversight and Government Reform, and the Budget,
for a period to be subsequently determined by the Speaker, in each case
for consideration of such provisions as fall within the jurisdiction of the
committee concerned

OCTOBER 14, 2009

Additional sponsors: Mr. KILDEE, Mrs. MALONEY, and Mr. BACA

OCTOBER 14, 2009

Reported from the Committee on Energy and Commerce with an amendment

[Strike out all after the enacting clause (other than sections 321 and 322, title IV of division
A, subtitle A of title I of division B, and title VIII of division B) and insert the part print-
ed in italic]

[For text of sections 321 and 322, title IV of division A, subtitle A of title I of division B,
and title VIII of division B, see copy of bill as introduced on July 14, 2009]

OCTOBER 14, 2009

Reported from the Committee on Ways and Means with an amendment

m-Health's Enabling Role in Healthcare Reform

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m-Health (mobile telehealth) solutions can help improve the present healthcare system and enable the legislative initiatives currently under way, including the National Broadband Plan, the HITECH Act and the Beacon Community Grants. Furthermore, m-Health can address many of the challenges that healthcare innovators collectively face in getting their health IT solutions deployed.

The Federal Communication Commission's (FCC) recent report, *National Broadband Plan - America's Plan,* and articles from *MobiHealthNews* served as a springboard for the issues presented in this document. In *Chapter 10: Healthcare,* of the *National Broadband Plan,* the FCC discusses the role of broadband in enabling health IT adoption to address the problems within the current healthcare system. In particular, the plan discusses repositioning healthcare initiatives with the right technology incentives to bring cost efficiencies into the system in a timely manner.

This healthcare chapter in the *National Broadband Plan,* has captured the key element of these issues. It recommends that we, as a country, switch from **"Volume Based Care"** to **"Value Based Care"**. We'll be faced with the increased challenge, over the coming years, of handling an ever growing number of people entering the healthcare system due to an aging population, a chronic disease epidemic, and a dwindling number of healthcare resources. We must take the time **now** to realign our healthcare resources. We can incent and reward those behaviors which encourage a healthier and less costly environment, rather than continue the ineffective transactional "point-of-care" based care model in order to achieve that ultimate objective.

The intent is not to re-quote the entire chapter of the *National Broadband Plan* in this paper, but to align with key elements, and emphasize how m-Health solutions could help achieve initiatives outlined in the chapter, that are required to move healthcare and this country forward. Making this kind of change is truly like turning a ship in mid–course – it doesn't occur overnight, nor does it occur easily, but there are key elements that can be implemented right now that can show efficacy, change mind sets on how we collectively view healthcare, and achieve immediate savings in the system.

Some key points that stood out in the *Chapter 10* included:

- A person dies every six minutes from an infection developed *after* arriving at the hospital.

■ The country is expected to have a *shortage of tens of thousands of physicians* by 2020. An aging physician workforce that is nearing retirement and working fewer hours exacerbates the situation. Supply will be further strained as the new Healthcare Reform Bill passes, causing previously uninsured Americans to enter the care delivery system.

The bottom line is: we need to offer a solution that does not require a patient to be admitted or re-admitted to a hospital, or come into a facility simply to be monitored and receive care, or for a physician to receive reimbursement for the patients' care. In this day of advanced technology, we still physically (and unnecessarily) bring our chronically ill and our seniors into the physicians' office, just so the doctor can receive reimbursement. We must realize that **"the exam room of the future" will be wherever the patient is located**. Further, we must adopt technology that allows healthcare to be brought to a patient wherever they are located, instead of requiring a patient to adapt to the technology or go to a point-of-care, in order to receive treatment.

We need to deliver the ability to improve healthcare outcomes, while simultaneously controlling costs and extending the reach of a limited pool of healthcare professionals. The m-Health solutions are well positioned to help with many, if not all, of these key initiatives. In particular, MedApps' innovative products address these factors.

What Solutions Can Be Implemented Immediately?

The FCC recognizes that outcomes-based payment reform is not necessarily coming any time soon, thus the Center for Medicare and Medicaid Services (CMS) should "proactively reimburse" for e-care technologies using payment models currently in use under "Fee for Service". Some of the ways the FCC thinks CMS can incent the use of "e-care" services today follows

(SOURCE: *MOBIHEALTHNEWS*):

• **Collaborating with physicians, researchers, vendors and government stakeholders to design tests that will prove system-wide expenditure reduction under CMS's "Fee for Service" Model.**

• **Widening coverage for currently reimbursed use cases where they have been proven to reduce system-wide expenditures.**

• **Providing feedback to the community of physicians, researchers and vendors who are trying to enact solutions. Through greater decision-making transparency, CMS could provide critical information that allows that community to target its efforts where they matter most.**

• **Incenting Medicare Advantage plans to invest rebates in the adoption of e-care technologies.**

Benefits of Wireless Remote Health Monitoring (mHealth)

mHealth technology enables physicians to manage patient care through remote monitoring of key physiologic data (e.g. blood pressure, glucose measurements, etc). This capability has proven to:

☐ Reduce the need for in-office visits

☐ Enable fewer physicians to provide care to a larger number of patients

☐ Reduce hospitalizations and re-hospitalizations

☐ Eliminate unnecessary transport (this technology is green)

Unfortunately, today's healthcare system cannot realize these benefits due to CMS reimbursement issues.

• **Health and Human Services (HHS) should identify e-care applications whose use could be immediately incented through outcomes-based reimbursement.**

• **When testing new payment models, HHS should explicitly include e-care applications and evaluate their impact on the models. Where proven and scalable, these alternative payment models would provide an additional solution for incenting e-care.**

• **As outcomes-based payment reform is developed, CMS should seek to proactively reimburse for e-care technologies under current payment models.**

• **For nascent e-care applications, HHS should support further pilots and testing that review their suitability for reimbursement.**

Looking at the National Broadband Plan

The MedApps Solution and the challenges the company faces in deployment can be broken down into each of the four categories referenced in the FCC's report *. Included are thoughts on how to make e-care available to more people quicker. *(SOURCE: *NATIONAL BROADBAND PLAN : CHAPTER 10 - HEALTHCARE*)

Create Appropriate Incentives for E-Care Utilization

* *"Congress and the Secretary of Health and Human Services (HHS) should consider developing a strategy that documents the proven value of e-care technologies, proposes reimbursement reforms that incent their meaningful use and charts a path for their widespread adoption."*

The biggest obstacle that faces the widespread adoption of wireless remote patient monitoring is the lack of reimbursement for m-Health / e-Care solutions.

Currently, patients are required to visit their doctor and come into a healthcare facility, in order for the physician to receive reimbursement for the services rendered, which often expends critical time resulting in a patient's condition to exacerbate to a more costly state.

Remote Patient Monitoring allows patients to be monitored outside of expensive care facilities, while allowing the clinician access to more accurate data delivered in a timely manner, and providing an opportunity for the physician to intervene before a patient's disease can progress to a more costly state.

Wireless Remote Patient Monitoring allows professional caregivers to deliver treatment in a more proactive manner, versus a reactive manner. Typically in today's environment, a patient must incur large ER / hospital charges and become a larger spender in the system before it can be justified to place them with an expensive remote monitoring system. These systems are hard wired to a point-of-care, usually by a land line and often comprised of proprietary expensive equipment. The laudable objective is to stabilize a patient's condition and keep them out of the hospital. But all too often, once a patient is stabilized, the monitoring equipment is removed, and the cycle repeats: patient conditions deteriorate and they are readmitted to a facility, racking up high care costs once again.

It is a recommendation that HHS start some very large and strategic Wireless Remote Patient Monitoring pilots as quickly as possible, in order to measure the benefits and return on investment of monitoring patients from a distance, and to re-align Current Procedural Terminology (CPT) codes to allow physicians to monitor patients from a distance, rather than requiring in-office consultations for reimbursement.

These pilots should address multiple disease states (e.g. diabetes, CHF, hypertension, asthma) utilizing various technologies (e.g. M2M cellular, smart phones applications, POTS [land] lines, log books, Interactive Voice Response) under the direction of nurse call centers or self-managed services, in order to determine the best combination of factors that promotes the most effective delivery of care to the largest population possible.

CPT codes currently exist for limited reimbursement, including 99444 (eVisits), PT/INR monitoring and post-care follow-up measuring effectiveness of oral anti-coagulants, but nothing is available to cover a wider spectrum, such as physically visiting a doctor's office or care facility. The recommendation is that CMS should open up codes for physicians that are similar to the codes utilized as "Fee for Service" in-office, until the time that value based codes can be established.

Modernize Regulation to Enable Health IT Adoption

* *"Congress, states and the Centers for Medicare & Medicaid Services (CMS) should consider reducing regulatory barriers that inhibit adoption of Health IT solutions."*

* *"The FCC and the Food and Drug Administration (FDA) should clarify regulatory requirements and the approval process for converged communications and healthcare devices."*

Referenced Terms and Definitions

Health IT	Information-driven health practices and technologies that enable them. Includes billing and scheduling systems, e-care, telehealth and mobile health.
E-Care	The electronic exchange of information-data, images and video-to aid in the practice of medicine and advanced analytics. Encompasses technologies that enable video consultation, remote monitoring and image transmission ("store-and-forward") over fixed or mobile networks.
EHR	An electronic health record is a digital record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, diagnoses, medications, vital signs, medical history, immunizations, laboratory data and radiology reports.
Telehealth	Often used as a synonym for e-care, but includes non-clinical practices such as continuing medical education and nursing call centers.
Mobile Health (m-Health)	The use of mobile networks and devices in supporting e-care. Emphasizes leveraging health-focused applications on general-purpose tools such as smartphones and Short Message Service (SMS) messaging to drive action health participation by consumers and clinicians.

The Food and Drug Administration (FDA) and FCC need to work together to establish consistent standards on m-Health, and determine who should be required to seek FDA and FCC clearance.

For instance, if a company develops a cellular device from the "ground up", it requires extensive costly testing (60601) in order to achieve FDA clearance. However, if an off-the-shelf cell phone is used, 60601 testing is not required, but the same potential harm to the patient exists. When a patient is using a smart phone (e.g. iPhone), they are able to plug it into a phone charger rather than a wired USB / 30 pin adapter that has the ability to plug into medical devices. Yet, who should assure that electrical isolation is occurring safely between the device and the patient, if the FDA is not involved?

If data from a smart phone is collected wirelessly, who assures that the correct wireless device for a given patient is connected to the correct Electronic Health Record (EHR)?

The scenarios can go on and on.

Of the over 100,000 iPhone applications that exist today, it is estimated that 2000 of them are healthcare related, yet only two of those are in fact FDA cleared. The FDA needs to determine if smart phones, as well as their applications, are indeed subject to safety related FDA regulations. And, if smart phones and applications are subject to FDA 60601 scrutiny, then the FCC should work with cell phone manufacturers to ensure that the models in question meet FDA requirements.

The MedApps Solution is a step forward in this direction. The MedApps HealthPAL is not a cell phone that is used for medical applications, but rather a dedicated medical communication device with an embedded cellular technology. HealthPAL's technology may be used as the basis for cellular applications in the near future. HealthPAL is strategically designed from the "inside-out", to be a medical device first, meeting all of the safety considerations that go with that, and incorporating cellular capability after a sound regulatory foundation has been set. This is significantly different than the cell phone model.

Simplicity, Flexibility, Mobility and Affordability are Key:

mHealth offers a low-cost and adoptable solution by:

- Maintaining an open, flexible structure, using existing, less expensive, retail medical monitors / sensors

- Providing monitoring equipment that is easy to install, operate and maintain

- Providing intuitive technology that is completely integrated and ready to use (e.g. Kindle Model)

- Bringing the "point of care" to wherever the patient is located

- Porting data to a variety of Electronic Health Records ("Open Architecture")

Unlock the Value of Data

> * *"The Office of the National Coordinator for Health Information Technology (ONC) should establish common standards and protocols for sharing administrative, research and clinical data, and provide incentives for their use."*

> * *"Congress should consider providing consumers access to- and control over- all their digital healthcare data in machine-readable formats in a timely manner and at a reasonable cost."*

MedApps believes in enabling the existing healthcare system that is already in place (reimbursement, shelf space, etc.), as opposed to creating new devices (glucometers, scale, blood pressure, pulse oximeters, etc.) which require additional purchases by consumers and payors in order to implement a system.

MedApps created the HealthPAL to allow for the consolidation of data through a central hub device, rather than utilizing separate devices for collecting data and transmitting to a central server. MedApps has chosen to be agnostic on the device side, with a mission of connecting to as many sensors as possible.

In addition, MedApps does not want to re-invent the wheel when it comes to EHRs.

Instead, MedApps' objective is to feed the data wherever it will be used by the patient and their healthcare provider. This data can be stored using a variety of EHR applications including Microsoft *HealthVault*, *Google Health*, *EPIC*, and *Allscripts*. MedApps will look at working with NHIN Direct in order to define the data and flow for remote patient monitoring, and in the future, once established, feed the data wherever it needs to reside.

MedApps is a member of *Continua Health Alliance*. This is a group of 220 worldwide companies that is setting standards for Wireless Medical Interoperability. This will allow medical devices to automatically pair together on a common protocol in order to exchange data.

Ensure Sufficient Connectivity for Healthcare Delivery Locations

* *"The FCC should replace the existing Internet Access Fund with a Health Care Broadband Access Fund."*

* *"The FCC should establish a Health Care Broadband Infrastructure Fund to subsidize network deployment to health care delivery locations where existing networks are insufficient."*

* *"The FCC should authorize participation in the Health Care Broadband Funds by long-term care facilities, off-site administrative offices, data centers and other similar locations. Congress should consider providing support for for-profit institutions that serve particularly vulnerable populations."*

* *"To protect against waste, fraud and abuse in the Rural Health Care Program, the FCC should require participating institutions to meet outcomes-based performance measures to qualify for Universal Service Fund (USF) subsidies, such as HHS's meaningful use criteria."*
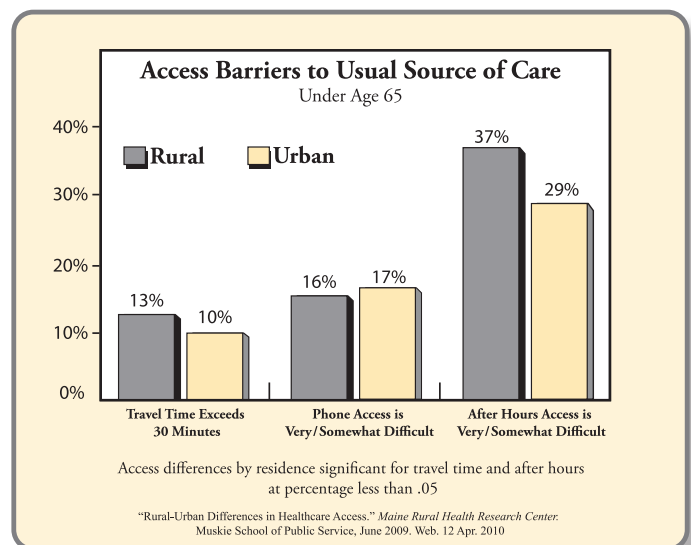
* *"Congress should consider authorizing an incremental sum (up to $29 million per year) for the Indian Health Services (IHS) for the purpose of upgrading its broadband service to meet connectivity requirements."*

* *"The FCC should periodically publish a HealthCare Broadband Status Report."*

One of the biggest concerns that MedApps recognizes is that multiple communication sources are needed in order to connect a patient to their EHR and ultimately to their healthcare provider (GSM/CDMA cellular, WiFi, WiMax, satellite, internet, etc.). MedApps' solutions will need to be adaptable and capable of switching to various different communication methods, in order to collect data and standardize the data going to the common online server (EHR).

The MedApps Solution is designed to sit between non-standard medical devices, sending data to non-standard EHRs, via non-standard communication protocols, in order to connect a patient to a healthcare provider seamlessly.

One of the initiatives should also embrace the ability to provide wireless SIM Cards (or subsidize them) for connectivity to lower-income patients and seniors. Another factor that must be determined: when healthcare services can and should be cut off for non-payment of telecom fees. (If federally subsidized, these may not need to be cut off.)

Access Barriers to Usual Source of Care
Under Age 65

	Rural	Urban
Travel Time Exceeds 30 Minutes	13%	10%
Phone Access is Very/Somewhat Difficult	16%	17%
After Hours Access is Very/Somewhat Difficult	37%	29%

Access differences by residence significant for travel time and after hours at percentage less than .05

"Rural-Urban Differences in Healthcare Access." *Maine Rural Health Research Center.* Muskie School of Public Service, June 2009. Web. 12 Apr. 2010

In rural communities where internet access is limited, public facilities such as libraries and schools could be built out as internet "Hot Spots" where patients with medical devices can come in and have their health data, which was collected at home (no internet), uploaded to their EHR before going to the doctor.

Indian Health Services should subsidize alternative methods of communication on Indian Reservations to allow healthcare providers to monitor patients in remote locations that do not have access to telecommunication or even electricity. One such method is illustrated by a MedApps project with Space Data Corporation and the Navajo Tribe of Arizona. As cellular connectivity is very limited in many areas of the Navajo Nation, MedApps and Space Data came up with an innovative solution of floating hydrogen payload balloons outfitted with a reflex transceiver above Arizona reservations each day. A reflex spectrum was created by uplinking data from a modified MedApps HealthPAL prototype to the balloon at a distance of 500 miles diameter. Users in the most remote regions were able to collect health readings (e.g. glucose, blood pressure) and then connect to the transceiver, successfully sending the data to a central location hundreds of miles away, allowing a nurse caregiver to monitor patient readings remotely.

Bringing Remote Health Monitoring to Remote Areas –
A Space Data Corporation hydrogen balloon, outfitted with a reflex transceiver, is released into the air above Arizona's Navajo reservations to collect health data transmitted from MedApps' HealthPAL™ Mobile Health Monitoring Device.

The Exam Room of the Future will be wherever the patient is located

m-Health solutions have been demonstrated to help minimize ER visits, hospital admissions and readmissions by improving patient compliance to their prescribed therapies (See MedApps' approach to m-Health on the back cover).

m-Health technology is able to dramatically reduce the cost of healthcare by enabling patients with chronic illnesses, working with their healthcare provider(s), to proactively manage care through wireless remote physiologic monitoring while the patients are at home, work, school and carrying out their daily activities.

There are several actions that can be taken to help achieve this. For example, mHealth organizations should be aligned with major remote patient monitoring pilots that allow clinical data to be collected and ROI to be established, in order to encourage CMS to re-align existing CPT codes, thus allowing doctors to be reimbursed for monitoring from a distance.

Another potential action to be taken is adopting a common EHR standard that will allow m-Health systems to seamlessly feed into them, providing a convenient method for patients to safely store their data. It is also recommended that the government adopt an existing EHR / PHR such as Microsoft *HealthVault* and/or *Google Health* as the standard. This adoption was proposed over the last couple of years for all government agencies including: HIS, VA, DOD, etc. The Veterans Administration's EHR should also be closely scrutinized for their forward thinking and adoption in this space.

The bottom line is that m-Health solutions are not an added "burden" in cost to the existing healthcare system. But should be seen as a means to realign current expenditures and incentives / reimbursement in order to maximize the greatest ROI from the existing system.