

Prepared Statement

of

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**“MOBILE MEDICAL APP ENTREPRENEURS:
CHANGING THE FACE OF HEALTH CARE.”**

BEFORE THE

HOUSE COMMITTEE ON SMALL BUSINESS

SUBCOMMITTEE ON HEALTH AND TECHNOLOGY

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Chairman Collins, Ranking Member Hahn and members of the Subcommittee, thank you for the opportunity to appear before you today to discuss mobile health (mHealth) and current regulations that surround it.

Over the last 20 years, information management and information technology have played a transformative role in shaping the future of healthcare. Current and future innovations in healthcare information technology (HIT) will be no different and they will affect every facet of healthcare including how it is delivered, how it is consumed, how hospitals compete with one another to provide best value and how the healthcare labor force is realigned to meet ever-changing requirements.

The nation's healthcare system is undergoing a significant transformation. The move from an "Episode of Care" (Fee for Service) to an "Outcomes Improvement" (Bundled Incentives and Payments) model is forcing healthcare organizations to look beyond the four walls of the hospital and into a "Patient Centered Home Care" model.

As a result of this change, the attention is moving from the inpatient (hospital) to the outpatient care settings (ambulatory, home, etc.). The focus is turning to all activities around outcomes improvement throughout the continuum of care in order to avoid unnecessary hospital stays and re-admissions.

The model is becoming more patient-centric and, at the same time, the consumer's level of sophistication is increasing the competition amongst providers who are quickly seeking differentiators by acquiring both specialists (primarily cardiologists and endocrinologists/diabetes specialists) and leading-edge technologies that can have a direct impact on chronic disease

management. The competition generated as a result of this trend is becoming fierce; payers are embracing ACOs and negotiating lower reimbursement, while providers are aligning clinical service lines with quality and costs.

These changes and challenges faced by the healthcare system have been exacerbated as the Baby Boomer generation is reaching retirement age and 16 million formerly uninsured additional patients that will be added to the system as part of Healthcare Reform. The change in scope (Patient Centered Model), coupled with the current caregiver shortages the industry faces and the move away from generalist doctors to specialists, will mean a greater reliance on mobile health and shared-medical technologies. The major driver behind this transformation is the prevention of disease and the management of chronic diseases while reducing costs.

Approximately 75% of the US population has at least one chronic disease, with cardiovascular diseases representing three of the top five (COPD, hypertension, cardiac heart failure, diabetes and stroke).

The focus on outcomes is forcing healthcare organizations to concentrate their strategic initiatives around federal and private sector *reimbursement and incentive payment programs* designed to support regional management of those chronic diseases (Accountable Care Organizations or ACOs, Meaningful Use and other similar payer programs). A key initiative is to attract a larger patient population by tapping into the regional specialist (i.e. cardiologist), partnering with other regional providers as well as the use of social media to reach out to the community.

Hospitals will need help as they move from a fee-for-service to a fee-for-value model since they are the ones leading the new paradigm. They've been focused on core operations in the hospital and not so much on the pre-hospital or post-hospital care. Integrated Delivery Networks (IDNs) are back to buying up physician groups as they were during the managed care days, but there is a much different motivation for doing it today. In order to integrate to a more collaborative model, they're going to need the type of technologies that will enable them.

Unfortunately, providers have been significantly reducing personnel in the inpatient areas, with massive layoffs starting in the second half of 2011 in anticipation of expected reimbursement cuts. In our opinion, this is not the right approach to take since it will only make things worse. Our approach is validated by new research from the New England Journal of Medicine suggesting that as hospitals prepare for an additional 16 million newly insured patients in 2014, they should be concentrating on adding more support staff to support specialists. The reasoning is that aside from providing care to newly insured patients, not only within the hospitals but also throughout the continuum of care, hospitals will need support staff to process applications, file insurance claims, submit data for regulatory compliance, and perform other administrative duties, according to the study.

Mobile technology will play a crucial role in the development of new federal and private reimbursement revenue models that can improve the quality of care, reduce costs, prevent job losses and create new, more specialized healthcare jobs.

Today, large integrated delivery networks are exploring reimbursement models focusing on the adoption of technology to improve workflow and generate revenues around clinical

services such as cardiology and diabetes. Payers are also following these models, realizing that the shift will occur with or without the momentum created by the federal government around Medicare and Medicaid programs and ACOs. Payers leading the way include Aetna, United, and Humana.

As previously stated, for the past decade, the healthcare industry has faced an ongoing shortage of caregivers impacting physician labor force distribution. Under the new labor model, primary care generalists are disappearing, replaced by specialists who are breaking down work previously done by one person into more specialized tasks performed by experts.

Doctors will no longer be paid by the episode of care, but rather by their expert interpretation of raw clinical data as well as improved outcomes. Relevant data will need to follow the physicians wherever they go, rather than bringing them to the data residing in one central location. At this point, technology becomes essential to support the new reimbursement and financial models. That includes mobile technology, analytics, and cloud computing.

As a result, physicians no longer practice medicine in one location. They are fast becoming mobile professionals, with mobile technology including tablets and smartphones developing as the ultimate tool to improve workflow under the new models.

Labor force changes include:

- Primary care generalists are decreasing by alarming rates.
- Rapid rise of hospitalists, who now account for approximately 40% of hospital admissions (55% from the emergency department and rest via primary care physicians).

- The shift to an ambulatory care model (home) will only add to the shortage since care was primarily provided within the four walls of the hospital.
- Hyper-specialization, which is increasing around new service line reimbursement models (i.e. cardiologists, endocrinologists, oncologists, etc.).

The Rise of the Virtual Specialist

Hyper-specialization requires technology to create virtual environments. The shift of medicine to outcomes improvement and care beyond the four walls of the hospital will add a significant burden to the existing shortage of caregivers. Mobile technology that enables physician virtualization will be critical moving forward.

Today, the biggest challenges in the advancement of Health Information Technology (HIT) are security, limited access to diagnostic quality solutions (FDA cleared or approved) and medical device interoperability. AirStrip has decided to proactively deal with the first two by seeking the highest level of certification for our mobile medical device solutions for security (DIACAP / Defense Information Assurance Certification Accreditation Process / DoD) and for diagnostic quality (FDA Class II, 510K). We are taking this proactive approach because we feel strongly about the need for the FDA to regulate (from both diagnostic quality and security perspectives) mobile applications that handle vital information for remote monitoring systems. Many vendors today are trying to question the need for FDA involvement with an argument around whether innovation is being slowed down or stifled outright. The reality is that the same requirements influenced AirStrip's innovative approach and today thousands of lives are impacted as a result of a partnership between federal and private sectors. Vendors opposing FDA involvement are concerned about the medical device excise tax as well as the strict "Good

Manufacturing Practices” regulations without looking at the quality of patient care. We on the other hand do not object to the FDA requirements and involvement, but do not want to be singled out (Excise Tax) for proactively partnering with the Federal Government.

In July 2011, The House Energy and Commerce Committee’s sent questions to FDA seeking much-needed clarification on the agency’s policy of regulating certain mobile medical apps as medical devices. I was pleased to see the FDA respond to attempts to clarify the “gray area” of the guidance it issued in July 2011. Moving forward, the FDA should immediately release the Final Mobile Medical Applications Guidance Document and take the following patient safety issues into consideration:

- *All mobile medical device applications displaying near and real time medical device waveforms and parameters data need careful regulation* – Traditionally, the FDA has focused on regulating hardware devices, but companies producing software-only medical device apps or even websites need to be regulated as well. Today, many websites or apps have crept into FDA-regulated territory without scrutiny by adding features or functionality that position them as clinical decision support systems. For example, a website where vital signs, demographic data or physiological observations are used to power a decision flowchart that guides diagnoses can easily extend out to a mobile platform. That, in essence, creates a medical device that is conducting clinical support, and should be regulated.
- *“Accessories” to primary devices should also be evaluated* – Currently, software “accessories” (as the FDA terms them) to primary devices do not require separate clearance by FDA. Not only could the network go down, but the mobile medical device

itself could be overloaded or failing in other ways. The FDA needs to also consider these accessories and potential failure points to ensure that manufacturers have addressed those issues in their testing.

- *Mobile applications capable of displaying mission-critical patient data should obtain security certification levels that go beyond the existing HIPAA requirements and FCC security regulations (Open SSL).* Patient privacy and security are also important to ensure FDA's goal of safety and efficacy of medical devices. The DoD's security certification process should be used as an example and cross-pollinate to the private sector.

The industry is greatly benefiting from mobile applications, but not all applications are created equal in terms of risk. Given the number of applications claiming to exchange or display patient data, the FDA should include many more mobile medical device apps under its jurisdiction.

Our approach to address interoperability has been around complying with interoperability standards - HL-7, Continuity of Care Document CCD and others.

Interoperability of health information has been heralded for decades as a way to make medicine more effective, efficient, and safer. However, the interoperability challenge has plagued hospitals and health systems for longer than any of us care to admit. The industry has largely over-promised and under-delivered when it comes to vendors "playing nice in the sandbox," integrating systems, medical device interoperability and making data across the continuum available in a simple and cost-effective way.

The answer to this challenge is mobility. With today's changing models of care, mobility enables coordination across multiple facilities and geographies, as clinicians increasingly need to make or discuss real-time decisions beyond the bedside. Mobility also overcomes what we've always known as the traditional barriers to interoperability – disparate data sources on the back end and conflicting and varied user preferences on the front end. In the race to accountable care, where health care organizations are being forced to figure out how to reduce costs and improve outcomes in record time, mobility is the first and fastest enabler of clinical integration and transformation. Without it, accountable care cannot be achieved.

However, even mobility vendors haven't gone far enough in addressing interoperability. We've attacked different pieces of the puzzle, understanding that we need to prove value and return on investment, but we are ready for the next step. When CEOs and CIOs of major hospitals witness the unifying power of mobility in areas like cardiology and obstetrics, beyond enabling them to make strides around specific quality metrics like door-to-balloon time or patient satisfaction, they are recognizing its potential to achieve clinical transformation throughout the entire health system. I've already seen this start to happen in the health systems I visit every day. This signals to me that mobility has been proven, and the industry is ready to take an enterprise-wide approach. We are entering an era in which health systems view mobility as a necessity for the entire care continuum.

A world where interoperability is achieved through mobility should not only provide secure, near-real-time data about a patient from any source across the care continuum – from admit to discharge and beyond – but it should also offer the “big picture” data health systems need to make broader decisions about their operations and ultimately, their financial future. This

will mean that health systems can finally make the shift from focusing on incremental or departmental operational changes to true transformational change that enables them to meet the broader demands of the new healthcare environment – improving population health and addressing pressing issues such as reducing readmissions.

Clinicians no longer work in stationary environments, but rather are frequently required to move across facilities and departments. To provide care to patients regardless of location, physicians need the data available whether they are at the bedside, down the hall or at a different hospital. For now, interoperability will continue to be a challenge in the future of HIT, but it is clear to me where the industry is headed. Mobility is the lynchpin, and we are not far from every hospital and health system’s “a-ha moment.”

I am often asked by hospitals CEOs and CIOs how they should prioritize mobility when it comes to different care areas. My first answer is to look at your current challenges and strategic initiatives, and then ask how mobility can help you to get there. While I always emphasize the benefit of mobility across all departments, cardiology is where I see the potential for mobility to make the most immediate impact – especially when it comes to improving outcomes and reducing readmissions.

Door-to-balloon time is one of the most significant metrics regarding cardiology. Today, the average in the U.S. is about 90 minutes. But when you equip cardiologists with diagnostic-quality ECGs coming right from the ambulance, they are able to make decisions immediately, saving valuable minutes and giving them the option to bypass the emergency department to send patients directly to the cath lab. I’ve seen hospitals drive door-to-balloon time down to 35 minutes. On the flip side, a hospital loses \$7,500 every time they unnecessarily put together a

cath lab team. Thus, the sooner clinicians can identify and communicate a false STEMI, the more savings the health system will see.

More importantly, reducing event-to-balloon time also puts patients in the ICU with less damage to their hearts and who are ultimately “healthier” on their road to recovery. I’ve seen hospitals shave nearly a day from their post-STEMI ICU stays, which saves anywhere from \$1,400 to \$2,500 per patient. Over the course of a year, a hospital that cares for 200 post-STEMI ICU patients could see a savings of at least \$280,000.

This leads me to cardiology-related readmissions, which are under the most scrutiny with the CMS penalties enacted by the Affordable Care Act (ACA) where hospitals can be docked up to 1 percent of Medicare DRG payments around acute myocardial infarction (AMI) and heart failure (HF). In general, patients who experienced a shorter event-to-balloon time and shorter ICU stay are much less likely to return with complications within 30 days. But there is even more to that story. For one hospital, we looked at 100 ECGs of discharged patients and noticed that a significant percentage of those patients had difficult-to-detect conditions when discharged, and therefore ended up coming back within 30 days. This was because those patients had a heart condition or weakness that was not detected by the physicians on the floor – because not all of them were cardiologists. Electro-physiologists and cardiologists need to be able to review patient data from anywhere to identify issues and prevent patients from leaving the hospital without proper care.

Mobility also plays a key role in the critical post-discharge period for heart failure patients. They can be sent home with sensors that are constantly uploading ECGs and other data that can be accessed by a group of electro-physiologists and cardiologists, who in turn identify

and ideally prevent potential causes for readmission. A two-year study of patients with congestive heart failure (CHF) showed a 44% drop in readmissions through the use of home telemonitoring. If a patient can go directly to the cath lab rather than the ED because a physician is able to remotely diagnose the condition, then the hospital is not penalized for a readmission under the ACA. And the physician doesn't need to be at a desktop in the hospital to make that happen. Not only that, when an electro-physiologist needs to consult with a cardiologist about a patient, the two can review the same ECG in virtually real-time on an iPad or other mobile device in two different locations.

The benefits of a mobility platform in every department across a health system are too significant to ignore, but with its time-sensitive and care-intensive environment, cardiology represents the most immediate opportunity for mobility to make a positive impact on both patient care and a hospital's bottom line. The management of other chronic diseases (i.e. diabetes, COPD, etc.) via mobile devices should be placed in the same category in order to quickly impact the quality of care.

I am honored to have the opportunity to be a part of the mobile healthcare industry, a partner with the federal government and even more so to be part of the exciting innovations which will deliver better patient care and better patient outcomes, now and in the future.