Robert Jarrin, Senior Director, Government Affairs, Qualcomm Incorporated, Washington, DC

Robert Jarrin: My name is Robert Jarrin. I'm Senior Director for Qualcomm government affairs. I'm based here in Washington, D.C. Qualcomm is a San Diego-based company. I will warn you I have about 60 slides and I'm going to try to rush through some of them and others I'm going to take a little longer to explain. Safe harbor which we are supposed to show. Mobile services are becoming the center of life. The reason why we say that is because the mobile phone has become the biggest platform in the history of man kind. Currently there are about 5.4 billion subscribers around the world that have a mobile device whether it be a mobile cell phone, smart phone or laptop that is connected via wide area network functionality which you've heard some people speak about -- 3G and 4G. It began with 1G and the natural evolution of technology has gone all the way to 4G. To give you an idea of context, there are more mobile devices than computing devices. Over five billion cell phone users, 1.3 billion TV households, .7 million desktop PC users and .3 billion mobile PC users. Globally, only 4.4 billion people have access to sanitation - so giving you context about how many people actually have cell phones. When I'm speaking about the different "G's", you can think about back in the days 20 years ago, 25 years ago when people had a cell phone that could only do voice, that was 1G. As we got into messaging we went into 2g. Why? Because you now had voice and data. The ability to transmit data is important especially as we are going forward over time because we are much more invested in things like entertainment and computing. The computing aspect is where things have

gotten technologically advanced and there has been somewhat of a convergence of different industries. On one side you have companies like Qualcomm. I'll explain Qualcomm's business a little bit later but as a technology communication company we are very interested in the transmission of voice and data. Every industry that exists, whether it be education, public safety, entertainment, and for me most importantly health care relies on communication and access to data so this is where we are coming at it. Qualcomm is a technology company that produces microprocessors that serve as the heart of all of these mobile products. At the core of each one of these phones is a microprocessor, a chipset. Qualcomm happens to be the world's largest producer of microprocessors for cell phones. We produced over seven billion of them. That is our leading dominance. That's what we bring to the table. As these technologies has evolved and throughput has evolved, you've needed denser chips that are smaller that have much more power management and that can do many other things which is where the health care component comes into place. The reason why I bring this up is because I believe today's objective was to speak about health care and broadband and a big part of this is wireless broadband. 3G and 4 G, are wireless broadband and Qualcomm has had a big role in all of them. I mentioned that the devices are becoming much more interesting. There are many more applications and services. Ruth, I feel bad. I took out my one slide on cloud computing. We can talk about cloud computing later but the idea is to be able to store a lot of functionality out somewhere in this virtual cloud so companies like Amazon or E-bay, those are cloud-based company. When you

have a KINDLE book reader, there is a Qualcomm microprocessor at the heart of that KINDLE so someone can download their favorite book. All of that information is out on the cloud. It's stored somewhere else. So you have convergence of devices, applications and services and networks, the broadband, that rich spectrum which is really really hard to obtain. There are so many other devices and different kinds of technologies that over time have taken up spectrum. It's a natural resource which is very scarce which is why so many companies like Jeff's company, AT&T, are interested in gaining spectrum and licenses to that spectrum are auctioned off at billions of dollars because they represent a way of being able to send information and give much more functionality to the user.   The mobile Internet is very important because the phone is always with you. It's in real time. It's context aware. It knows what's going on around it because it has things like location based services and assisted GPS and other features like augmented reality. It's highly personalized and it leverages this cloud. So the phone in our opinion - knows, it learns, it discovers, it filters, it sees, it interacts, it senses so it's a wonderful device to start talking about things like chronic disease. I believe Dr. Dicianno had a great slide which spoke about the disability report. His numbers were much more correct. The one's I have may be dated, but according to Cornell University in 2008 the prevalence rate of people with disability was 12.1 percent accounting for 36 million people out of the 299 million individuals that were in the U.S. at that time. But to go back to chronic disease it's a major problem. Seven out of 10 deaths are from chronic disease. One out of every two adults in 2005 had at least one

chronic illness. One in every three adults is obese. These numbers are from the CDC. They are not as current as I had hoped they would be. The idea behind merging health care and technology is to bring about this transformational change on how health care is delivered. The notion is rooted in collapsing space and time within health care. The device itself acts like a portal to sensors, products, applications and even services for the user and you're going to see more and more of this evolve over time but there has been a lot of movement in both industries to work together. To give you an idea of what the wireless health ecosystem is you'll have an environmental sensor, health device, actual medical product, fitness, aging devices etcetera which all operate on something either called a BAN which is a body area network so it needs something to connect with. That's where the wireless transmission is so important. Like the cell phone which is where we are interested in because we give you wide area network functionality so that's were the sensor being able to interoperate with "something" and that "something" is that which you carry around like your cell phone. What is the one thing most people carry around with them? Their keys, money and your cell phone and arguably speaking, money and keys will disappear over time. There are many smart services that offer near field communications or you can pay for things like your parking meter with your cell phone by texting. That's the idea behind the cell phone. It's always with you. So if you have these products that are medical or health care related, they will connect with your cell phone, send the information out to an IP-based wide area network and then out to a bigger network which will then aggregate the information. It will help you

address things that you may want for services. It will help you interact with doctors, care providers, loved ones. This also applies to things like smart phones, net books, laptops because they now have that wide area functionality. Most computers in America that are made by Dell, IBM, Panasonic actually have a wide area network chip integrated in them so you can go to Verizon, AT&T or sprint and enable it. You have wide area functionality. Just like a cell phone – for example the Apple iPhone just got on Verizon's network, they have been on AT&T's. You can access your information anywhere. At the heart of that most often is a Qualcomm chip set. Many wireless health segments have different goals, whether it be acute care to improve or prevent never events or remote monitoring to reduce hospitalization or aging in place to enable the elderly to live longer at home or have access to fitness, or just looking to improve overall health. The solutions are coming about through different applications and medical devices which had an interest already in those areas but did not have wireless functionality. So Qualcomm has partnered with a number of companies. All the companies I'm about to show have spoken with Qualcomm. I can say that some of them are partners. Some of these partners are out in the marketplace. Some are in clinical trials. I'm not making any claims on the products I'm showing you. You can find out about them on the Internet. Some are products which are actually sold. This is a Holter device that actually sends its information wirelessly through a Sprint cell phone. It's the first company that did that. They have been in operation for about six or seven years. CardioNet. This is a personal emergency response system, LifeComm. Remember, Mrs. Fletcher

who had fallen and can't get up? Mrs. Fletcher was using an old device that needed a hub that was attached to a plain old telephone system, the old regular RJ-11. This one works wirelessly and the person has it with them at all times and it has an accelerometer in it to sense if you have fallen and you can't get up and it will call the care provider or emergency system to help you. CORVENTIS. This is a continuous surveillance system and the idea is that this patch surveils things like heart rate, fluid status, activity level, posture, respiratory rate, arrhythmia detection, temperature and ECG rates. This is an application that's available on the iPhone store. It instantly recognizes U.S. currency. It's called the LookTEL money reader. It's intended to help those that are visually impaired and allow them to read U.S. currency. They are working on a number of recognition applications. Irhythm is a cardiac rhythm monitor; the patch which they developed is ECG and heart rate. Again all of these are wireless devices. The EPI is going to be the world's first ECG phone. It has voice capability, camera, blood pressure, glucose level, monitoring cholesterol, ECG 24 hours. Wireless enabled defibrillator and wireless cardiac system. Airstrip technologies makes a virtual real-time data application which doctors can access hospital ECG as well as maternal fetal monitoring. 3M makes the Cardio Littman stethoscope wirelessly. Class two medical device. You can hear it, record it, send the information and confirm what's going on. There is medication adherence software. A little company called VOCEL held a study with 50 Medicaid patients here in D.C. The idea being that the pill phone application actually documents all of the pills that are in the marketplace. It's basically the

pill book but put into a software. That way the user can then document their pills and it would give you the information of what the pill looks like, what the interaction or allergy issues may be. If it notices that you're taking two pills that already have an interactive pill, allergic reaction, it will warn you. It will remind you to take it via phone messaging, calls. Jitter bug makes easy to use mobile solutions, phones with larger numbers, easier to use for the elderly population. They feature a live nurse call in center. Pharmacies now are really implementing the idea of downloading applications to help you fill in your medication via the serial scan that's put on the side of their own pill bottles and then the smart system on the back will remind you when you're coming up for a refill or when you should be coming up with a refill and if you need a refill you can use text messaging to notify them and they will fill it for you. Vitality. Jeff mentioned this product. You put these pill bottle caps on top of your pill bottles and then it reminds you by making an audible alert if you don't take your pill because it knows when you actually opened it. It sends you a text message. If you don't take it then then it will start vibrating and making more noise and noise increases and if you don't do it by then it will send you text messages or phone calls to people that are actually in your network that you assign so that they can call you and remind you that you have to take your pill. Ingestible markers. These are pills that have microprocessors on them. You swallow them. They let the care provider or hospital know what's going on on the inside. These are actually prototypes. WellDoc is the other solution that Jeff Dygert from AT&T mentioned which is automated coaching using behavioral algorithms on glucometers that

send it to a phone and cloud based system. SANOFI Aventis is working on a glucose meter which you plug into your iPhone. It connects into an iPhone and sends out the information. DEXCOM is working on a seven-day blood glucose sensor. Which is wireless and water resistant. CellNOVO is working on a continuous tracking and delivery insulin pump enabled wirelessly. TELcare is working on a wireless glucose meter. You don't have to pair it to a phone or you don't have to connect it to a phone. Sotera wireless is working on rapid response monitoring ambulatory system. It's a hospital-based system eliminating those big vital signs monitoring systems. These are wireless and they are put on the patient and send information automatically within the hospital and outside of it. Fitness. You may have seen these kinds of devices already. There are sensors that go into certain sneakers that work with an apple iPhone and you can track how fast you're going. Can you track how much time you've taken, input other information and it will give you a caloric reading based on algorithms. While you sleep you can strap one of these ZEO belts on your head. You can download the information to your phone and trend and track and watch it later on to see what's affecting you. Body media makes personal health performance gadgets. There is wireless fertility. It comes with a patch, the patchworks directly with the monitor, sends information out to a phone the idea when it's the right time to do certain things. Obstetrics today looks like this. Technology, GE makes a wireless portable handheld sonogram, MOBISANTE just had their sonogram approved. So when I speak of all those devices and you compare them to things like the traditional Holter monitor, I think we can all see there is a big difference in

how health care has been provided before and how it will be in the future. I know that I don't have a lot of time but I wanted to rifle through some of these. In order to bring these things to the market there are a lot of considerations that have to come into play and a lot of them have to do with regulatory and policy issues that are in place now. So just to give you an idea, the FDA medical device regulations that allow for medical devices to come to market actually were written back in 1976. So that means Internet, fax machines and cell phones did not even exist. But it's not just about the FDA, there are many, many agencies and branches of the U.S. government that are working on either what they like to call health information technology or telehealth or telemedicine. Some of them include Congress. With the passage of ARRA and last year's Affordable Care Act, there have been a lot of changes in the way that health information technology have been viewed. I consider ARRA the watershed moment where emphasis by the U.S. government on incentivizing the use of health information technology. Unfortunately, the way that it has been interpreted according to the Office of National Coordinator is to focus on electronic health records and the exchange of those electronic health records and systems that govern those electronic health records. Those are important but the EHR does not touch the patient. What touches the patient is a medical device, a sensor, a doctor using a medical device that takes that person's data and sends the information into a system. Unfortunately the EHRs aren't looking at physiological data. They are focusing on clinical quality requirements that they have been given by the ONC. Thus we feel that's a problem because really there should have been a focus on

both sides of that ecosystem. Health information technologies are not limited to EHRs. They encompass everything from the patient to beyond. Passage of ARRA very important. Affordable care act very important and included Independence at homes, wellness visits, creation for the center for Medicare and Medicaid innovation. That's really important. All of those things will impact the way health care is delivered and paid for which is a big deal. There were a couple hearings last year that the Congress had. This year, we are anticipating legislation on including remote patient monitoring services for certain segments of the Medicare population. There are actually 20 physicians in the Congress so talk to your legislators because some of these things are really important and should be important to them. The centers for Medicare and Medicaid Services, CMS innovation center are paying out the $27 Billion incentive payment program for EHR's that I mentioned which is part of the ONC effort. CMS recently signed a memorandum of understanding with FDA. What I wanted to talk about is how the Medicare telehealth services reimbursement definition is defined and basically in order for a doctor to be reimbursed for telehealth service they have to perform their service in person. It has to be live real time voice and video so it cannot be a store and forward technology. The specific site of care is stipulated by the CMS. Like a Skilled nursing facility. If the doctor does the service from his car or on the road it does not qualify. That falls outside of the definition. The beneficiary has to live in a health professional shortage area or not in a metro statistical area. Which basically eliminates I think 86 percent of the country if I'm not mistaken. The specific care has to either be an inpatient consultant,

psychiatrist, psychotherapy, pharmacology or nutrition. No store and forward unless you're a demonstration project in Alaska or Hawaii. If you look at the proposed budget for the CMS for 2011 that's $874 billion (as in billion with a B). It's more than the Pentagons budget which was under $700 Billion. I'm not an expert but the Medicare budget alone was $549.8 billion. The point being is how much money do you think was actually reimbursed for telehealth services last year? Close. She said zero. About $2 million (and that's million with an M). Somewhere in this budget I am sure that we can trim a lot of money by using remote patient monitoring devices which today won't be used by doctors because they won't get reimbursed for using this type of care. That's the issue. The doctor in a sense is incentivized to use traditional methods of delivering care because he is going to get paid for it. And if he won't get paid for it he is not going to adopt the much more expensive unit that will eventually save money in the long run. The technology that collapses time and collapses space so is the reason I bring this up. The New York Times a couple of years ago had a great article about this woman who I believe her son was autistic and she had ALS and she used what is basically a dumbed down laptop that did one single thing because that was what had been put through CMS as a durable piece of medical equipment and her doctor had actually encouraged her to use this thing. It was for speech recognition. I believe that the amount of money it was in the article was $8,000. A smart phone with a similar application, say the best you can find would probably cost about $300 or $400 but she won't get reimbursed for that. She will get reimbursed for the $8,000 unit. Something has got to change. The

FDA is very specific in what is a medical device. Definition is instrument, apparatus, implement, machine, contrivance implantable in vitro or other similar or related article intended for use in the diagnosis of disease or conditions or in the cure, mitigation, treatment or prevention of disease in man or other animals. Many people in my industry up until about three or four years ago did not realize that by saying certain things about cell phones and services cell phones rely on or the products that are attached to cell phones would actually trigger this definition and would then need to be regulated by the FDA. You can't just go out and say I'm going to make something that's going to help your diabetes. If you say that you actually are regulated by the FDA. We are okay with that. We want to make sure that products that are touching people and hopefully will change their lives are regulated the way they should be but what about claims that kind of lie in the middle like you're too heavy, you need to lose weight? Well, it's a little unclear and that's been a problem with the FDA and a problem with the industry so Food and Drug Administration has really taken it by the horns. They have given indications that they are working on guidance related to mHealth and applications. They also have something called the home use medical device initiative. They signed an MOU with the FCC to work on wireless products and getting them to market quickly. They have a draft radio frequency wireless technology guidance they are updating. They have drafted a new plan for getting other devices to market. They also have a new Medical Device Innovation Initiative and they recently passed a new rule for class I devices to make things like transport mechanisms, those that transfer, store or convert from one

language into another and do nothing more, a class I medical device thereby reducing the medical device regulatory obligation and hurdle. We are very encouraged by all the steps that the FDA has taken. The ONC I already spoke about. Basically they are looking at how they incentivize doctors to use health information technologies. We are hoping that they start focusing on engaging patients and their families and bringing remote care to the people that need it the most. Those concepts have been put in possibly for stage three. They are currently looking at stage II. Stage I is the stage we are currently in now, stage II they are trying to define and stage three is just a probability. It could happen. Thus, we've seen encouraging concepts and language in stage III. We want it to be accelerated to stage II. That's something that's important. I think Jeff Seidman from ONC is going to be speaking later on so he is overseeing this effort. The office of national coordinator this past Monday held a health IT standards committee clinical operations work group meeting where they spoke specifically about identifying barriers and enablers to device interoperability and how those medical devices can speak to each other and within systems. They are focusing again on the patient, the consumer and how these devices will interoperate and how they are going to send data so we are really encouraged by that effort as well. The FCC I think you have someone coming in from the FCC later so I think I'll leave this information to them. However I will mention when the national broadband plan came out this year there was an entire chapter devoted to health care. It was important because there were a number of recommendations to talk about things like FDA, to talk about things like the CMS

and reimbursement obstacles and more importantly to define certain terms

including mHealth and that was important to the industry. The National Institutes

of Health which is not a regulator, but the research branch of the U.S.

government in the area of health are very, very involved in mHealth. They have

an mHealth working group. They have an mHealth workshop that happens once

a year. They also have a wireless medical technologies interagency working

group. The foundation for the NIH has an ambitious event called the mHealth

Summit. Last year it was keynoted by Bill Gates and I believe Ted Turner and a

number of other luminaries who came in to talk about Mobile Health so look for

very interesting things coming out of the NIH. They are also hosting this year in

the summertime something called the mHealth summer institute. We,

Qualcomm, are the co-sponsors and it's happening in San Diego. And then there

are a number of interagency efforts that are going on between all of the

agencies. One of them is being spearheaded by NIH which I mentioned which is

the wireless medical technologies working group. My understanding is

HRSA/ONC has concluded. They are starting a new group. There is this HHS

task force which is an interagency task force being spearheaded out of the office

of the Secretary for Health and Human Services. Now, a little bit about

Qualcomm and I promise I'll be done. So we are a leader in developing and

delivering innovative wireless communications technologies and services based

on 3G and other advanced technologies. We are the world's largest fabless

semiconductor company in the world. One third of our income comes from the

licenses that we have with all of the manufacturers involved in our 2G, 3G or 4G

technologies. The other two-thirds of our income comes in from the chip set sales. We are not a greedy company and have reinvested I believe close to $16 billion over the company's history to make these technologies, continue to evolve and bring richer services to the user. These are our three engines of growth our licensing unit, semiconductor business and we have another one called wireless Internet which deals with everything else that we can try to put a chip into or value added services, including things like health care. To date we have shipped over 7 billion chipsets over the history of the company. I believe last year we were producing an average (over the year), of around one million chips per day. So that it – that's my presentation! That's my information if anybody wants to contact me, please do so (rjarrin@qualcomm.com). Thank you for inviting me to speak today, thank you very much.