



In Response to the Honorable Joseph R. Pitts:

Question 1: During the hearing you said that regulation of mobile medical applications disproportionately affect certain patient groups. Would you please elaborate?

Newborns will be disproportionately affected by the regulation of mobile medical applications.

The development of traditional medical devices for newborns is a relatively small market. Technologies and devices designed specifically for newborns are inherently higher risk and are subject to significant regulatory oversight. Developers of these technologies incur non-trivial costs during the FDA regulatory process, which increases the up-front investment required to bring a product to market and lengthens the timeline for a product to become profitable.

The high costs associated with bringing newborn-specific products to market have caused many medical device manufacturers shy away from designing products specifically for newborns. It is often the case that the exact same product can be brought to market with lower regulatory costs if the product is designated for use in adults.

An example is the pulse oximeter, a FDA regulated medical device that is used to measure the level of oxygen in a patient's blood. This technology has an array of uses in newborns including the identification of hypoxia, neonatal sepsis, and congenital heart defects. To date, fourteen states and the District of Columbia have passed laws that require all newborns be screened using a pulse oximeter before they are discharged. However, despite the common use of this technology since its advent in 1972, it was not until 2012 that FDA cleared a pulse oximeter specifically designed for use in newborns. The forty years without newborn-specific pulse oximeters was not do to lack of demand, but rather it was because adult pulse oximeters could be used on newborns, albeit not as accurately, and the developers could bring the product to market with less regulatory scrutiny.

In the absence of a product that has been developed specifically for newborns, families and providers have come to rely on technologies for which there is a market such as consumer-focused information and communication tools such as apps on smartphones and tablets. The question is not if some mobile applications should be regulated, certain mobile applications do present very real patient safety issues, but rather if all mobile applications should be regulated in the same way.

My concern is if mobile medical apps are regulated the same way as medical devices are currently, then we can likely expect to see a reduction in the number of mobile medical apps that are designed specifically to serve newborns and their families. As demonstrated by the pulse oximeter, where there is a need the market will respond, but if there is an opportunity for a

higher rate of return elsewhere, we must expect investment to flow to those areas first and that means fewer tools available to those that need them.

Question 2: You stated in response to a question there are non-reimbursement barriers to telemedicine services that preclude their widespread use. Please specify what these non-reimbursement barriers are and how they might be addressed.

Telemedicine has the ability to transcend geographic barriers but is often limited by bureaucratic issues such as state licensing. Currently providers have to be licensed in every state where they practice medicine, including telemedicine. If a provider physically located in the state where he or she is licensed, that provider cannot treat a patient via telemedicine that is located across state lines without first being licensed in both states.

Telemedicine is a way for a provider to make a house call regardless of where the patient is located. The United States has long faced provider shortages in rural communities and we are now seeing shortages in the urban setting as well. Medicare beneficiaries will become increasingly aware of these shortages as more and more seniors seek healthcare and they are unable to find a provider.

This problem can be solved by pursuing an approach similar to what the Veterans Administration and Department of Defense have done to address provider shortages great success: allow VA and DOD providers to treat patients regardless of where they are located.

Something similar can be devised to address shortages in Medicare by allowing Medicare providers to treat their patients (those with whom they already have a relationship), regardless of where the patient located, and allow these providers to do so with their current state license.

The Honorable Michael C. Burgess

Question 1: The Health Information Management Systems Society Recommends that FDA not define “medical device” to cover software or hardware that provides clinical decision support, EHRs, simply transmits or allows other parties to read information originally sent from a medical device, or technologies that are widely used in other industries. These seem like a strong request that FDA not use mission creep to go into areas for which it has little expertise and little ability to properly review.

a. How would FDA use a clinical trial system for clinical decision support?

The process of using clinical trials to regulate clinical decision support (CDS) tools would be complex. The trial would have to be designed to investigate the efficacy of different kinds of CDS tools both as standalone interventions and as a part of a system.

The issue of “mission creep” will become more apparent as CDS tools become more advanced and rely on individuals personalized health information instead of more fixed information sets such as drug formularies.

The concern here is that a CDS tool will have to be regulated as though it is a standalone medical device. This becomes increasingly complicated when we think of the EHR as being the central control for many CDS tools; the tools would then not only have to be individually regulated but also regulated as a device designed to work in concert with others.

In this instance the regulation of CDS tools would likely extend to EHR developers as well if their systems use regulated CDS tools, because the system itself may be subject to additional regulation. CDS tools are already required for certification in the Meaningful Use program and have widely been incorporated into EHR systems. The concern here being that what began as the regulation of CDS tools may quickly lead to the regulation of the Electronic Health Record systems that Medicare providers have been required to purchase by the HITECH Act.