



March 28, 2011

Medical Device Hearing
9:00 a.m. to 5:30 p.m./Eastern Time
Renaissance Washington, DC Dupont Circle Hotel
1143 New Hampshire Avenue, NW, Washington, DC

Written Testimony from Robert Bosch Healthcare

Before the Clinical Operations Workgroup for recommendations to the HIT Standard Committee and the Office of the National Coordinator

About Robert Bosch Healthcare

Robert Bosch Healthcare Inc. is a leading provider of innovative telehealth systems. Bosch's product spectrum ranges from patient terminals to comprehensive evaluation software allowing healthcare professionals to efficiently evaluate the data coming from the patient terminals and other connected devices. Bosch Telehealth strives to improve diagnosis and treatment through systematic patient monitoring and involvement. The result is that health professionals are able to provide a higher quality of care providing for patients with chronic conditions, patients lead happier and healthier lives, and the cost of healthcare is reduced for funders. Robert Bosch Healthcare, Inc. is a fully-owned subsidiary of the Bosch Group.

More information about Robert Bosch Healthcare can be found at:

<http://www.bosch-telehealth.com>

Introduction

Robert Bosch Healthcare is honored to address the questions raised by the Clinical Operations Workgroup, and feel that the questions present an opportunity to develop a framework for new innovative devices, better compliance to standards of care, better usability for patients, and measurable systems of excellence for the medical device industry.

Our testimony will focus on questions raised by the Clinical Operations Workgroup, focusing on the following:

- I. Response to "waving a magic wand to effect one change"
- II. Data Integration and Interoperability
- III. Unique Device and Patient Identification

I. If you could “wave a magic wand to effect one change” to enable more effective and widespread use of health care devices, what would that be?

The Clinical Operations Workgroup has presented a tempting question of “waving a magic wand to effect one change,” which is both wonderfully empowering and frustrating at the same time, as there are more than a single wand-worthy change that should be made. That said, the change we would request would be the implementation of a scoring and standards program for medical devices, not unlike that of the British Hypertension Society (BHS) and blood pressure monitors.

Not unlike the BHS, it should not be necessary for a specific medical device organization to test each device, but to accept the testing of independent third parties on an established set of criteria, developed with industry. These rankings should test compliance to a given set of use-cases, including shipment materials, instructions, and usability, accuracy, and integration protocols.

Such a system would allow the industry to set baseline requirements for key contracts, and not unlike the BHS rating systems, exclude devices that are not of 'A' quality. The implementation of such a system would provide more transparency to the consumer, the clinicians, and the EMR systems which can then apply rules and intelligence to the collected data, even choosing to use different data in different algorithms or clinical settings, based on the quality of the collection device.

II. Data Integration and Interoperability

A. What data about devices is needed in EHRs?

To better support EMR systems, we believe it is necessary to enhance current guidance with the concepts of a “*method*” identifier. Specifically, the 510(k) classification, such as Over the Counter (OTC) or Prescription, approval for hospital use, or other such categorization can be used as the basis for a *collection method framework*. This *method* can be expressed in the data stream to allow for more intelligence and reporting clarity in the EMR system. Today, it is nearly impossible for a telehealth system – never mind an EMR or central data repository – to understand the *collection method* of the data. Was it collected by the patient in the home, or by a professional in a clinic? Was it observed by a professional or self reported?

In addition to their obvious clinical value, the *method* identifiers have technical advantages as well. *Method* identifiers will allow systems to publish and share data based on use models. Specifically, the industries current data integration model is trending towards a single, massive datastore with all patient data transmitted to a few integrated EMR or PHR systems. A more scalability and robust system would mirror the architecture of the internet itself, with no single point of failure. This system, distributed

across networks, would allow systems to publish the data that they possess, and the relative value of that data.

Leveraging the previously discussed BHS rankings for blood pressure cuffs as an example, it is logical and clear that an EMR system should be able to build workflow and alerting based on incoming data Blood Pressure data. In today's market, it would be impossible to know if that data was collected professionally, self-reported, or collected by a "B" class Blood Pressure Cuff. The lack of method data presents limited set of options to the EMR or central warehouse. The EMR can choose to ignore data it cannot verify, or accept possibly faulty data. In addition, once it is accepted, with no interoperable standard for collection method, the source data becomes does not exist in the EMR, possibly giving a home-collected "B" class Blood Pressure Reading as much value professional collection at the hospital bedside.

If we are to achieve true scalability in this market, we need to be able to adjust the rules and usage criteria in real time, rather than accepting a "water hose" of data for which each EMR must build evaluation and acceptance criteria.

B. What is the impact of the recent FDA MDDS rule on device integration with EHRs?

The FDA MDDS rule will make a strong positive impact on the collection, analysis, and dissemination of medical device data – collected in the home or elsewhere – into the clinical decision making process. Although Decision Support Tools are not covered under MDDS, these tools are dependent on accurate and timely data to support the clinical process.

III. Unique Device and Patient Identification

A. What are the requirements for unique device identification? How do they relate to the use of EHR technology? For providers vs. patients? For different care settings?

We believe that Unique Device Identification (UDI) and the specific amendments of H.R. 3580 are excellent propositions for addressing issues of patient safety, recall compliance, and adverse event reporting. Overall, UDI provides a major step forward in the overall safe and accurate use of medical devices. However, the UDI language falls short of addressing some of the key issues in distributed, home based medical device systems.

Economically and technically, UDI does not address the issues of patient identification in the use of medical devices. This can lead to cost overruns, patient safety, and data integrity issues. Let's explain a specific example of a married couple, living together, both suffering from the chronic disease in their later years. The husband, a CHF patient, and the wife, a CHF and Diabetic patient, both take their weight every day on a wireless weight scale, which is uploaded to their physicians EMR for review.

In today's Medical Device environment, without a patient identification system, it is impossible to be sure who steps on which scale, and when the wrong data is sent into the wrong EMR record, it is often impossible to remove it from the record, assuming that it can even be identified as belonging to the wrong patient. This incorrect data may even trigger an alert that needs to be cleared by a nurse or physician. A cursory review of the costs, including nurse efficiency, time spent on the wrong patient, EMR record management and change control, and cost of individual devices for each member of the family leads us to believe this may be the most expensive barrier, both clinically and financially, still facing the telehealth market in the United States today. We believe that the lack of patient identification guidance from the FDA is a deterrent to the establishment of a large scale, cost effective, home-based clinical care system that can accurately inform EMR and other clinical systems.

This is not to say that UDI is without merit, as it is an important step forward in the ability to safely track, recall, update, and manage medical devices spread into patient homes and places of work. With specific desire to meet both the spirit and the letter of the MDDS, and enhance the use of home-based and personal medical devices, the FDA can serve the industry by pushing for patient identification processes as part of or in parallel to the UDI implementation requirements.

Closing Statement

Robert Bosch Healthcare would like to thank you for the opportunity to share concerns and suggestions with the Clinical Operations Workgroup. Robert Bosch Healthcare would be honored to continue to present and further discuss our case around the questions discussed here today, and other ideas on how to improve patient safety while increasing the value of data collection, both economic and clinical.

To contact Robert Bosch Healthcare for questions or additional information contained in this written testimony, send email to: Michael Howells, Michael.howells@us.bosch.com