March 28, 2011 invited testimony to the ONC FACA HIT Standards Committee Clinical Operations Subcommittee on Medical Device Interoperability

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My name is Elliot Sloane, and I would like to thank you for allowing me to offer testimony about medical device interoperability. I will be addressing the standards, development, maturity, testing, capability, demonstrations, limitations, and product availability of clinical and patient care devices that interoperate with each other and with electronic medical record and personal health record systems. Disclosure: I receive no compensation from medical device, EMR, or related technology manufacturers or distributors, and have no conflicts of interest with the following testimony.

I am also pleased to offer testimony on behalf of Integrating the Healthcare Enterprise USA, Incorporated (IHE USA). IHE USA (www.iheusa.org) is a not-for-profit organization and a national deployment committee of IHE International, Incorporated ® (IHE®). IHE is a global organization that brings healthcare providers and the HIT industry together to improve interoperability and exchange of health information. With over 370 member organizations representing clinicians, provider organizations, hospitals, medical societies, researchers, standards development organizations, health IT vendors and government agencies, IHE has developed a framework for standards-based interoperability of health IT systems and fostered its adoption worldwide. IHE USA serves as a voice for U.S. health IT stakeholders and a partner in efforts to promote national adoption of a consistent set of information standards to enable more effective use of health information.

Executive Summary of my testimony on behalf of IHE USA

1. I have personally worked with – and have had senior management responsibility for – a large variety and quantity of medical devices used in hospital, home care, and many other settings for 36+ years, and I have a very thorough understanding about medical device capabilities, limitations, and patient safety risks.
2. I have personally worked with – and have had senior management responsibility for – a large range of computer, information, and telecommunications systems for 34+ years, and I have a very thorough understanding about their capabilities and limitations and, in the healthcare setting, I have a thorough understanding of the existing and emerging patient safety risks.
3. I have been on the IHE Board of Directors since 2003, and have been the Co-chair of IHE International since 2008. IHE USA is a not-for-profit organization and a

national deployment committee of IHE International, Incorporated ® (IHE®). I co-founded the IHE-PCD Domain in 2005, which was chartered by IHE to develop HL7- and IEEE-compatible IHE Interoperability Specifications to allow medical device data too automatically, reliably, and seamlessly share clinical and alarm data with EMRs, other enterprise information systems, and the devices themselves. Those specifications comply with formal IHE infrastructure profiles, including, for example Consistent Time (CT), and have been in continuous use since 2006.

4. The National Institute of Standards and Technology (NIST) has been an integral partner for our extensive and rigorous IHE-PCD testing and demonstration activities since 2005, using, in part, ISO/IEEE 11073.x medical device testing tools it had independently developed since 2003. We are indebted to NIST, as all of this excellent work has been gratis, for the public good, and is posted by NIST as an open source software resource.
5. IHE-PCD interoperability has been publicly tested and demonstrated using life-critical, FDA-regulated medical devices such as anesthesia systems, infusion pumps, physiologic monitors, and ventilators since 2006, and IHE and those vendors have consistently demonstrated effective device-EMR and device-device data and alarm exchange for nearly half a decade. Over a dozen medical devices and EMR products with these capabilities are on the market today, and several companies have designed and are selling universal IHE-PCD adapters and integrators for legacy devices.
6. At the request of ONC, between 2007 and 2009, IHE-PCD and the Continua Health Alliance worked with HITSP technical committees to create two ANSI/HITSP technical documents (IS77 & TN905) that carefully and clearly identified the process and specifications needed to allow all patient care device data – whether FDA-regulated medical devices or Continua-certified personal health devices – to automatically, reliably, and seamlessly send data to EMR, EHR, or PHR systems.
7. Although the NHIN DIRECT transport mechanism did not exist when the ANSI/HITSP project ended in 2009, because the IHE-PCD and compatible Continua-WAN data is HL7-2.6 compliant, we believe IHE-PCD data can be readily using the NHIN DIRECT SMTP protocols, and the IHE PCD data can be integrated into a C32 CCD format when sufficient contextual patient and clinician data is available. IHE USA would be pleased to work with ONC to accomplish that.
8. Until ONC identifies a preferred medical device interoperability profiles, and includes specific Use Cases in Meaningful Use requirements and CMS incentive reimbursements, hospitals, physicians, patients, and payors like CMS will be subjected to almost limitless costs, complexities, risks, and delays that proprietary, 1:1 interface solutions necessarily create. Perpetuating the status quo solely benefits companies that have large and growing revenue streams from creating and maintaining proprietary 1:1 solutions.
9. It is IHE USA's recommendation and request in my testimony today that, based on IHE's well proven, well tested, and well documented profiles and specifications, and a growing IHE-PCD compliant vendor base, ONC will improve patient care and reduce costs and risks by adopting and specifying the IHE-PCD and Continua-WAN profiles for patient care and personal health applications, and Meaningful Use clinical practices and incentive thresholds should be included in the upcoming Stage 2 and Stage 3 Meaningful Use requirements.

All Panels – General Questions

1. *What is your experience with health care devices and device interoperability? Have you experienced specific problems where standards might contribute to solutions?*

Response:

Since the beginning of my career in 1975, I have worked continuously with health care devices and device interoperability issues. For 15 years at ECRI Institute I served as a medical device product evaluation engineer, a medical device product accident and forensic investigator, and helped design and build a medical device registration, maintenance management, problem reporting, action alerts, comparison, and recall management data warehouse and publication system that is still largely in use today. During that era, medical device data was generally limited to low-bit-rate, low resolution 5-volt serial or parallel data that was solely vendor and model-specific. ECRI participated in the earliest medical device standards development efforts on behalf of the US FDA, focusing on life-critical products such as infant apnea monitors and heart arrhythmia detection systems, and ECRI also designed and build a series of electronic simulation and testing devices for general biomedical equipment testing, calibration, and repair. Device interoperability was essentially non-existent, and data acquisition for each device required hand-built electronic interfaces and software adapters for each model and brand under test. Even when interfaces were fabricated, very little output data interpretation was possible because there was no semantic framework to allow comparison of data to actual clinical phenomenon. In general, device performance characteristics required manual data interpretation and loose statistical inference of "accuracy."

From 1990-2000 I led the biomedical technology support programs for a large nationwide medical device rental, leasing, repair, and manufacturing company named MEDIQ/PRN Life Support Services, Inc. At its peak in the late 1990s, MEDIQ owned, manufactured, rented, or serviced nearly 500,000 moveable medical devices for home care, nursing home, and hospital applications. Products included electric and pressure support beds and mattress systems, wearable and portable infusion and PCA pumps, infant incubators and UV biliruben/warmer systems, surgical lasers, portable and fixed ventilators, diagnostic sleep apnea recording systems, and most physiologic monitoring modalities, including ECG, infant and adult apnea, pulse oximetry, non-invasive blood pressure, and other modalities. MEDIQ supplied over 5,000 hospitals, 5000 nursing homes, and 5,000 home care agencies from over 100 offices in all 50 states with these life support devices, supplies, and pharmaceuticals on a 24x7 basis. Because of the diversity of its 15,000 customers, MEDIQ owned, inventoried, serviced, and rented virtually every brand and model of FDA-approved medical device manufactured between approximately 1971 and 2000 on a near-daily basis. During that period, none of the medical devices used in the US had any form of compatibility other than with its own brand- and generation-specific "nursing central station" hardware and software interfaces. Even the most basic Alarm or Nurse Call function required custom-developed hard and soft interfaces if multiple brands, models, or generations were mixed. At this time, a few "gateway" interfaces began to enter the market to allow modest data transfer from clinical systems to very limited electronic medical record

environments. Also, a few medical devices began to offer Ethernet LAN access, and those typically were used to transfer data to proprietary, network-based, brand- and model-specific central nursing monitoring systems. Unfortunately, in the intervening years, the interoperability of commercially available products has not markedly improved.

I have been in the academic field since 2000, doing research and teaching general information systems, health information systems, and health systems engineering topics. In 2002, while President of the American College of Clinical Engineering, I started a Task Force that began exploring development of a more permanent, cross-industry multi-brand and multi-modality interoperability with HIMSS and the Integrating the Healthcare Enterprise (IHE) Board of Directors. Developing an IHE-compatible medical device interface was a priority for IHE because the 5,000 or so medical devices each hospital has far outweighs the number of information systems (perhaps 300) and imaging modalities in use (perhaps 30). Even the most fastidious hospital has to support many hundred different brands, models, generations, and versions of medical devices, too, making medical device interoperability much more complicated than prior IHE modalities. There were several key and critical goals for initiating that work, including 1) automating the capture and logging of physiologic data from all brands, models, and configuration of medical devices into patients' permanent electronic health records, 2) allowing life-critical alarm and alert signals to be transported reliably between devices and to EMR systems, and 3) enabling real time physiologic waveform data to be shared across devices and stored in the patient's permanent EMR. In 2004 that Task Force evolved into a new Patient Care Device Domain within IHE, and in early 2005 the first IHE PCD Integration Profiles began to take shape. By 2006, patient care devices and EMRs were being tested in US and international IHE Connectathon events using NIST-provided testing software and systems, and since Spring, 2006, many dozens of patient care devices and EMR systems have been included in international IHE Connectathons and Interoperability Demonstration Programs at regional and national conferences (including HIMSS sponsored events in Europe and Asia-Oceania).

Secure IHE-PCD data logging and exchange of basic physiologic monitoring was first demonstrated and tested between devices, EMRs, and surgery and anesthesia information systems in 2006, and ventilation, anesthesia, and basic infusion devices were added in 2007. From 2006 onward, medical device data capture and exchange with well-regarded EHR systems from companies like Cerner, Epic, GE, IBM, and PatientKeeper has repeatedly been tested and retested at IHE Connectathons, and has been shown at HIMSS Interoperability Showcases.

Basic IHE-PCD alarm integration, legacy device integration, and implanted defibrillator data capture and programming were added in 2008. In 2009, 2010 and 2011 many more complex combinations of products were added and demonstrated, including multi-brand real time infusion pump medication safety integration and Continua Personal Health Device data capture and integration.

Although many large companies are well represented, several small startup firms have also successfully participated, which shows that the IHE-PCD tools can be understood and applied without major resources. It is also noteworthy that new IHE-PCD-compatible companies and products continue to be developed while we have been awaiting recognition by ONC. Sadly, the purchase and deployment of IHE-PCD compatible interoperable medical and personal health devices and EMR interfaces has

faltered because most providers have focused their attention only on achieving Meaningful Use Stage 1 goals. Many hospitals who are undertaking medical device interoperability projects are reporting extremely high interfacing costs, in the neighborhood of $1,500 per device. That is truly a shame, since that cost exceeds the original cost of many basic medical devices like pulse oximeters, it adds significant costs to all but the most expensive devices on the market, and there is no guarantee the hospitals will not have to pay additional costs to maintain EMR compatibility as Stage 2 and Stage 3 upgrades come to market.

2. *Are there areas where standards are more mature or less mature?*

2b. Response: Mature & well established, tested, and demonstrated:

(1) Episodic electronic physiologic data capture and transport between medical devices or personal health devices and EMRs or PHRs. This is achieved using an IHE-specific HL7 Version 2.6 data structures based on ISO/IEEE 11073 XML semantic tagging.
(2) ISO/IEEE 11073.x semantic tagging has been cross-referenced to well over 300 vendor-specific data tags in the IHE PCD Rosetta Project Terminology Mapping (RTM) tables that are publicly available and downloadable from www.IHE.net.
(3) The Rosetta RTM tables have also been extended to map medical device and personal health semantic tags, and are further mapped to Unified Medical Language System (UMLS) units of measurement within the Rosetta Project tables.
(4) A Continua Health Alliance Wide Area Network (WAN) interface from the Continua-certified device aggregator to EMR, PHR, or other systems has been unified with the IHE PCD Device-to-Enterprise Communication profile (DEC). This allows unified data transfer using the same data architecture by direct or web-application connections, and ensures that a specific data bit is sent and retained that allows segregation of FDA-regulated medical device data from personal health device date when or as necessary.
(5) All IHE PCD profiles implement IHE-compliant Consistent Time, with the exception of the real time implanted defibrillator profiles.
(6) NIST has built a large library of open-source IHE PCD HL7 verification and validation software tools that have been well tested at public IHE Connectathons since 2005. These include DEC, Point-of-care Infusion Verification (PIV), and Alarm Communication Management (ACM).

2b. Response: Less mature, opportunities for further development:

(1) System of Systems Engineering (SoSE) approaches for healthcare technologies like interoperable medical devices and EMRs are only at the earliest stages of development. There are only a limited number of research or application articles in the literature, as compared to several hundred in other industries and applications. SoSE research and methodologies have been designed in other fields to account for complex device and system interactions, interdependencies, and risks. Legal and regulatory SoSE concepts are not well developed yet either. e.g., how does strict liability or FDA regulatory law apply to a multi-vendor, multi-modality SoSE? Which product, interface, or maintenance procedure was the primary cause of a failure, injury, or death, and which company should be held accountable? e.g., if three different brands and models of infusion pumps are separately but

simultaneously infusing three different brands and concentrations of medications, and the medication safety is being monitored by three different software systems plus a Pharmacy and EMR system, how can a missed drug-drug interaction or overdose be accurately detected, let alone assignment of responsibility? Of course, many more basic interoperable tasks such as collection of simple vital signs are far less complex, but SoSE issues still exist.

(2) Device-patient data "binding." Currently, IHE PCD relies upon well proven core IHE-Infrastructure profiles to provide optional patient identity binding of the device data to the patient. More generally, however, a patient may have some or many devices used in her/his care, and those devices may need to move flexibly into different areas of daily living and ambulatory care. In addition, group living situations like nursing or assisted living facilities may have multiple patients surrounded by multiple devices for their individual care. Safe and adaptable clinical care will require a reliable, secure, and efficient facility to ensure flexible binding, and PCD is working on Point of Care Identity Management (PCIM) to ensure ready release and re-binding of patients with devices as care needs changes. In a related area, PCD is working on interoperable Real-Time Location System (RTLS) messages which will complement PCIM by helping us automatically match patients with the devices, supplies, and medications in their immediate care area.

(3) Smarter devices and device systems have local data storage, analysis, and display capabilities. IHE PCD has a basic DEC-SPD (Subscribe to Patient Data) facility that allows sub/pub orchestration, but, like DEC-PCIM above, supporting multiple ambulatory patients will require general-purpose, secure, and reliable method to ensure all relevant patient data (e.g., oral medications) are "visible" to all device, EMR, and data-integration systems (like Surgical Information Systems, for example). In order for evolving diagnostic and treatment systems to properly maintain and disclose "context" of care (e.g., including recent medication or diagnosis changes), this area will need more development.

(4) Real time and near-real-time waveform data and system capabilities will eventually need "streaming" data capabilities of some sort. The bulk of the present IHE PCD data is handled like a snapshot, with time-stamped data encapsulated in an HL7 object that can be moved between devices or EMRs. Although that object can include a digitized DICOM or jpg image, such images are not only lose resolution, continuity, and motion accuracy, but they also wipe out or grossly distort the underlying digital data details. (e.g., a digital copy of a photograph may become coarse and grainy, and fine details may disappear, unless great care is taken.)

(5) Network and System Quality of Service (QoS) limitations can delay or distort alarm or waveform representations, and it is a problem in all modern technologies including cell phones and GPS traffic information systems. As medical device interoperability allows more complex and risky patient care, QoS problems may introduce significant safety, complexity, and other risks that must be understood and managed.

(6) Life cycle Verification and Validation (V&V) processes are not well developed or understood for multi-vendor, multi-modality, multi-communication method systems. V&V methods for all phases of system design, acceptance, change management, and decommissioning will become more and more important. The military and other industries and governments have adopted and are expanding complex System of

System V&V tools to meet such needs, but those are simply not available or understood in the healthcare field.

(7) Medical device maintenance management, including, potentially, predictive failure detection and remediation, adaptive system configuration, and/or recall management is an area that is in an early stage of IHE PCD Integration Profile development. That effort may benefit from some of the proposed UID efforts, but only if the devices remain relatively rigid "from cradle to grave." Given the 20-year life cycle of many medical devices, and the potential that field-, app-, and real-time product reconfiguration may offer, a fixed UID may not quite match emerging products' in the coming decade.

(8) The MD-PnP (Medical Device Plug and Play) environment being developed by CIMIT and Partners Healthcare may eventually offer novel ways that devices can self-disclose interfacing and interoperability methods. Ideally, such solutions will be IHE PCD, Continua, and ISO/IEEE transparent, so the technologies complement each other and leverage existing proven solutions.

(9) Real time device control, interlock, and interdependency are part of a new ASTM Integrated Control Environment standard under development. The applications described thus far are mostly slower-moving chronic or acute care situations with anticipation of appropriate clinical, caregiver, or self control of the environment of care. Robotic-like real-time control of devices, and/or the autonomous safety management of an environment are relatively new areas of research and development.

3. *What standards or standards-related capabilities are most relevant and important to the meaningful use of EHR technology?*

Response:

If one focuses on Meaningful Use as "Putting Patient Data To Work" in the moment to moment decisions that a clinician, caregiver, or patient him/herself must make about health care, I think that the initial priority can and should be given to automating the capture and logging of vital signs and basic diagnostic data needed for general patient care. One estimate offered by University of California San Francisco's CIO at the Clinical Engineering Symposium at HIMSS '11 is that their cost for vital signs and medication data entry by nurses runs about $100/hour, and that the average nursing data entry lags the actual physiological measurements and drug administration by about 2 hours (and can be much more). Not only is nursing time ever more scarce, but the cost, delay, and inevitable data entry errors all work against efficient, effective, or safe healthcare.

Healthcare is possibly one of the very last businesses where manual data entry is still used. Postal, retail, hospitality, logistics, aviation, and most other industries use automated, near-real-time data acquisition directly from sensors or devices that are integrated into the service or manufacturing process itself. Automating the capture and integration of as much vital signs and medication data as possible will substantially improve the clinicians' Meaningful Use of HIT by ensuring the most timely and accurate data is available to them at the point and time of care.

In high-acuity settings like ICUs, CCUs, NICUs, and ORs proprietary closed systems already integrate many pieces of data in near-real-time. However, the cost of proprietary gateways, and the difficulty of interfacing each gateway to proprietary EMR,

EHR, PHR, and HIE systems causes ongoing operational and reliability problems, confusion and complexity, and increases overall costs and risks.

As ONC stabilizes an improved CCD for Stage 2 of Meaningful Use, I think an opportunity emerges to create relatively consistent IHE-PCD-enabled device gateways that will save time, money, and risk for all stakeholders, and will help us provide better, safer, and more cost-effective patient care.

4. *What do you see as key barriers to effective use of health care devices to advance health and wellness?*

Response:

AHIC and ONC originally identified Remote Monitoring of patients with chronic diseases in individual or group living settings. HITSP developed Interoperability Specification 77 (IS77) to initially fill that need in 2007. There was a gap in IS77 that needed to be filled to ensure that both IHE PCD and Continua devices could co-exist with a single interoperability framework. That solution was created in 2008, and released in the HITSP Technical Note 905 (TN905) in 2009.

I think that the absence of any Remote Monitoring requirement in Stage 1 or even in the proposed Stage 2 or Stage 3 Meaningful Use requirements has all but completely deflated or deferred interest by many, perhaps most, providers. It is true that at HIMSS '11, a surprising number of hospitals and health systems described their efforts to achieve medical device and EHR interoperability, but, unfortunately, absent a national standard of any sort, most seemed to be paying a very high price for one-off interfaces on a product by product and HIT system by HIT system basis. This is not only expensive, but will be expensive to maintain over time and very, very difficult to manage without any consistent Verification and Validation strategy.

The IHE-PCD profiles can help reduce medication and data transcription errors cited in the IOM reports, they improve nursing productivity at home and in equipment intensive areas, and they can improve patient care by returning some of the 2 hours/day that nurses spend charting, and can reduce the errors and multi-hour delays inherent in manual data entry.

Stated simply, since 2004, industry, IHE, Continua, NIST, providers, and vendors have been working together and with AHIC, ONC, and HITSP to develop, test, and demonstrate affordable, achievable, and demonstrable medical device and EHR interoperability solutions. Those solutions are proven and ready to be put to work improving healthcare and Meaningful Use.

5. *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?*

Response:

Put HITSP/IS77 (updated with the IHE PCD – Continua-WAN reconciliation) into Stage 2 requirements, and define a roadmap for Stage 3 to expand the proportion of patient care that is covered (examples here) AND add a modest set of full medical device interoperability deliverables such as automatically collecting vital signs at physicians offices, hospital admissions, public health centers, and general non-acute patient care wards based on HITSP/TN905.

Interoperability/Data Integration Panel Questions

6. *What data about devices is needed in EHRs?*
   (1) Devices that are prescribed, implanted, or become part of the care record
   (2) Devices that transmit or record data used in the EHR

Response:

I don't see much difference with either of the two categories above. Neither class of devices can be marginalized, and both can – and will continue to -- produce bad, mediocre, delayed, and inefficient clinical outcomes if not automated and integrated into the EHR/EMR/PHR systems developed for Meaningful Use.

7. *Questions related to Meaningful Use*
   (1) How would device data in EHRs affect Stage 1 measures?

Response:

Automated device data integration as described in the original AHIC Remote Monitoring Use eliminates data delays, errors, and omissions, and supports Meaningful Use of HIT many cost-efficient, clinically efficacious, and safety-improving ways. E.g., in addition to the UCSF example cited earlier, when I ran a large data-entry department at ECRI Institute, we found that proficient data entry clerks can produce 98% accurate transcription. Even if a fatigued physician or nurse could reproduce 98% accuracy, there would still be 2 errors in every 100 keystrokes, which is simply an insufficient level for safe or effective healthcare. When 2 hour delays are added, the overall system efficiency, efficacy, and safety cannot be good, regardless of the metric.

   (2) What device-related patient safety and/or quality issues should be measured or reported?

Response:

Several categories come to mind. 1. Device compliance: use or misuse of diagnostic devices like glucose meters or blood pressure monitors becomes more transparent; 2. medication errors, and compliance and allergy prevention/detection become more transparent and timely when automated interoperability is enabled. 3. Critical unsafe operating conditions, including frequent alarms, conflicting alarms, disabled alarms, or device disconnection become visible and can be remedied before substantial harm or death occurs. e.g., one observation MEDIQ found with infant apnea monitors was that some SIDS-risk parents became so fatigued by false alarms that the family simply turned off the devices. 4. Certain safety- and accuracy-related device failures and risks can be identified and remedied prior to substantial harm or death. e.g., failure to change Oxygen Generator (molecular sieve based) filters will cause oxygen levels to fall to the point where not much more that room air is delivered to the patient. Several simple equipment maintenance profiles can help avoid similar risks caused by failing batteries, unchanged patient filters/hoses/tubing, and blocked filters can make home, nursing home and hospital care much more successful and cost-effective.

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

Response:

Not known at this time. If FDA intervenes directly at hospitals, as the FDA was forced to do when confronting the re-use and reprocessing of single-use disposable medical products, the costs for hospitals may go up dramatically. Substantial costs could include many or most of the following, either directly or through a third party:

(1) Hospital registration as a manufacturer with the FDA for their locally-fabricated MDDS (including networks, wireless access points, storage and storage area networks, and related network, security, and storage management software and systems);
(2) Detailed written identification, inventory, and feature documentation of each component of the hospital's MDDS;
(3) Compliance with FDA Quality Systems Regulations, including master product files for each component in the system; written change management procedures for each hardware and software component and subsystem; written evidence of component, subsystem, and system verification; validation, and re-verification and validation of each component, subsystem, and system after all maintenance, repairs, recalls, or changes; failure tracking, analysis, and documentation for continuous quality management; and periodic or on-demand reporting and site visits to FDA's satisfaction;
(4) Written and tested failure and recall systems to ensure that any affected component, sub-system, or system is removed from service as appropriate, and a written and tested system to perform a recall if required by the FDA;
(5) Compliance with mandatory Medical Device Reporting regulations in the event of an actual or potential patient injury or death;
(6) Intellectual property and risk management consultants or staff to ensure that all appropriate steps and tasks are accomplished to avoid legal breaches and compliance;
(7) Staff, including the technical and administrative staff to support the above activities, and a single high-level person of authority who will be responsible for the QSR; and
(8) Liability and D&O insurance that covers the institution and individuals in the event of a law suit by FDA, patient, family, or other party.

9. *How should integration of home and remote monitoring with EHRs be addressed?*

Response:

I think this has been well defined in HITSP/TN905 already. Devices can individually store and transmit data to an EMR, or an in-home integration hub can serve that function for one or more devices. As a side note, it is probably important to maintain the means to identify and, if desired, separately display and analyze, personal health device from FDA-regulated device data. A lower-cost personal health device used in a chronic care home setting might not be as durable or accurate as an FDA-regulated medical device, because under CMS regulations, the FDA-regulated device must be maintained in correct operating condition by the rental or servicing agency (and/or CMS will pay for the routine maintenance after rental has ended.)

It may not be obvious to the casual observer, but the home environment is extremely harsh. It was not uncommon for MEDIQ's home rental devices to be returned with dust, dirt, mold, liquids, foreign objects, or corrosion inside. Insect infestations

were common, too, especially when the device's warm charger, battery, and display provided the warmest place in an unheated home.

For successful and safe remote monitoring to deliver the intended benefits, CMS will probably need to promulgate basic safety and performance assurance methods to ensure that large numbers of home-based devices are working within expected tolerances.

10. How should integration of regulated clinical devices with EHRs be addressed?

Response:

Addressed above. It is worth noting that clinical annotations may be useful in additional to the data itself. e.g., has the data been individually reviewed and confirmed/accepted by a qualified clinician, or is the data "original," or pre-processed by some device- or system-imposed software. Those might well be accomplished with a C32 CCD document that accompanies or encapsulates the IHE-PCD record.

11. Please consider comments on identification of devices related to use of EHRs

(1) In supply chain management and other management processes

Response:

At the most basic level, each device needs some sort of unique "fingerprint" such as a MAC address so that the system can ensure patient data binding persists. The system also needs a way for the device to disclose the precise measurement it is capturing and sending, which is currently accomplished using by the Rosetta Terminology Management project in IHE PCD.

In order to support most of the priority chronic diseases identified by ONC and CMS, such as Asthma, Congestive Heart Failure, Chronic Obstructive Heart Disease, Diabetes, and Morbid Obesity, only a modest variety of medical devices and measurements are needed (e.g., blood pressure, ECG, glucometer, heart rate, weight, and, perhaps, temperature.) A complex device identification system is not needed by IHE-PCD to support these measurements.

A more complex device-specific Unique Device Identifier (UDI) may be useful for recall purposes, but the UDI may not solve any or all of our medical device and EMR interoperability challenges. For example, just because a multipurpose monitoring device includes blood pressure, ECR, heart rate, pulse oximetry, and temperature functions, only one or two of those functions may be in use – or even functioning. A valid IHE-PCD transaction may need more specific information, including the specific patient accessory or physiologic measurement being captured, details about any meta-data and analytics provided by the device (e.g., mean blood pressure), and contextual information such as alarm and alert configuration and settings. Further, a single UDI may be problematic to maintain in light of current trends that allow device functions to be altered over its lifetime of use. A UDI may also be difficult to interpret in a complicated interoperable multi-vendor, multi-modality system of systems, because the device's role in that system of systems may be primary, secondary, or backup, or even disabled. e.g., three of the devices might have pulse oximetry modules, but a visiting nurse may prefer to use their own because that is the one they are most familiar with.

Other devices, such as medical supplies and accessories, as well as medications could all benefit from a common, cross-industry UPC-like bar code and/or unified RFID tagging system. Such a unified system cold improve overall healthcare

efficacy and efficiency, and more so when integrated with device and personnel location services.

Other than unit-dose prescription medication management, and over the counter medications, the extent that other auto-ID applications would directly benefit Meaningful Use in most situations is a bit less clear at this moment. Medication management is of great importance for error reductions and safety, and that capability is built into the IHE-PCD PIV integration profile. The PIV profile would be much more powerful and more generally beneficial if it could rely on a single national auto-ID system instead of relying on local or enterprise-specific ID systems.

A very nice demonstration of an RFID-enhanced patient room was shown in the HIMSS '11 RFID kiosk, and, if properly implemented, such tools could help address and automate the IHE PCD Point of Care Identity Management and Subscribe to Patient Data profiles. A single cross-industry RFID and bar-coding standard could accelerate the delivery of such systems.

If an industry-standard UDI is designated to benefit recall management and investigation of adverse events, which are not that common in day to day healthcare, the IHE-PCD data structure could readily updated to include the UDI in any relevant data communication. The IHE-PCD domain team would be glad to work with ONC and FDA if and when such a decision is made.

12. In safety processes including identification of recalled implanted devices

Response:

For over two decades there have been FDA regulations regarding implant tracking and record keeping, and there are well-developed procedures in hospitals to maintain these records. I think that such information should be required to be included to the EHR/EMR/PHR so that all clinicians, caregivers, and the patients themselves can see and properly address any emergent risks or problems. I think that information can contribute to a clinician's Meaningful Use of HIT data, especially with the large variety and quantity of such implant procedures in the US. Allergic reactions, complications, and best practice decisions may all require transparent, accurate, and complete disclosure of implants at the moment and place of care.

Closing remarks:

At HIMSS '11, speakers in the general sessions repeatedly lamented at the high cost, complexity, and delay they're encountering as they try to integrate medical device data into their EHR environment and systems because no cross-industry standard has been imposed. Until and unless ONC acts to instantiate a very specific interoperability framework and standards for medical devices, and a future roadmap for expansion of such interoperability, providers – and vendors – will continue to face hefty costs and risks. The problem is described as an n^2 (n-squared) problem. Each doubling of devices and or systems to interconnect ultimately requires a quadrupling of hardware AND software interfaces (it is actually a 3 x n^2 problem if you need a hardware interface and two separate software interfaces on both sides of the interface) . This and costs challenge is reduced from a geometric one (n^2) to a nearly linear one if a single common interface standard like IHE-PCD is selected. e.g., the USB standards allowed most PCs and ancillary devices to support a very rich and low-cost repertoire of generic solutions so that users and vendors can depend on a consistent, simple, generic solution.

In conclusion, since 2004 IHE and IHE PCD have been working with ACCE, ASTM, Continua, HIMSS, HITSP, HL7, IEEE, NIST, ONC, and many, many hospitals and vendors to narrow down the interoperability standards options into a workable set of medical device interoperability profiles and tools. The IHE-PCD integration profile are well tested, well proven, and well respected, and the approved and draft documents are available for free at the http://www.IHE.net web site.

We would very much like to seem these IHE-PCD integration profiles called into purposeful everyday use in ONC's and CMS's Meaningful Use Stage 2 requirements, and we would also recommend that the clinical applications be expanded in the Stage 3 requirements to begin capturing more challenging acute-care data.

Thank you for the opportunity to provide this testimony to the Committee.

Appendix 1: Commercially available devices solely from the 2011 HIMSS Interoperability Showcase Demonstration (other products may be available from 2006-2010 demonstrations, and many more IHE-PCD-compliant products have been tested in 2006-2011 IHE Connectathons.)

Appendix 2: 2011 IHE Connectathon's IHE-PCD company testing results, listing the companies and products that were tested by IHE and NIST for conformance to the IHE-PCD Integration Profiles. Note: not all companies elected to display all products at the HIMSS Interoperability Showcase, and different companies have demonstrated IHE-PCD compatibility for many different products in the 2006-2011 IHE Connectathons.

Appendix 1. EXAMPLES OF COMMERCIALLY AVAILABLE IHE-PCD DEVICES AND SYSTEMS **Sampled only from the 2011 HIMSS Interoperability Showcase**

COMPANY	SYSTEM	DEVICE OR SYSTEM TYPE	IHE-PCD PROFILES	IHE-ITI PROFILES	IHE-PCC Profiles
Amcom	Commtech Messenger	Event Notification Middleware	ACM	CT	
BIOTRONIK SE & Co. KG	Home Monitoring Service Center	Implantable Cardiac Device Observer System	IDCO	CT not required yet; so no assumption made	
B Braun	Outlook Infusion Pump	Infusion Pumps	DEC, ACM, PIV	CT	
	Space Infusion System	Infusion Pumps	DEC, ACM, PIV	CT	
	DoseTrac Infusion Management Software	"Gateway" software	DEC, ACM, PIV	CT	
Cerner	CareAware iBus	Middleware/device architecture	PIV, DEC, ACM	CT	
Epic	EpicCare Inpatient and associated modules	EMR/EHR	DEC, PIV,ICDO	CT	
Medtronic	Medtronic Mainspring Connected System Gateway	Implantable Device Follow-up System	IDCO	CT not required yet; so no assumption made	
Mindray DS USA, Inc.	eGateway Integration Manager	HL7 Gateway	ACM, DEC	PAM	
	A5	Anesthesia machine	ACM, DEC		
Nuvon	IDM-MG 3000	Interface Appliance	DEC	CT	
Philips Emergin		Alarm Manager	ACM	CT	
St. Jude Medical, Inc.	Merlin.net MN5000	Implantable Cardiac Device Observer System	IDCO	CT not required yet; so no assumption made	
Surgical Information Systems	SIS Periop	CIS, EHR, AIMS	ACM, DEC	ATNA, T15, T17; CT, T16; PAM; PIX; XDS.b, T13b	C32, XPHR, XDS-MS
	SIS Anesthesia	CIS, EHR, AIMS	ACM, DEC	ATNA, T15, T17; CT, T16; PAM; PIX; XDS.b, T13b	C32, XPHR, XDS-MS

Appendix 2

2011 IHE N.A. Connectathon IHE-PCD Participant Listing – These companies' products were tested and certified by IHE and NIST for conformance to the IHE-PCD profiles. This is but a small subset of the 100+ companies and products that were tested at the 2011 IHE N.A. Connectathon.

IHE-PCD-compatible products included anesthesia and surgical information systems, blood pressure monitors, ECG, infant incubators and warmers, infusion pumps, pulse oximeters, and ventilators as well as EMR and surgery management and information systems and multi-product interface/gateway systems.

1. **B.Braun Medical**
2. **Baxter International Inc.**
3. **CapsuleTech Inc.**
4. **CareFusion**
5. **Epic**
6. **Hospira**
7. **iSirona**
8. **Lamprey Networks Inc**
9. **Mindray**
10. **Nuvon**
11. **PatientKeeper**
12. **Philips Healthcare**
13. **Polycom**
14. **Sisoft Healtcare Information Systems**
15. **St. Jude Medical, Inc.**
16. **Surgical Information Systems**
17. **Welch Allyn**