Panel on Economic Incentives for Medical Device Cybersecurity

Wednesday, February 1, 2012
9:00 am - 10:30 am
Marriott Residence Inn, 1199 Vermont Avenue NW

Brian Fitzgerald
Deputy Director, Division of Electrical and Software Engineering, FDA CDRH OSEL

Kevin Fu
Associate Professor, Computer Science, UMass Amherst (moderator)

Louis Jacques
Director, Coverage and Analysis Group, Centers for Medicare and Medicaid Services

James Keller
Vice President, Health Technology Evaluation and Safety, ECRI Institute

George Mills
Director, Department of Engineering, The Joint Commission

Erich P. Murrell
Lt. Col., CISO, Medical Devices, Office of the Air Force Surgeon General

Suggested topics for discussion:

- What are the economic barriers to improved cybersecurity of medical devices?
- Discuss definitions of medical device cybersecurity.

- Does the market provide sufficient options for providers to purchase medical devices with sufficient cybersecurity? Why or why not?
- What if Medicare reimbursements of medical procedures were conditional on the cybersecurity practices during use and manufacture of devices in the procedure?
- What if provider reporting of cybersecurity incidents were necessary to meet CMS' Coverage with Evidence Development (CED) data collections requirements?

- What if hospital accreditation requires disclosure of cybersecurity incidents?
- What if hospital accreditation requires cybersecurity insurance?

- What if cybersecurity training and vulnerability/incident reporting/gathering practices determines cybersecurity insurance premiums for a manufacturer?
- What if the presence/absence of a CSO/CISO affects the cybersecurity insurance premium for a manufacturer?

About the Panelists

Brian Fitzgerald

Brian Fitzgerald was educated in England and received his engineering degree from University College Cardiff in Wales. He became a US citizen in 2003.

He left the private sector in 1992 after a multidisciplinary engineering career, and joined Underwriters Laboratories (UL) in Raleigh, NC helping to start their software safety initiative. He has contributed to the development of several national and international standards for programmable systems UL 1998, IEC 60601-1-4, AAMI SW68 and most recently IEC 62034 and IEC 80001. He was nominated as a US National Expert by AAMI to WG22 of IEC SC62a dealing with programmable systems, to ISO TC210 WG1 dealing with quality systems and to JWG7 of IEC and ISO for Medical IT networks.

He is a member of the AAMI software committee and the AAMI IT committee. Prior to joining FDA he was an accredited software expert and lead auditor for two European notified bodies. He continues to conduct public seminars in software safety, risk management, 21 CFR Part 11, medical device cybersecurity, software related regulatory affairs and medical quality systems. He is a member of the US National Council of the International Electrotechnical Commission. He is the current chair of the GHTF ad hoc software committee.

He joined FDA's CDRH in October 2003 in the Office of Science and Engineering Laboratories to specialize in systems, software evaluation and safety research activities. He is currently Deputy Director of the Division of Electrical and Software Engineering.

Current projects include researching the use of formal methods as they relate to generalized 'assurance cases' including safety cases and compliance cases, and the development of forensic techniques for detecting and investigating software failure. He is active in the internal governance structures of FDA computational science and manages both the FDA's new high performance computing center and semantic text mining activities.

Kevin Fu

Kevin Fu is an Associate Professor in Computer Science and Electrical & Computer Engineering at the University of Massachusetts Amherst. Kevin makes embedded computer systems smarter: better security and safety, reduced energy consumption, faster performance. Kevin works on energy-aware software and cryptographic technology for computational RFIDs —tiny embedded computers that operate without batteries. Kevin contributed to the security analysis of several systems ranging from contactless no-swipe credit cards and implantable cardiac defibrillators to access-controlled Web sites and automated software updates. His most recent contributions on trustworthy medical devices and computational RFIDs appear in computer science and medical conferences and journals. The research is featured in critical articles by the NYT, WSJ, and NPR.

Kevin served as a visiting scientist at the Food & Drug Administration, the Beth Israel Deaconess Medical Center of Harvard Medical School, Microsoft Research, and MIT CSAIL. He is a member of the NIST Information Security and Privacy Advisory Board. He received a Sloan Research Fellowship, NSF CAREER award, and best paper awards in computing. He

was named MIT Technology Review TR35 Innovator of the Year. Kevin received his Ph.D. in EECS from MIT where his research pertained to secure storage and web authentication. http://www.cs.umass.edu/~kevinfu/

Louis B. Jacques

Dr. Jacques joined the Centers for Medicare and Medicaid Services (CMS) in 2003 and has been director of the Coverage and Analysis Group (CAG) since October 2009. The group reviews evidence and develops Medicare national coverage policy. From 2004 through 2009 he was Director of the Division of Items and Devices within CAG.

Prior to his arrival at CMS, Dr. Jacques was the Associate Dean for Curriculum at Georgetown University School of Medicine, where he retains a faculty appointment. He served on a number of university committees including the Executive Faculty, Committee on Admissions and the Institutional Review Board. He previously worked in the Palliative Care program at Georgetown's Lombardi Cancer Center where he covered the gynecologic oncology service and he made home visits as a volunteer physician for a rural hospice on the Maryland Eastern Shore.

James P. Keller, Jr.

James Keller directs ECRI Institute's internationally recognized health technology evaluation program referred to by the New York Times as the "country's most respected laboratory for testing of medical products"[1]. He is responsible for numerous ECRI Institute print and Web-based publications and databases, consultation services, educational programs, software tools, and instrument design services. He is a recognized expert and frequently invited speaker on a wide range of medical technology-related topics including patient safety, equipment management, strategic planning and forecasting, device utilization, nomenclature and asset management, and on the convergence of medical devices and information systems.

Mr. Keller serves as a member of ECRI Institute's Executive committee which is responsible for overall governance of ECRI Institute operations. He is responsible for all operations, sales and marketing support, and product and business development for the Health Devices program. His staff consists of approximately 35 scientists, engineers, writers, editors, product support specialists, and product managers. The products and services for the Health Devices Program are relied on by thousands of healthcare organizations throughout the world for objective advice on the safe and cost-effective selection, use, and management of medical devices.

The principle responsibility of the Health Devices Program is production of ECRI Institute's flagship publication, the Health Devices Journal. Health Devices is best known for its Consumer Reports-like comparative laboratory and clinical evaluations of medical technology. Health Devices also contains technical guidance on prepurchase selection, safety, and management of medical technology, and medical device hazard reports.

Mr. Keller is member of the board for the Health Technology Foundation, is a member of the executive board for the Health Technology Certification Commission, and is President-Elect of the board for the American College of Clinical Engineering. He is also a former member of the editorial boards for Today's Surgical Nurse and Minimally Invasive Surgical Nursing. He was also the recipient of the Association for the Advancement of Medical Instrumentation's 1993 Biomedical Engineering Achievement Award, presented every two years to recognize individual excellence and achievement in the field of biomedical engineering. Mr. Keller joined ECRI Institute in 1984 after completing a Master of Science degree in biological engineering from the University of Connecticut and a Bachelor of Science degree in zoology from the University of Massachusetts.

George Mills

George Mills is the Director for the Department of Engineering at The Joint Commission. In this role, Mr. Mills provides standards interpretation and education to The Joint Commission's Surveyors and accredited organizations, reviews equivalency requests, conducts surveys, and is a nationally recognized speaker.

Mr. Mills has over 25 years of experience in the health care setting, and previous experience in the construction industry and structural steel fabrication. Prior to joining The Joint Commission, he served as a Director of Facilities; held national positions related to Codes and Standards, including serving as Director of Codes & Compliance for ASHE; and consulted.

Mr. Mills is a Fellow with the American Society for Healthcare Engineering (FASHE), a Certified Healthcare Facility Manager (CHFM), a Certified Energy Manager (CEM), a Certified Healthcare Safety Professional (CHSP), and is also a past President of HESNI – an ASHE local state chapter.

Mr. Mills earned an MBA from California Coast University in Santa Ana, California.

Erich P. Murrell

Lt Col Murrell was commissioned in the Air Force (AF) in 1993. He has served in a variety of healthcare executive positions at headquarters and base-level facilities. In addition, he has held special duty assignments as an instructor at the Air Force School of Healthcare Sciences and was competitively selected for an Air Force Institute of Technology program.

Currently, Lt Col Murrell is the Chief Information Security Officer (CISO) for Medical Devices and Director, AF Medical Device Information Security Program Management Office (PMO) at the Air Force Medical Operations Agency (Office of the Air Force Surgeon General). In this capacity, he designs, manages, conducts acceptance tests, and follow-on support for Information Assurance (IA) issues related to over $450M in medical devices/systems utilized throughout the 70+ AF medical facilities. Additionally, he provides recommendations for IA, medical device, and systems improvements to Air Force and Department of Defense (DoD) healthcare policies to ensure quality care is provided to 8M+ beneficiaries. He also serves as an advisor and subject matter expert to the AFMS's Telehealth Division and sits on numerous DoD and International Standards Working Groups.

Lt Col Murrell is a Fellow in both the American College of Healthcare Executives (ACHE) and Health Information Management Systems Society (HIMSS), is a Certified Information System Security Professional (CISSP), and a Certified Professional in Healthcare Information and Management Systems (CPHIMS); serving on numerous committees over the last fifteen years.

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Fed Regist. 1987 Jul 23;52(141):27756-65.

Cardiac pacemaker registry--FDA, HCFA. Final rule.

[No authors listed]

Abstract

The Food and Drug Administration (FDA) and the Health Care Financing Administration (HCFA) are issuing jointly a final rule to establish a national cardiac pacemaker registry, as required by the Deficit Reduction Act of 1984. This action is based on a proposed rule that was published in the Federal Register of May 6, 1986 (51 FR 16792). The final rule requires that certain information be submitted to FDA for inclusion in the registry from physicians and providers of services requesting or receiving Medicare payment for an implantation, removal, or replacement of permanent cardiac pacemaker devices and pacemaker leads. The final rule permits HCFA to deny Medicare payment to physicians and providers who fail to submit the required information to the registry.

PMID: 10301665 [PubMed - indexed for MEDLINE]

http://www.ncbi.nlm.nih.gov/pubmed/10301665

http://www.hrsonline.org/policy/icdregistry/icd_registry.cfm

U.S. to Force Drug Firms to Report Money Paid to Doctors

By ROBERT PEAR
Published: January 16, 2012

WASHINGTON — To head off medical conflicts of interest, the Obama administration is poised to require drug companies to disclose the payments they make to doctors for research, consulting, speaking, travel and entertainment.

Many researchers have found evidence that such payments can influence doctors' treatment decisions and contribute to higher costs by encouraging the use of more expensive drugs and medical devices.

Consumer advocates and members of Congress say patients may benefit from the new standards, being issued by the government under the new health care law. Officials said the disclosures increased the likelihood that doctors would make decisions in the best interests of patients, without regard to the doctors' financial interests.

www.nytimes.com/2012/01/17/health/policy/us-to-tell-drug-makers-to-disclose-payments-to-doctors.html?pagewanted=all