

TESTIMONY OF MICHAEL J. MIRRO, MD, FACC, FAHA

AMERICAN COLLEGE OF CARDIOLOGY

United States Senate Health, Education, Labor, and Pensions (HELP) Committee Hearing
Achieving the Promise of Health Information Technology: Information Blocking and Potential Solutions

JULY 23, 2015



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BIOGRAPHY OF MICHAEL J. MIRRO, MD, FACC, FAHA

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Michael J. Mirro, MD, received his medical degree from Indiana University School of Medicine. He completed his Internal Medicine Residency, Cardiology Fellowship and EP/Research Fellowship at Indiana University Medical Center. Dr Mirro is board certified in internal medicine, cardiovascular disease, clinical cardiac electrophysiology, and geriatrics. He is a Certified Cardiac Device Specialist (IHRBE-CCDS).

The past 30 years, Dr Mirro has focused his clinical work on implantation of CIEDs and clinical investigation into new and advanced technology to enhance CIED function. Part of this work has led to a focused effort to improve remote patient monitoring and improving methods to transmit remotely recorded CIED data from patient specific device back to the patient electronically in an understandable format. Dr Mirro was part of the IHE-IDCO work group that developed the data standard to allow electronic transmission of structured data from CIED to EHR/PHR and his team just completed a feasibility study demonstrating this function. He has been a practicing cardiologist with Fort Wayne Cardiology (PPG-Cardiology) for 3 decades specializing in the fields of cardiac electrophysiology, informatics and clinical research. In addition to his clinical work, Dr Mirro has been a leader on a national level in the field of cardiology and as an advocate for reimbursement of cardiac technologies, having served as a member of the Board of Trustees of the American College of Cardiology (ACC) from 2003 to 2009 and having served as the co-chair of the ACC Advocacy Committee from 2002 to 2004. The Advocacy Committee is the interface between the ACC and private and governmental payers regarding reimbursement of cardiac technologies. Dr. Mirro is also a national thought leader in the area of Health Information Technology (HIT) and has served as the Chair of the ACC HIT Committee from 2007 to 2012 and is a current member. He is a past member of the Certification Commission for Health Information Technology, serving as co-chair of the Cardiovascular Work Group and the Advanced Quality Workgroup. He is also a past member of the NQF electronic quality measure work group, and is past Chair and current member of the HRS Informatics/Quality Committee. His recent work has focused on research pertaining to export of ICD data into EHR-PHR environments and patient engagement. Federal Funding : EP-HIT-10-002 American Recovery and Reinvestment Act of 2009, State Grants to Promote Health Information Technology (Health Information Exchange Challenge Program)

Dr. Mirro currently serves as a Trustee for Indiana University.



TESTIMONY SUMMARY OF MICHAEL J. MIRRO, MD, FACC, FAHA

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EHR Vendor Contracts

- Transparency of additional (or hidden) fees should be evaluated
- EHR vendors should not be allowed to include gag clauses

Data Fluidity

- Patient information should reach the provider without delay in a fast, secure manner
- EHR vendors' products should be universal and connect to other EHRs offered by different companies
- Health IT vendors and providers should be incentivized to establish networks for patients to monitor their devices and to empower them to actively participate in their health decisions
- Adoption of public data standards should be expected and supported in the best interest of patients

Meaningful Use Stage 3

- Stage 3 of the Meaningful Use program should be delayed in its entirety

Endorsement of Actions Outlined in ONC's April 2015 Report to Congress on Information Blocking

- Strengthen in-the-field surveillance of health IT certified by ONC
- Constrain standards and implementation specifications for certified health IT
- Work in concert with HHS to improve stakeholder understanding of the HIPAA provisions related to information sharing
- Work with CMS to coordinate health care payment incentives and leverage other market drivers to reward interoperability and exchange and discourage information blocking

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Chairman Alexander, Ranking Member Murray, and members of the Committee, thank you for the opportunity to speak today about the important issue of information blocking, unforeseen problems that have been created, and possible solutions to help improve patient care.

My name is Michael Mirro and I am testifying today on behalf of the American College of Cardiology, a 49,000-member medical society that is the professional home for the entire cardiovascular care team. I am board certified in internal medicine, cardiovascular disease, clinical cardiac electrophysiology, and geriatrics. *[In addition to seeing patients, many who suffer from multiple chronic conditions, I also serve as Chief Academic Research Officer at Parkview Health System in Ft. Wayne, IN where I manage over 90 clinical trials.]* I have focused the majority of my clinical work on cardiac implantable electronic devices in patients with serious heart rhythm problems and clinical investigation into new and advanced technology to enhance their function. *[I have worked extensively on remote monitoring of cardiac devices and electronic messaging patients their data from their individual device.]* I have worked in the development of health informatics tools since 1995, assisting in the refinement of clinical decision support software to improve point of care quality related to congestive heart failure.

The private practice that my partners and I owned was an early adopter of electronic health records. These systems, implemented before HITECH's passage, had a user-centered clinical design, as opposed to the software centric certified EHR systems of today. Additionally, many current systems lack clinical usability and thus create substantial practice inefficiency and reduced quality patient-physician interaction during an office visit.

I first became aware of information blocking when my colleagues in other private cardiology practices adopted EHRs and were forced to spend substantial resources to interface with their health system's EHR. These practices would have been able to better plan financially if these costs had been disclosed at the outset. *[Fortunately, the practice was in a financial position to absorb these costs, but many other practices are not.]* **Transparency of additional (or hidden) fees within contracts with EHR vendors should be evaluated.** Many contracts between providers and EHR vendors include gag clauses which prevent providers from speaking publicly about problems associated with EHRs. **EHR vendors should not be allowed to include such clauses.**

The delay of information sharing is another form of information blocking. I once had a patient admitted to the emergency room in cardiac arrest. *[The patient was a*

truck driver from out of state.] Because of a delay in receiving his cardiac history, data critical to his care was not available in a timely fashion. The patient experienced a complication during the emergency heart procedure resulting in prolonged illness. *[The support of electronic messaging of standard clinical summaries is a critical issue with respect to quality and safety of patient care.]* Rapid, secure exchange of health information is critical and in some cases can mean the difference between a patient living and dying. **Data fluidity should mean not only that information reaches the provider, but that the data is transmitted quickly and securely.**

Many EHR vendors provide the functionality needed, but require the user to purchase their health IT products to make the elements of the EHR interoperable. Like other products such as consumer electronics, you are able to connect, but you must buy a specific company's products to do so with ease. The ramifications of technology in health care that are unable to communicate are serious, resulting in decreased care quality and stunting improvements in population health. **EHR vendors' products should be universal and connect to other EHRs offered by different companies.**

Another advantage of the free flow of data is to empower patients in their health care decisions. One of my recent projects was to establish a way for patients to remotely monitor their implanted devices. Each element of the four devices available in the market had a different vendor, requiring us to contract with four different vendors and pay four different set-up costs to allow patients to accomplish one task. **Health IT vendors and providers should be incentivized to establish networks for patients to monitor their devices, empowering them to actively participate in their health decisions. In addition, adoption of public data standards should be expected and supported in the best interest of patients.**

Many information blocking problems stem from the financial incentives of EHR companies to obstruct data. The HITECH Act, along with implementation of the Meaningful Use Program, has improved data sharing and data liquidity. With that stated, the unintended consequence of Meaningful Use is that systems were designed to facilitate charge capture and revenue cycle management and focus less on clinical data and usability. *[The importance of exchanging a clinical summary document has been enhanced by this program, but we need surveillance of individual vendor behavior.]* Although the Meaningful Use program has brought favorable results within the context of data transfer, many of the requirements set

forth in the program are unattainable. Recognizing that only 11 percent of physicians have attested to stage 2, I recommend, in concert with the ACC, that stage 3 of Meaningful Use be delayed in its entirety.

In addition to what I have discussed, the College has called for many of the same actions recommended in the Office of the National Coordinator's April, 2015 Report to Congress on Information Blocking, including:

- **Number 1: Strengthen in-the-field surveillance of health IT certified by ONC.** [The ACC feels strongly that a program such as this is needed and that ONC would be the appropriate entity to administer such a program. ONC could hire an outside contractor to affirm compliance – similar to what CMS has done with the Meaningful Use program.]
- **Number 2: Constrain standards and implementation specifications for certified health IT.** [This committee has debated whether the federal government or the private sector should establish common standards, and the ACC believes it should be a combination of both. Medical specialty societies are well-equipped to engage in the creation of these standards, while the federal government is needed to oversee enforcement of the standards.]

- **Number 3: Work in concert with HHS to improve stakeholder understanding of the HIPAA provisions related to information sharing.**
[HIPAA is outdated and in many cases is actually an impediment to patient care. The ACC would encourage the committee to reevaluate HIPAA in its entirety – including its successes and failures – and whether all aspects of HIPAA remain appropriate given today’s technology.]
- **Number 4: Work with CMS to coordinate health care payment incentives and leverage market drivers to reward interoperability and discourage information blocking.** [As with my example given earlier about creating a mechanism to remotely monitor devices, this is proof that when coupling providers with innovative companies, we can improve the wellbeing of our patients and reduce costs.]

In closing, I commend you, Chairman Alexander and Ranking Member Murray, and your excellent staff for gathering us today and taking the initiative to accomplish specific goals related to interoperability and information blocking. Furthermore, I applaud your collaborative, bipartisan approach. Thank you again for the opportunity to be here today. I look forward to the discussion.

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Enclosure: “American College of Cardiology – EHR Interoperability Top Concerns – Senate HELP Committee – 061615.pdf”



**AMERICAN
COLLEGE of
CARDIOLOGY**

Heart House
2400 N Street, NW
Washington, DC 20037-1153
USA

202.375.6000
800.253.4636
Fax: 202.375.7000
www.ACC.org

President
Kim Allan Williams, Sr., MD, FACC

President-Elect
Richard A. Chazal, MD, FACC

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Carole A. Warnes, MD, FACC
Kim Allan Williams, Sr., MD, FACC
William A. Zoghbi, MD, MACC

**ex officio*

Chief Executive Officer
Shalom Jacobovitz

*The mission of the American College of
Cardiology and the American College
of Cardiology Foundation is to transform
cardiovascular care and improve heart health.*

June 16, 2015

The Honorable Lamar Alexander
Chairman, HELP Committee
United States Senate
Washington, DC 20510

The Honorable Patty Murray
Ranking Member, HELP Committee
United States Senate
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray:

The American College of Cardiology (ACC) is a 49,000-member medical society that is the professional home for the entire cardiovascular care team. The mission of the College is to transform cardiovascular care and to improve heart health. The ACC leads in the formation of health policy, standards, and guidelines. The College operates national registries to measure and improve care, provides professional medical education, disseminates cardiovascular research and bestows credentials upon cardiovascular specialists who meet stringent qualifications. The ACC also produces the Journal of the American College of Cardiology, ranked number one among cardiovascular journals worldwide for its scientific impact.

The ACC has a vested interest in complete interoperability of health information technology not only because of its diverse membership of cardiovascular care team members including physicians, nurse practitioners, nurses, and practice administrators, but also because of its operation of five hospital-based, one outpatient, and two multi-specialty clinical data registries.

The College would like to applaud you and your respective staff for taking the initiative and working to accomplish specific goals related to interoperability of EHRs. The College appreciates the opportunity to provide input and encourages you to address these pertinent issues.

The ACC views the following as key priorities that should be addressed related to EHR interoperability:

VENDOR DATA BLOCKING

Issue: The ACC has been on the record with the Senate HELP Committee in bringing the issue of “vendor data blocking” to the forefront and the College is appreciative of the Committee’s responsiveness and eagerness to address this issue. The ACC views vendor data blocking as one of the largest barriers to EHR interoperability. EHR vendors charge exorbitant fees to transfer data from hospital to hospital or hospital to physician office, undermining the very purpose of EHRs. Many times, hospitals are in a better financial position to incur these costs. Physician practices, which are typically smaller and have fewer resources, are not in the position to absorb these costs.

Example: For each patient, cardiologists are often required to reference several tests to obtain a complete understanding of a patient’s condition. These required tests are sent to various labs, each of which operates its own separate EHR system, often administered by different vendors. In order to fully exchange information, EHR vendors charge physician practices upwards of \$20,000 to fully interface with each lab’s EHR system. While this is usually a one-time fee, many physician practices cannot absorb these unexpected start-up costs. In order to provide appropriate and effective levels of care to their patients, these providers face fees to interface with necessary ancillary systems to facilitate the transfer of data between settings. Once the connection is established, there are often additional charges for the exchange of information. The College feels these exorbitant fees must be brought under control.

Solution: The ACC acknowledges that an initial fee to establish a connection could be appropriate. Our concern lies with the amount of fees these vendors have arbitrarily

established. Perhaps a solution could be for vendors to work these fees and others into the initial agreement signed with physicians, including (but not limited to) bundling open application programming interface (API) costs into the overall maintenance fees. This would require vendors to be upfront and transparent with their pricing both at the time of purchase and throughout the use of the implemented EHRs and the peripheral elements included in these contracts. Additionally, it would be ideal to know upfront the costs associated with purchasing interfaces to exchange with another vendor's EHR. Penalties should also be established for vendors whose actions prohibit the exchange of data under any circumstances, which leaves the practice without options to solve the problem. The ACC looks forward to working with the Committee to determine the most appropriate way to address this issue.

EFFECTIVE EHR STANDARDS

Issue: The Office of the National Coordinator for Health Information Technology (ONC) has attempted to establish effective common EHR standards since the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009. The Certified EHR Technology (CEHRT) criterion (2011, 2014, and the proposed 2015 criteria) aims to set a floor for certification to avoid stifling innovation while still working to require EHRs to meet the specific needs of clinical settings. With the current EHR standards in place, clinicians not only face continual challenges exchanging the simplest elements of data between EHRs – that have all met the EHR standards in place at the time of their certification – they also face basic usability issues. Despite these issues, there is still a widely felt concern that if effective common EHR standards were to be established, they would be too prescriptive and would stifle innovation.

Example: As a part of certification, EHRs are tested to meet varying criteria and specific definitions. The criteria are tied to components of the Meaningful Use program such as computerized order entry, secure messaging, and e-prescribing. Definitions address other items of the Meaningful Use program as well, such as how a 'base EHR' is defined, along with other items such as how patient health information is captured and how to import, calculate, and report clinical quality measures. This is in addition to base requirements relating to privacy and security, accessibility-centered design, and safety-enhanced design. Once the EHRs are certified and implemented, many times data received by a certified EHR from other certified EHRs populates in inappropriate fields or the data is received in a format that is unusable. For example, a clinician may receive a chart mapping a patient's blood pressure rather than individual data points. Another example is that clinicians in the outpatient setting frequently refer their patients to a hospital across the street from their office for procedures. The inpatient setting, however, often uses a different EHR and the different systems cannot communicate. When patients are admitted to the hospital, clinicians have to print out their notes and send a copy to the hospital so the notes from the clinic can be incorporated into the hospital's electronic records for the inpatient setting. This information is often scanned and inserted into the hospital's EHR as a PDF and is therefore far less usable. Thus, in order to truly achieve health information exchange these providers and their small clinics are forced to incur additional fees to replace their outpatient EHR vendor to match the hospital's system and make the records interoperable.

Solution: The ONC should provide a clearer path to certification that includes an enhanced focus on usability and interoperability. These standards could include the ability for systems to connect with multiple Health Information Exchanges (HIEs). The most important aspect of a standard is that they be clinically relevant and useful, as would occur if the standards were created in cooperation with specialty societies such as the ACC. Through its rigorous process of creating clinical guidelines, societies such as the ACC are well-equipped to make these specific determinations as to what standards need to be applied and how they should be applied. In addition to adjusting the certification criteria, thorough testing must be performed not just of the EHR itself but in exchanging information with other EHRs and other actors in the health IT sphere such as HIEs and registries. This can lead to the higher level of bi-directional data exchange that we need in order to achieve the true benefits of health information exchange.

POST-CERTIFICATION SURVEILLANCE OF EHR SYSTEMS

Issue: Since the passage of the HITECH Act in 2009, the federal government has invested over \$30 billion in EHRs. Currently, no programs exist to ensure that existing EHRs are functioning properly. Implementation of a post-certification surveillance program of EHRs would add value to the federal government's already substantial investment and set the nation on a path of complete interoperability of EHRs.

Solution: The ACC requests that ONC or the HHS Secretary conduct post-certification surveillance of EHRs to properly evaluate what elements are effective and what elements are not working with respect to basic usability and interoperability functionalities providers require of EHRs. This includes the removal of contract gag clauses to enable documentation by the federal government of any data portability issues and to provide for further transparency in pricing. It should be clearly stated that the burden for upgrades would pass to the EHR vendors rather than physician practices or hospitals. Additionally, a quarterly report from the federal government summarizing the surveillance findings would further aid in fixing usability and interoperability issues of CEHRT. The ACC applauds CMS for launching the initiative to collect feedback via email from patients, clinicians, and others whose health data was stymied.

REEVALUATION OF HIPAA AND SECURITY OF DATA

Issue: The ACC operates five hospital-based, one outpatient, and two multi-specialty clinical data registries within a suite of registries collectively known as the National Cardiovascular Data Registry (NCDR). As a result of the Health Insurance Portability and Accountability Act (HIPAA), hospitals and health systems within which the NCDR conducts business require security contracts to transmit data. The ACC understands that certain measures must be taken to comply with HIPAA and ensure data security. However, HIPAA has resulted in overly risk-averse interpretations of an almost 20 year old law that was based largely on paper data storage. This in turn has created unnecessary demands from multiple layers of compliance officers with several layers of review which may not actually be relevant or afford the best protections in a digital, mobile-enabled environment.

Example: Compliance officers from larger health systems and academic medical centers require NCDR to complete over 40 pages worth of security questionnaires that are unique to their own institutions. It may be possible for larger vendors with large numbers of staff to accept this as a cost of doing business, but for society-operated quality improvement programs and startups, these practices are extraordinarily burdensome and stifle innovation by creating barriers that only the largest entities can reasonably overcome.

Solution: The ACC has been on the record requesting the reevaluation of the Health Insurance Portability and Accountability Act (HIPAA) and its appropriateness in a 21st Century digital landscape. Technology has changed substantially since HIPAA was originally adopted in 1996. The ACC urges Congress to convene a hearing to reevaluate the role of HIPAA, including its successes and failures and whether all aspects of HIPAA remain appropriate given today's technology.

DELAY OF MEANINGFUL USE STAGE 3 IN ITS ENTIRETY

Issue: The Centers for Medicare and Medicaid Services (CMS) released a notice for proposed rulemaking on March 20, 2015 outlining the third and final stage of the Meaningful Use Program to be in place starting in 2018. The proposed changes increase thresholds for objectives and measures to an unattainable level in an aspirational attempt to achieve greater care quality through the use of health information technology.

Example: The Health Information Exchange objective (#7) of the Stage 3 proposal requires program participants to provide or retrieve a summary of care record when their patient moves to or from their care, and calls for the participants to incorporate summaries of care from other providers into their EHR using the functions of certified EHR technology. This is required for a certain percent of transitions that is far too high given the existing problems outlined in previous examples of this letter and the lack of solutions currently in place. In full disclosure, other issues exist with this objective and the other seven objectives proposed.

Solution: The College has provided comments to CMS on this proposal outlining our concern with the overreaching requirements. In light of these concerns, the College has called for a delay in the implementation of Meaningful Use Stage 3 in its entirety. Delaying only certain parts of Meaningful Use Stage 3 would cause further confusion around the program and lead the government to veer off the current course of reducing complexities of the program. Given the lack of participant data available from Meaningful Use Stage 2 coupled with the data exchange issues that already exist, it is not feasible to implement the increased demands of the program in 2018. Time is needed to reevaluate the issues participants are facing in Stage 2 of the program and to develop and enact solutions.

The ACC applauds you and your respective staff for taking the initiative to accomplish specific goals related to interoperability of EHRs and commends you for your collaborative approach. On behalf of the entire cardiovascular care team and the patients who we serve, the College appreciates the opportunity to provide input on these concepts and encourages you to address these very pertinent and closely connected issues. For additional information on the perspectives of the ACC, please contact Charles Cascio (ccascio@acc.org) and Lucas Sanders (lsanders@acc.org).

Sincerely,



Kim Allan Williams, Sr., MD, FACC, FAHA, FASNC
President