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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