American College of Physicians
Leading Internal Medicine, Improving Lives

February 2, 2016

Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20510

Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray:

On behalf of the American College of Physicians (ACP), I thank you for the opportunity to provide feedback on the Senate HELP Committee discussion draft to help improve Health Information Technology for doctors and their patients, as released on January 20, 2016. We applaud your efforts and support the intent of this draft, which is to reduce the burdens associated with health information technology (health IT, HIT), improve electronic health records (EHRs), and enhance interoperability. However, we believe that there are several elements of the bill that could be improved, as discussed below.

The ACP is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 143,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

Our recommendations are summarized as follows:

- Data transparency is needed at the point of care to alleviate burdens, such as prior authorizations.
- Establish a process to require that CMS reform/replace the existing E/M documentation guidelines with input from practicing physicians and in collaboration with their professional organizations.
- The certification process must be more collaborative with input from medical specialty societies, and must recognize the cost impact on practices forced to transition from decertified to certified HIT products.
- Utilize the technology comparison system that is called for under the Medicare Access and CHIP Reauthorization Act (MACRA), as opposed to adopting a star rating system for certified health information technology.

- While ACP strongly agrees with the goal of prohibiting information blocking, physicians and practices should be protected from being asked to absorb excessive costs associated with purchasing expensive EHR interfaces that have little clinical value.
- Congress should require that the majority of the members on the HIT Advisory Committee be clinicians.
- The legislation should not be overly prescriptive on common data elements but rather requirements for health IT should be able to change based on discovery and evidence.
- A standardized format is needed when providing patients' access to their health records, and that format must be understandable and useable.

The following outlines ACP's detailed comments on the discussion draft. We appreciate your willingness to consider our suggestions.

Assisting Doctors and Hospitals in Improving the Quality of Care for Patients

Reducing Regulatory and Administrative Burden to Improve Quality Care

We strongly support the goals of *Section 13103 of the discussion draft, Assisting Doctors and Hospitals in Improving the Quality of Care for Patients.* ACP shares the committee's concern about the growing burden of regulatory and administrative requirements. Much of the potential value of health IT to improve care is lost due to these regulatory and administrative requirements and ACP applauds the Senate HELP Committee for attempting to address this serious problem.

We believe that the discussion draft could be improved, however, by adopting a *broader and more expansive approach to addressing unnecessary burdens (regulatory, administrative, and operational), which have existed prior to the widespread adoption of EHRs.* One of the promises of EHRs was to reduce existing burdens within healthcare operations, such that clinicians using EHRs could gain time that could be spent on patient care and improving quality.[i] Unfortunately, the mandates surrounding the Medicare and Medicaid EHR Incentive Programs, or Meaningful Use (MU), only added burdens.

The goal of reducing regulatory and administrative burden should be to reduce unnecessary process frictions of healthcare operations and not solely focused upon use of EHRs. Thus, if a healthcare operation is intrinsically burdensome, such as prior authorization, the burden cannot be remedied just by enhancing the EHR. The burden remains the same, but is often more visible, due to the "bright light" that EHRs and other health IT often shine on poor processes.

A recent Brookings Policy Brief,[ii] which outlined basic principles of health IT usefulness (which in and of itself reduces time and burden for clinician and patient), including a requirement for payers, plans, and pharmacy benefit managers to supply to patients, consumers, physicians, and other clinicians, timely, accurate, transparent, understandable, and actionable information on costs and coverage, in electronic format – embedded into certified EHR technology. The ACP described this same process as key to lowering costs and resolving much of the burden of prior authorization – namely by making patients/consumers/clinicians aware of cost and coverage,

and where prior authorization is required, the reason why, and what alternatives if any are covered.[iii]

Accordingly, we recommend that the committee consider making the following specific improvements in the discussion draft:

- Include a requirement that all payers, plans and pharmacy benefit managers supply to patients, consumers, physicians, and other clinicians, timely, accurate, transparent, understandable, and actionable information on costs and coverage, in electronic format – embedded into certified EHR technology.

- Revise section 13103 to state that, "The Secretary of Health and Human Services (HHS) in consultations with public and private stakeholders <u>including practicing physicians and their professional societies,</u> health care suppliers, health care payers, health professional societies, health information technology developers, health care quality organizations, public health entities, states, and other entities be required to establish a goal to reduce regulatory and administrative burdens with regard to electronic health records (EHR) <u>and other administrative and regulatory processes</u>. The HHS Secretary will develop a strategy and recommendations for meeting this goal within a year after enactment. "

<u>Clinical Documentation</u>

ACP supports the effort to address the burden of clinical documentation requirements. ACP believes that the purpose and content of clinical documentation should return to supporting excellence in patient care. While we support the discussion draft's intent of creating a process to address the problems with clinical documentation, we believe that any such process must include sufficient input from actual practicing physicians and other clinicians, and specifically address the burden of the existing 1995 and 1997 Evaluation and Management Documentation Guidelines. In a recent position paper, ACP offered a number of solutions to clinical documentation that should be considered.[iv]

The College is also concerned that the absence of true clinician input has damaged the work of many other initiatives, such as the Health IT Policy Committee and the Health IT Standards Committee. Practicing clinicians are uniquely qualified to provide input on the specific information requirements needed to support the delivery of healthcare services to patients.

Accordingly, we recommend the following improvements in the draft discussion:

- *Sec. 3002*. Health Information Technology Advisory Committee, which requires that the HIT Policy Committee and HIT Standards Committee be combined into the HIT Advisory Committee: ACP recommends that this section be improved by requiring that a majority of the HIT Advisory Committee's 25 members be clinicians, including practicing physicians and nurses. We believe this approach is in keeping with other technical advisory committees. We also recommend that the HIT Advisory Committee be charged with focusing on health IT usefulness, usability, and burden reduction.

- Require CMS to reform or replace the existing 1995 and 1997 Evaluation and Management (E&M) Documentation Guidelines, which we believe are the primary source of documentation burden, as well as poor EHR usability.[v]

Transparent Ratings on Usability and Security to Transform Information Technology

Health IT Developer Attestation Requirements

ACP supports the enhanced collection and dissemination of factual information about health IT products and services provided by the developers. We believe that the discussion draft could be improved by adding requirements to achieve greater transparency in the information that HIT developers need to share.

- Specifically, we recommend that Health IT developers be required to describe and explain the additional charges they impose in implementing and supporting interoperability functions. Excessive charges can and do impede practices from fully implementing interoperability functions.

Enhancements to Certification

EHR technology is an enabling infrastructure and, as such, it should support very different workflows and needs of different specialties and settings of care. For example, a procedural specialist, such as an orthopedist, may feel that their MU-certified EHR is too complex and too focused on functions that they never use; whereas many internists may complain that the capabilities that have resulted from MU certification has led to a "dumbed-down" EHR that is too simplistic to support chronic disease management and care coordination.

ACP supports efforts to assist physicians and practices in selecting high-quality health IT systems and services; however, regulations that require the use of certified systems may go too far. Certification can assist practices in evaluating technology, but the limitations of the certification system make it inappropriate to require use of certified technology for any particular purpose. The existing certification program has made EHRs less usable, as EHR developers have had to satisfy highly prescriptive certification requirements. Furthermore, enhancements and innovations requested by clinicians or developers have had to "take a back seat" to development of certification standards. And finally, if the purpose of EHR certification was to provide a degree of certainty to EHR purchasers in what they are purchasing, ACP believes that has not happened.

ACP believes that the current EHR certification process is not the best way to achieve specialty-specific capabilities and more rapid innovation. A simpler, lighter-weight process that supports and encourages innovative approaches would be preferable, as discussed below:

- As an alternative to the existing certification process and standards, ACP recommends that the HIT Advisory Committee collaborate with the various medical specialty and professional societies to jointly describe specialty-specific requirements. ACP has commented at length to CMS on certification requirements for electronic clinical quality measures – as we believe this approach is scalable across multiple specialties and the anticipated rapid growth in quality measurement.[vi]

The discussion draft includes a provision establishing a compensation fund for practices that need to switch from decertified products or services and reimburses users for the cost of purchasing new, certified HIT products:

- ACP supports the discussion draft's goal of establishing a compensation fund for practices that need to switch from decertified products or services. However, the price paid to the developer for the license to the system or component (software), is often only a small fraction of the costs incurred in de-installing one system and then implementing a replacement. Many times the majority of costs are not up-front costs, but for ongoing costs, i.e., monthly subscriptions and other user fees. If the fund is to provide meaningful assistance to practices, the amount available to a practice must be several times the purchase price of the license.

The discussion draft proposes a one-year hardship exemption for those users whose HIT products become decertified and then must transition to certified HIT products. While we support the goal of providing a hardship exemption, the proposed hardship exemption, as designed, applies only to protection from MU penalties; it would not apply to practices as they migrate to MIPS and APMs. Also, a one-year MU hardship exemption would not address problems caused from practices participating in other programs, such as the Comprehensive Primary Care Initiative (CPCI), that require use of a certified EHR system. Participants successfully meeting all other requirements of the program would be eliminated from the program if their EHR system were to be decertified.

- We believe that the discussion draft should be improved by providing a hardship exemption for all programs that require use of certified technology, including for practices that are transitioning to the MIPS and APM program and those that are participating in the Comprehensive Primary Care Initiative.

Health Information Technology Rating Program

The discussion draft calls for the establishment of a star rating system for certified health information technology. We have concerns that this rating system will not provide sufficient assistance to physicians and practices in evaluating options for adding or changing health IT components. An EHR system may achieve a high star rating; yet perform poorly on a particular function that a practice considers critical. Physicians and practices need detailed comments from actual users of systems in order to adequately determine the value of a system or component for their particular uses.

We also are concerned that the proposed rating system would fail to account for the migration of the market from giant all-function EHR systems to individual components that perform single or small sets of functions. A single-function product or service could achieve a top rating, while a comprehensive system might achieve a lower rating based upon its inclusion of certain features that may not score as well but which are not needed by a particular practice. For physicians and practices attempting to implement health IT, the smallest detail of another's experience can be crucial in determining whether a particular component will be a good fit and

a star rating does not convey that type of practical guidance. We also are concerned that the proposed rating system would require an enormous amount of overhead to function.

- As an alternative to the discussion draft's proposed star rating system, we believe a more workable approach would be to utilize a technology comparison system, as is already called for in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). For example, the ACP, in collaboration with many other medical societies, has already developed AmericanEHR Partners[vii] which meets the comparison-system requirements identified by MACRA and provides physicians and practices with the comprehensive range of information and tools needed to thoroughly evaluate health IT options.

Information Blocking

ACP appreciates the discussion draft's intent to improve the availability of usable clinical information to physicians and other treating clinicians. We are concerned however that the definition of information blocking in this discussion draft could be too broad to be helpful. For instance, software, services, and infrastructure are not free and the discussion draft does not fully recognize the cost associated with this infrastructure in the provisions or description of information blocking. Practices must currently pay for each connection from their EHR system to an information source or delivery target. ACP is concerned that under the discussion draft, physicians and practices could be found to be engaging in information blocking simply by refusing to purchase expensive interfaces that might be used rarely if at all.

Accordingly, we recommend the following improvements in the discussion draft:

- Physicians and their practices should be protected in the law from being required to purchase connections to every information source or delivery target – no matter how expensive they might be. They should not be liable for declining to purchase connections to every information source or delivery target. Consideration should also be given to the need to define a fair value for the provision of these services.

Interoperability

ACP strongly supports the improvement of interoperability between clinical IT systems. The proposed definition, in the discussion draft, of interoperability is an improvement over previous definitions with the requirement to be able to use the information. However, the College believes that the phrase, "without special effort on the part of the user," needs clarification.

- ACP recommends this draft language be further specified to protect physicians and practices from excessive costs that would arise if they were required to purchase and install expensive interfaces (including the need to map clinical terms used in each interface with the terms used in the EHR system) with little clinical value. We recommend that the excessive expenditures associated with costly interfaces should fall within the definition of "special effort."

Common Data Elements

ACP supports in principle the discussion draft's efforts to harmonize the definitions of common clinical data elements. We are concerned, however, that the proposed process to include all stakeholder groups in the initial definition will result in a massive and cumbersome set of elements that will create a new and unacceptable burden on developers to implement and on physicians and other clinicians to collect and manage. Furthermore, the ACP believes that what may appear to be appropriate to harmonize may change over time. The College recommends that requirements on health IT should avoid being overly prescriptive, and also be able to change based on discovery and evidence.

- ACP recommends that the initial set of common data elements be limited to just those elements deemed absolutely necessary for care delivery by physicians and other treating clinicians. Stakeholders should be required to spend a significant period of time attempting to use these clinical common data element set before other elements are added.

Empowering Patients and Improving Patient Access to their Electronic Health Information

ACP supports the discussion draft's efforts to improve communications between patients and their physicians and other clinicians. We also support the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to provide patient access to their clinical information and further applaud the Committee for taking this opportunity to clarify HIPAA requirements and to call for a better understanding of the implications of HIPAA for patients, for provider organizations, and for business associates. However, we would also like the committee to consider some suggested improvements.

- While we appreciate the desire to provide patients with, "access to their electronic health information, including in a single longitudinal format that is easy to understand, secure, and may be updated automatically," we are concerned that there is no currently available standard to support such a data format. Few EHRs (if any) give physicians and other clinicians a single longitudinal format that is understandable and highly useful. We also believe that if such a function existed, it likely would be very different based on specialty.

Encouraging Trust Relationships for Certified Electronic Health Records and Trusted Exchange

ACP believes that trust relationships must exist prior to a decision to exchange health information between provider organizations and appreciates the discussion draft's consideration of the issue. However, the current draft is lacking in that it does not define the trust relationship so, without further clarification from the committee, we cannot comment further.

GAO Study on Patient Matching

ACP supports the intent of the discussion draft and believes that patient matching is a significant and growing problem as more health IT systems come online and begin attempting

to exchange data. ACP is concerned however that this provision requires the use of a relatively large set of identifiable patient demographic data to support matching. We believe this dependence on so many data elements presents a privacy risk for all patients.

- Accordingly, ACP recommends the use of a voluntary national patient identifier as the most secure and accurate way to match patients.

Conclusion

ACP greatly appreciates your and the HELP Committee's steadfast leadership in working to improve health IT for physicians and their patients and looks forward to working with you to further develop this discussion draft. We applaud the goals and intent of the discussion draft of reducing the major sources of administrative burden on physicians and their patients and providing increased opportunities for innovation. The College's recommendations for improvements in the draft are offered in the spirit of ensuring that any legislation achieves these laudable goals. Please let ACP know how it can be helpful as you continue to work to develop and advance this draft through the 114th Congress.

Sincerely,

Wayne J. Riley, MD, MPH, MBA, MACP
President

CC: Members, Senate Committee on Health, Education, Labor and Pensions

[i] Cutler D, Wikler E, Basch P. Reducing administrative costs and improving the health care system. N Engl J Med 2012;367:1875-1878

[ii] http://www.brookings.edu/research/papers/2015/03/16-health-it-value-based-payment-interoperability-mcclellan

[iii] http://www.ncvhs.hhs.gov/wp-content/uploads/2015/02/Basch-operating-rules-150226-final.pdf

[iv] Kuhn T, Basch, P, et al. Clinical Documentation in the 21st Century: Executive Summary of a Policy Position Paper From the American College of Physicians
Ann Intern Med. 2015;162(4):301-303

[v] This was a conclusion of the AMA-ACP-EHRA Usability Summit of Dec 2015

[vi] https://www.acponline.org/acp_policy/letters/acp_comments_cms_certification_frequency_rfi_2016.pdf

[vii] http://www.americanehr.com/Home.aspx