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April 27, 2015

The Honorable Fred Upton
2183 Rayburn House Office Building
Washington, DC 20515

The Honorable Dianne DeGette
2368 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Congresswoman DeGette,

The American College of Cardiology (ACC) appreciates the opportunity to provide feedback on the 21st Century Cures discussion draft. The 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 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, promotes cardiovascular research and bestows credentials on cardiovascular specialists who meet stringent qualifications. The *Journal of the American College of Cardiology* (JACC), which publishes peer-reviewed research on all aspects of cardiovascular disease, is the most widely read cardiovascular journal worldwide. JACC is ranked No. 1 among cardiovascular journals worldwide for its scientific impact.

This is the second communication from the College in response to this draft. The first letter, dated February 10, focused primarily on the provisions affecting clinical data registries. This second letter provides comments on the other provisions.

Key Recommendations

The ACC makes the following recommendations to the Committee:

- Ensure patient access to innovative therapies and appropriate care by
  - Relying on CED where appropriate during expedited NCD process for breakthrough technologies approved by the FDA via priority review
  - Providing appropriate Medicare payments for new technologies
  - Identifying the effects of rulemaking on various clinical practice settings
- Provide FDA with flexibility to determine appropriate use of DTC advertising by medical products companies
- Increase funding to FDA and NIH to support innovative research into pediatric and chronic diseases by investigators at all career levels
- Encourage FDA to work with stakeholders to develop appropriate guidance and regulatory schema for new technologies
- Promote interoperability and ensure that government regulations do not impose roadblocks to it
- Publish data from NIH-funded trials to a broader audience with appropriate limitations on individually identifiable information to protect patient privacy
- Support the development of personalized medicine with the appropriate level of government involvement
- Exempt funding for independent CME faculty and medical education materials from the Physician Payments Sunshine Act

Title I, Subtitle E – Priority Review for Breakthrough Devices

Sec. 1082 CMS Coverage of Breakthrough Devices

FDA approval of new technologies is critical, but coverage of these new technologies by CMS and other payers is no less important and must be taken into account early in the process. Often times, manufacturers design clinical trials with the FDA in mind but fail to consider the needs of insurance companies and CMS, inhibiting the ability of patients to gain access to these new technologies, particularly those that are groundbreaking. This may be in part the result of manufacturers' failure to understand different missions of the Agencies. After all, FDA's primary focus is safety and effectiveness, while CMS' primary considerations are reasonableness and medical necessity. These are very different thresholds that must be addressed.

One mechanism for remedying this problem is CMS' Coverage with Evidence Development (CED) program. In a number of instances, the ACC and other stakeholders have requested national coverage of new technologies under Coverage with Evidence Development. National clinical data registries have provided the infrastructure necessary to collect data about the new technologies, procedures, operators and facilities. This data has then been transmitted to the company, FDA and CMS. CED has already been used to expand FDA indications and will be used to evaluate the effectiveness of both the application of therapies and any coverage revision in the future. For breakthrough technologies approved via priority review, the ACC supports an expedited national coverage determination process that utilizes CED to facilitate dispersion of the technology to Medicare patients.

Title I, Subtitle I – Modernizing the Regulation of Social Media

Sec. 1161 Dissemination of Information about Medical Products Using the Internet

One of the ACC's central tenets is that the practice of medicine must be evidence based. This means a reliance on guidelines, peer-reviewed scientific publications and other such information for diagnosis and the development of treatment plans, not advertisements by companies that manufacture medical products, regardless of the advertisement medium. The College has serious concerns regarding directives to the FDA to make it easier for medical products companies to advertise their products for unapproved uses. Instead, Congress should urge companies to take any evidence they have regarding additional uses for their approved products to the FDA for consideration of label expansion.

It is already difficult for clinicians and patients to sort through the information available regarding various therapy options. Allowing companies to make this information even more available through social media will only confuse patients and caregivers even further. Studies regarding the implications of direct-to-consumer (DTC) advertising have clearly demonstrated the influence of DTC advertising on patients, with clinicians reporting an increase in the number of interactions they had with patients where patients requested particular therapies by brand name. While DTC advertising can be positive by raising awareness regarding certain conditions that might have previously remained hidden, the increased recognition of brand name products and requests for such is not advantageous to anyone other than the company. The ACC recommends that Congress allow the FDA the freedom to determine the appropriateness of communications by medical products companies to consumers.

Title II – Building the Foundation for 21st Century Medicine, Including Helping Young Scientists
Subtitle A – 21st Century Cures Consortium Act

Sec. 2001 Innovative Cures Consortium

The College has long supported investments in research for innovative cures, treatments and preventive measures for patients. Rather than merely creating another mechanism for encouraging this work, the ACC urges Congress to increase funding to FDA and NIH to support additional initiatives in this arena. Creating yet another mechanism for encouraging research will only further dilute our ability to actually innovate. With each new organization, additional costs are generated for administration, monies that could be better spent on actual research and innovation. The College recommends that Congress consider housing this initiative at the NIH or FDA, rather than creating a new organization to this work.

Title II, Subtitle E – Sensible Oversight for Technology Which Advances Regulatory Efficiency

Secs. 2061-63 The SOFTWARE Act

Technology, as it evolves, forces the practice of medicine to evolve with it. This is particularly true for cardiology. Regulatory schema must not be so strict as to stifle innovation, but also must be robust enough to ensure patient safety. To that end, the College supports the FDA's efforts to provide balanced guidance to industry regarding its expectations, but the ACC also recognizes industry's need for some degree of certainty regarding the regulatory process they must follow to market their technology. Given the effect of this technology on cardiovascular care, the College is particularly interested in this area. As such, the ACC urges Congress to allow the FDA, industry and other stakeholders to continue to work together to navigate this complex path, rather than imposing an entirely new process for the approval of new technologies.

Title II, Subtitle H – Coverage with Evidence Development

Sec. 2121 Authority for coverage with evidence development for medical devices under the Medicare program

The establishment of Medicare coverage for new technologies can be challenging for providers, industry, and patients to navigate. Several services and technologies utilized by cardiologists to treat patients have been covered using the existing CED mechanism implemented by CMS. The ACC understands concerns have been raised in the past regarding CMS's legal authority for the use of coverage with evidence development. As a mechanism to clarify the existing framework by which CMS is authorized to utilize CED, the ACC supports Section 2121.

Title II, Subtitle I – Combination Products

Secs. 2141-42 Regulation of Combination Products by the Food and Drug Administration

Given the ongoing concerns regarding authority to review combination products, the College looks forward to the clarification of those authorities across the different FDA centers and supports efforts to do so.

Title II, Subtitle K – Interoperability

Sec. 2181

Interoperability is fundamental to fulfilling the promise of electronic data exchange and improved patient care. The ACC appreciates efforts to begin to address this issue in the recently enacted Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). In the event that the Committee intends to address concerns regarding interoperability further, the ACC looks forward to receiving that information and working with the Committee towards our common goal of a true nationwide health information network.

The College also recommends that the Committee examine the requirements of the federal Electronic Health Records (EHR) Incentive Program as it considers the barriers to interoperability. The EHR program is driven by the requirements set forth by CMS and the Office of the National Coordinator for Health Information Technology (ONC), rather than the needs of clinicians and patients, and without regard to vendor development cycles. This has created significant difficulties for stakeholders and delayed the promise of EHRs. As a result, physician adoption of EHRs and participation in the EHR Incentive Program remains low, despite the penalties that are imposed on non-participants and unsuccessful participants beginning this year. Those that have adopted and implemented EHRs have high levels of dissatisfaction with them because of their focus on the EHR Program requirements, rather than the needs of the end users. In fact, many physicians have consciously chosen to accept the financial penalties, rather than invest in EHR adoption and implementation of the federal EHR Program requirements, despite the fiscal challenges physicians and medical practices face in today's economic climate.

Given these challenges, the ACC urges that the Committee incorporate recommendations made by the American Medical Association pertaining to the EHR Incentive Program. Specifically, the College joins the AMA in supporting the following:

- Ending the pass-fail approach of the EHR Program
- Promotion of interoperability by addressing the costs of interfaces and data exchange fees, as well as information formatting and data standardization, problems highlighted by the recent *Report on Health Information Blocking* submitted to Congress by ONC
- Streamlining EHR certification
- Alignment of various Medicare quality reporting programs
- Expansion of current hardship exemptions

Implementation of the above recommendations will help achieve the promise of health IT and break down the current silos that interfere with the ability to create the efficiencies sorely needed to improve care and reduce costs in the US healthcare system.

Title II, Subtitle L – NIH-Federal Data Sharing

Sec. 2201 Sharing of Data Generated Through NIH-Funded Research

The College supports efforts to make data from NIH-funded trials more widely available with appropriate limitations on individually identifiable information to protect patient privacy.

Title II, Subtitle N – 21st Century Chronic Disease Initiative Act

Sec. 2241 Plan for Longitudinal Study on Outcomes of Patients with a Chronic Disease

Over the course of three decades, cardiovascular disease has largely transitioned from a death sentence to a chronic disease. As such, the study and understanding of it is critical to improving the outcomes for patients living with cardiovascular disease. The College supports the development of a plan for a

longitudinal study focused on this concern and urges Congress to ensure adequate funding for the study, as well as involvement of all relevant stakeholders, including national medical specialty societies.

Title II, Subtitle Q – Precision Medicine

The College looks forward to learning more about the Precision Medicine Initiative and to working with both Congress and the Administration to achieve the goal of "patient-powered research that promises to accelerate biomedical discoveries and provide clinicians with new tools, knowledge, and therapies to select which treatments will work best for which patients."[1] As the College's immediate past president, Patrick O'Gara, MD, FACC, discussed at the Committee's Roundtable on July 23, 2014, the promise of personalized medicine is tremendous. Given the current size and cost of randomized clinical trials for novel cardiovascular drug therapies, the potential for the development of research methodologies that could reduce costs and speed access to patients is appealing. The ACC encourages Congress and the Administration to tread lightly in this arena to ensure that new laws and regulations do not interfere with the anticipated scientific discovery and adoption of the potential outcomes.

Title III, Subtitle D – Pediatric Research Network Improvement; Subtitle E – Global Pediatric Clinical Trial

Sec. 3041 National Pediatric Research Network; Sec. 3061 Sense of Congress

Research into therapies for pediatric diseases and conditions is woefully under-resourced. As such, the ACC urges Congress to provide additional funds and incentives for pediatric research and commends the Committee for raising the profile of this important issue. All too frequently, pediatric specialists are forced to adjust therapies and technologies approved for adults for use in pediatric patients, patients with still-evolving body chemistries, shapes and sizes, all of which differ greatly from adults, leading to less-than-optimal treatment. The College encourages the Committee to include language recommending collaboration with relevant medical specialty societies, such as the ACC and the American Academy of Pediatrics, that are already working to support increased pediatric research.

Title IV, Subtitle H – Local and National Coverage Decision Reforms

Sec. 4161 Improvements in the Medicare local coverage determination (LCD) process

The specific requirements for LCD development created by Section 4161 are similar to those already employed by Medicare Administrative Contractors (MACs) under existing authority in Chapter 13 of the Medicare Program Integrity Manual. As a codification of existing standards in LCD development, the ACC supports Section 4161.

Title IV, Subtitle I – Telemedicine

Sec. 4181 Advancing Telehealth Opportunities in Medicare

Cardiovascular disease is, by-and-large, a disease of aging. Many individuals with cardiovascular disease suffer from a number of other health issues, as well. As such, easy access to care is critical. However, patients in rural settings may not have that same level of access experienced by patients in suburban or urban environments, making telehealth essential to the provision of high-quality care to all patients. The technology exists today to make this a reality; however, the payment systems have not yet caught up with the technology, translating to underuse of telehealth technologies. The College urges Congress to address

[1] FACT SHEET: President Obama's Precision Medicine Initiative. http://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative *accessed* Mar. 3, 2015.

this disconnect and to enable patients who live in rural areas and suffer from cardiovascular disease to receive the same quality of care afforded to those who live in the suburban and urban environs.

Title IV, Subtitle J – Revise IPPS New Technology Add-On Payment (NTAP) Reimbursement Amounts

Sec. 4201 Coding and Reimbursement Reforms

The ACC supports the New Technology Add-On Payment program as a way to expedite patient access to new services that can provide a substantial clinical benefit over current treatments. The College recognizes that there may be cases where an applicant believes the agency has not given proper consideration to the cost and clinical evidence presented. However, the ACC believes the New Technology Add-On Payment application process allows for sufficient engagement between CMS and applicants. In addition to the ability to engage directly with CMS staff, the process allows for comment through the rulemaking process and public town hall meetings. The College urges additional consideration of this section to ensure that any new appeals process will truly facilitate the introduction of new technologies and will not divert resources from other CMS activities.

Title IV, Subtitle M – Providers Consolidation and Medicare Payments Examined Through Evaluation

Sec. 4261 Rulemaking that implements certain Medicare payment changes to consider effects on provider consolidation

No current statute or regulation prohibits the Secretary from considering the impact proposals may have on provider consolidation. ACC interprets this section as a directive for the Secretary to place greater emphasis on the consequences—sometimes unintended—rulemaking proposals may have on provider practice structures. With a goal of placing greater emphasis on how proposals affect clinicians, the ACC supports the concepts espoused in Sec. 4261. The College has found that public comments may go unheeded by Agency officials at various points in time regarding the effect of rulemaking on providers, sometimes leading to backtracking after rule implementation. Given these concerns, the ACC hopes that this provision would encourage CMS to place greater weight on such comments in the future.

Title IV, Subtitle P – Medicare Pharmaceutical and Technology Ombudsman

Sec. 4321 Medicare Pharmaceutical and Technology Ombudsman

The prospect of a designated ombudsman who may be responsive to the entities that produce drugs, devices, and equipment is appealing. However, the ACC wonders whether this role may be duplicative of the existing beneficiary ombudsman to some degree. CMS staff has generally been responsive to complaints, grievances, and requests. Stakeholders may not agree with the outcome of any given decision, but the staff does their best to be responsive to questions and concerns. Additionally, on some issues, they are simply executing decisions that have been made at higher levels that may be political or ideological in nature. However, the College questions whether such a position would divert resources that would be better appropriated on hiring and retaining high quality staff that execute the details of CMS's work in coverage, coding, and payment. The ACC sees value in concurrently directing the Secretary to take steps to ensure these teams are fully staffed and in Congress providing the Secretary with the resources with which to do so.

Title IV, Subtitle S – Continuing Medical Education Sunshine Exemption

Sec. 4381 Exempting From Manufacturer Transparency Reporting Certain Transfers for Educational Purposes

The ACC has long been an advocate for transparency in relationships between physicians and industry. That said, the College has also clearly supported efforts to ensure that transparency programs educate patients, rather than simply interfering with the patient-physician relationship. To that end, this section would help to clarify and promote the distribution of medical education materials, such as journal articles and medical textbooks. This will increase the availability of information on the latest research to physicians, leading to improved patient outcomes. The College supports this provision.

Conclusion

Removing barriers to innovation and bringing new therapies to the healthcare space are worthy goals. We applaud the Committee for this important effort. The College looks forward to working with you and your staff as the process moves forward. Nick Morse (nmorse@acc.org), ACC's Director of Congressional Affairs, will follow up to offer further assistance.

Sincerely,

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