Alliance of Specialty Medicine

Sound Policy. Quality Care.

February 20, 2015

The Honorable Fred Upton
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
United States House of Representatives
2368 Rayburn House Office Building
Washington, DC 20515

RE: 21st Century Cures Comments on January 26, 2015 Discussion Draft

Dear Chairman Upton and Representative DeGette:

The Alliance of Specialty Medicine appreciates the opportunity to provide comments in response to the 21st Century Cures January 26th discussion draft (F:\WPB\CO14R\CURES\CONSOLIDATED). The Alliance is a coalition of national medical societies representing specialty physicians in the U.S. and is dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care. We greatly appreciate your leadership to improve the discovery, development and delivery that support continued innovation in our health care system.

The Alliance offers specific comments on the following provisions included in the discussion draft.

TITLE I—PUTTING PATIENTS FIRST BY INCORPORATING THEIR PERSPECTIVES INTO THE REGULATORY PROCESS AND ADDRESSING UNMET NEEDS

SUBTITLE B—SURROGATE ENDPOINT QUALIFICATION AND UTILIZATION (SECTIONS 1021-1024)
The Alliance supports establishing a transparent process at FDA with specified timeframes for the development of evidentiary standards and the review and qualification of surrogate endpoints for broader utilization in regulatory decision-making. It is critical to support innovation in the drugs, biologicals and devices that diagnose, treat and monitor our patients. We support efforts to help expedite the development and approval of safe and effective drugs for unmet needs. **We would encourage inclusion of these provisions in the final legislative language if clarification is made regarding data ownership.**

The Alliance supports the focus on public-private-partnerships, but has concerns about the possible implications regarding ownership of the data collected through these private-public partnerships. We believe that patient data collected through privately-administered registries should be the sole property of the private entity administering the registry, and **we believe that public agency access to those data should be at the discretion of their private entity owner. We respectfully request clarification on**

ownership of data and stand ready to work with the committee based on the collective experience our member organizations have in establishing and running registries.

SUBTITLE H—FACILITATING RESPONSIBLE COMMUNICATION OF SCIENTIFIC AND MEDICAL DEVELOPMENTS

The FDA does not allow pharmaceutical, biological and medical device companies to actively distribute key clinical information, even if it is related to the on-label indication, unless it is explicitly referenced in the package insert. By limiting the sharing of information, physicians are hampered in their ability to gain all of the firm scientific rationale and sound medical evidence needed to treat patients. The Alliance is **pleased to see that the committee included a placeholder** to address this issue and stands ready to work with you to clarify and rationalize these rules so that scientific and medical developments on pharmaceuticals, biologicals and medical devices can be shared with physicians, with appropriate safeguards, in order to optimize patient care. We recommend that the committee develop standards for qualifying real world data, through a public process; expand the current process of review of materials beyond what is included in the package insert to also cover other key data, such as subpopulation, pharmacoeconomic or comparative cost data; and ensure a timely review process for such information.

TITLE II—BUILDING THE FOUNDATION FOR 21ST CENTURY MEDICINE, INCLUDING HELPING YOUNG SCIENTISTS

SUBTITLE B—MEDICAL PRODUCT INNOVATION ADVISORY COMMISSION
SEC. 2021. MEDICAL PRODUCT INNOVATION ADVISORY COMMISSION.

The Alliance urges you to slightly modify this provision which would create the Medical Product Innovation Advisory Commission. Similar to the Medicare Payment Advisory Commission (MedPAC), this Commission will advise Congress, analyze medical product innovation in the United States and recommend policies to accelerate the discovery, development, and delivery of new medical products. We appreciate that the membership of the Commission requires the participation of physicians to ensure the first-hand input of those on the front lines of patient care. However, we believe that this provision should also apply to products with indications that expand or change, and not merely apply to new products coming to market. Because it is important to continue to support innovation, the Alliance **supports maintaining this provision with the suggested modification to strike "new" in the section**.

SUBTITLE F—BUILDING A 21ST CENTURY DATA SHARING FRAMEWORK
PART 1—IMPROVING CLINICAL TRIAL DATA OPPORTUNITIES FOR PATIENTS
SEC. 2081. STANDARDIZATION OF DATA IN CLINICAL TRIAL REGISTRY DATA BANK ON ELIGIBILITY FOR CLINICAL TRIALS.

This section would establish a data sharing framework to enable patients and physicians to better identify ongoing clinical trials. The Alliance agrees that the clinical trials registry should be easy for physicians and patients to access and that entries and results data should be easily compared in a standardized format employing comprehensive health care terminology that includes clinical trial inclusion and exclusion criteria. We appreciate that the HHS Secretary is required to convene a meeting of stakeholders (including physicians) to provide advice on enhancements to the clinical trial registry data bank. **The Alliance encourages you to retain this provision.**

PART 3—BUILDING A 21ST CENTURY CLINICAL DATA SHARING SYSTEM
SEC. 2085(b). ACCESS TO MEDICARE DATA BY QCDRs.
The Alliance supports the requirement that HHS make Medicare, Medicaid, and CHIP claims data available to Qualified Clinical Data Registries (QCDRs), but we request that the committee broaden this provision so that it ensures access to such data for all clinical data registries (i.e., not just QCDRs). Furthermore, we are concerned that the discussion document requires the Secretary to charge a fee to cover the cost of such data. Running a registry already requires a significant investment of resources, a challenge that is heightened by the fact that many registries are run by non-profit entities. Registries should have unfettered access to federal claims data, which, when combined with more robust clinical data, can result in more accurate evaluations of quality and value performance.

SEC. 2087. HIPAA COMMON RULE EXCEPTION.
The Alliance appreciates the inclusion of language requiring an exception to the Common Rule for registries and other entities that collect identifiable data, but have no direct interaction with patients and comply with all applicable HIPAA regulations. Current regulations for informed consent are outdated and create unnecessary regulatory barriers that limit the ability of registries to engage in prospective, systematic tracking of practice patterns and patient outcomes that lead to better care.

SEC. 2091. COMMISSION ON DATA SHARING FOR RESEARCH AND DEVELOPMENT.
This provision would establish a Commission on Data Sharing for Research and Development. While the Alliance supports efforts to ensure the integrity of clinical registry data and the need for guidelines related to the use of registries, we are concerned that overly prescriptive standards may result in a one-size-fits-all approach to registries and ignore the fluid and diverse nature of registries and the unique needs of different specialties and different patient populations. Government involvement in this issue should be restricted to setting standards that ensure an adequate infrastructure for the collection of registry data, such as ensuring that EHR vendors are interoperable with registries, protecting data privacy and security, and providing funding to promote innovative registry practices. The registry community, which is already well coalesced, should remain responsible for reaching consensus on other standards related to how registries work.

If a Commission is established for this purpose, we urge the Committee to revise the language in this section to specify that the Commission is advisory only; representative of relevant stakeholders, including physicians and others directly involved in registry design and implementation; and that appointments must be non-partisan and non-political (i.e., the Speaker of the House should not make these appointments; instead we recommend that the U.S. Government Accountability Office take on this task, similar to MedPAC appointments). The role of the advisory board should be to highlight best practices and potentially inform the Secretary's recommendations in Sec. 2092

SEC. 2092. RECOMMENDATIONS FOR DEVELOPMENT AND USE OF CLINICAL REGISTRIES
The Alliance appreciates many of the recommendations proposed under this section, including the promotion of bidirectional, interoperable exchange of information between EHRs and registries. As mentioned earlier, it is critical that the Secretary adopt and better enforce interoperability standards to ensure the seamless exchange of information between certified EHRs and qualified clinical data registries. The current language seems to put the onus on registries, while the most significant current barrier to integration of EHR data in registries is EHR vendor refusal to share data with registries or charging excessive fees for such access. We urge Congress to mandate that EHR vendors adopt interoperability standards as a condition of receiving federal certification.

TITLE III—MODERNIZING CLINICAL TRIALS

SUBTITLE A—CLINICAL RESEARCH MODERNIZATION

SEC. 3001. PROTECTION OF HUMAN SUBJECTS IN RESEARCH; APPLICABILITY OF RULES.

The Alliance applauds efforts to streamline the institutional review board (IRB) process, particularly for clinical trials conducted at multiple sites. This provision is consistent with the recently released draft NIH policy on the use of a single IRB for multi-site research and **we urge the committee to maintain this provision.**

SEC. 3002. USE OF INSTITUTIONAL REVIEW BOARDS FOR REVIEW OF INVESTIGATIONAL DEVICE EXEMPTIONS.

The Alliance also **supports this provision** as it allows review by a centralized IRB.

TITLE IV—ACCELERATING THE DISCOVERY, DEVELOPMENT, AND DELIVERY CYCLE AND CONTINUING 21ST CENTURY INNOVATION AT NIH, FDA, CDC, AND CMS

SUBTITLE I—TELEMEDICINE

SEC. 4181. ADVANCING TELEHEALTH OPPORTUNITIES IN MEDICARE.

The Alliance appreciates the inclusion of this provision to advance opportunities for telemedicine and new technologies to improve the delivery of quality health care services and improve Medicare beneficiaries' access to specialty physicians. The Alliance agrees with the sense of the Congress encouraging States to collaborate, through the use of State medical board compacts, to create common licensure requirements for providing telehealth services. This is necessary to facilitate multistate practices and allow for specialty physicians to provide services across State lines.

SUBTITLE O—ACCELERATING INNOVATION IN MEDICINE

SEC. 4301. ESTABLISHMENT OF MANUFACTURER OPT-OUT PROGRAM FOR MEDICAL DEVICES.

Under the current structure for making coverage decisions, CMS evaluates newly FDA-approved products based on clinical evidence and comparative effectiveness to other already CMS-covered products. Because it can be difficult to compile adequate clinical evidence at the time that a product is initially approved or cleared by the FDA, cutting edge medical technologies are often subject to limited coverage or inadequate reimbursement under Medicare, especially when these products and procedures warrant greater reimbursement than Medicare will offer without supporting data. As a result, manufacturers sometimes choose not to make these products or procedures available in the United States, or when they do, beneficiaries interested in self-paying face discouraging bureaucracy, time delays, and uncertainty.

This provision seeks to address this problem by providing an option for medical device manufacturers to "opt-out" of the Medicare coverage determination process for at least three years to allow time to obtain the necessary clinical evidence in support of a stronger case for a future Medicare coverage decision. This change would reduce the obstacles Medicare beneficiaries face in trying to access these new technologies, ensure they are informed of the costs, and allow them to self-pay before Medicare coverage is sought by the manufacturer. By allowing beneficiaries to have this option, clinical studies and data collection can take place and these innovative technologies will help patients in the United States, instead of solely in foreign countries. **The Alliance encourages the committee to maintain this option for Medicare beneficiaries in the final bill.**

SUBTITLE Q—ENSURING LOCAL MEDICARE ADMINISTRATIVE CONTRACTORS EVALUATE DATA RELATED TO CATEGORY III CODES

SEC. 4341. ENSURING LOCAL MEDICARE ADMINISTRATIVE CONTRACTORS EVALUATE DATA RELATED TO CATEGORY III CODES.

The Alliance would like to work with the Committee on this provision as you refine the discussion draft. We are concerned that the Medicare Administrative Contractors (MACs) automatically put Category III codes on their non-covered lists because they are categorized as "new technology" and resulting non-coverage adversely impacts patient access to potentially life-saving treatments and technologies. The Alliance would like to better understand this provision; specifically what is meant by "all data" and whether this would include data from observational research registries, peer-reviewed journals, abstracts, presentations at conferences, etc. We are concerned that the language may be too broad and would suggest that the MACs review all reference studies and literature considered by the AMA CPT Editorial Panel when the Category III code was approved in addition to any peer-reviewed, published data and data from observational research registries to date.

SUBTITLE S—CONTINUING MEDICAL EDUCATION SUNSHINE EXEMPTION*

SEC. 4381. EXEMPTING FROM MANUFACTURER TRANSPARENCY REPORTING CERTAIN TRANSFERS USED FOR EDUCATIONAL PURPOSES.

The Alliance **strongly supports the inclusion of this provision** which clarifies that peer-reviewed journals, journal reprints, journal supplements, and medical textbooks are excluded from the reporting requirement under the Sunshine Act. Physicians must have access to the most up-to-date independent medical knowledge to support their delivery of high quality patient care.

The Alliance appreciates this ongoing process toward the introduction of bipartisan legislation and looks forward to continuing to work with you on this initiative. Please let us know if our expertise may be of assistance, especially as you seek additional feedback or would like assistance in developing content for the placeholders.

Sincerely,

American Academy of Facial Plastic & Reconstructive Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American Gastroenterological Association
American Society for Dermatologic Surgery Association
American Society of Cataract and Refractive Surgery
American Society of Echocardiography
American Society of Plastic Surgeons
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
National Association of Spine Specialists
Society for Cardiovascular Angiography and Interventions
Society for Excellence in Eyecare

CC: Members of the House Energy and Commerce Committee

**NASS has not yet taken a formal position on Sec. 4381 and remains neutral on the provision.*