



January 29, 2016

The Honorable Lamar Alexander  
Chairman  
Senate Health, Education, Labor and Pensions Committee  
U.S. Senate  
428 Dirksen Senate Office Building  
Washington, D.C. 20510

The Honorable Patty Murray  
Ranking Member  
Senate Health, Education, Labor and Pensions Committee  
U.S. Senate  
428 Dirksen Senate Office Building  
Washington, D.C. 20510

**RE: Bipartisan Legislation to Improve Health Information Technology for Patients and Families**

Dear Chairman Alexander and Ranking Member Murray:

The undersigned members of the Physician Clinical Registry Coalition would like to thank you for your leadership in the development of the staff discussion draft of the Committee's bipartisan legislation to improve health information technology (HIT) for patients and families ("the Draft Bill"). We especially appreciate the inclusion of several provisions facilitating the exchange of clinical outcomes data from electronic health records (EHRs) to clinician-led clinical data registries. Providing better access to such data will enhance the ability of clinician-led clinical data registries to improve clinical outcomes and follow-up treatment.

The Coalition is a group of more than 20 organizations that sponsor and support physician-led clinical data registries. We are dedicated to improving quality of care by working for policies that promote the creation and development of outcomes-based clinical data registries. Our specific comments on the Draft Bill are set forth below.

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1. Information Blocking

The Coalition applauds the Committee for proposing language in the Information Blocking section of the bill (Section 4) that would require developers of health information technology, as a condition of certification and maintenance of certification, to attest that the developer does not take any action that constitutes information blocking, except for legitimate purposes specified by the Secretary. The definition of information blocking (at pp. 22-23), which in pertinent part covers “business, technical, or organizational practices that... the developer, exchange, or network knows, or should know, are likely to interfere with or prevent or materially discourage the access, exchange, or use of electronic health information,” is appropriately general. However, Coalition members have found that some EHR vendors’ excessive fees have effectively blocked registries’ access to data from electronic health records. These fees are often a greater impediment to data access than technical, interoperability barriers. We would, therefore, respectfully request that the Committee add specific language to the definition of information blocking to clarify that charging excessive fees is a form of information blocking. We would be comfortable letting the Secretary further define what constitutes “excessive fees” for these purposes.

The Coalition also strongly supports the language giving the HHS Inspector General (IG) jurisdiction to investigate false attestations or actual instances of information blocking and to impose civil monetary penalties in cases where it finds violations. This language adds sharp teeth to the provisions against information blocking. Our only request here is that the HHS IG be directed to give such investigations a high priority to ensure that the IG takes aggressive and timely action against EHR vendors that engage in information blocking.

2. Health Information Technology Rating System

The Coalition supports the requirement in HIT Rating System section of the Draft Bill (Section 3) that the Secretary obtain input from relevant stakeholders on new reporting criteria for health information technologies. These criteria “may” include measures such as submitting, editing, and retrieving data from registries, such as clinician-led clinical data registries. We request that this measure be moved from the subsection on discretionary measures up to the previous subsection on mandatory reporting criteria. In addition, given the inclusion of this registry-specific measure, we would respectfully request that the Draft Bill specifically include clinician-led clinical data registries in the types of stakeholders from which the Secretary would seek input on these measures. The list of stakeholders includes “data sharing networks, such as health information exchanges.” It should be a short step to add clinician-led clinical data registries to this group of stakeholders. Lastly, we would appreciate clarification regarding the

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mechanism by which EHR vendors will be required to report this information to the government.

### 3. Interoperability

The Coalition is generally supportive of the interoperability provisions in Section 5 of the Draft Bill. We would respectfully request the HIT Advisory Committee that is created in this section include representatives of clinician-led clinical data registries as members. This new Committee will play a significant role in advising the Secretary and the Office of the National Coordinator (ONC) on many of the health information technology issues covered in the Draft Bill. Having representatives of clinician-led clinical data registries on the Committee would provide the Secretary and ONC with an important perspective on ways that health information technology can be used to facilitate the development of such registries.

The Coalition also strongly agrees with the requirement in Subsection 5(g) that the Secretary “adopt standards, implementation criteria, and certification criteria . . . for a core set of common data elements and associated value sets to enhance the ability of certified health information technology to capture, use, and exchange structured electronic health information.” Establishing common data elements is crucial to harmonizing registry operations across medical specialties. It also would reduce the burden and cost incurred by hospitals and other health care providers in participating in multiple registries. In this regard, we request that the Committee add “the facilitation of clinician-led clinical data registry access to clinical outcomes data” to the list of priorities that the Secretary will consider in setting these common data element.

### 4. Leveraging Health Information Technology to Improve Patient Care

Section 6(a) of the Draft Bill requires, as a condition of certification, that health information technology “shall be capable of transmitting, receiving, and accepting data from registries, including clinician-led clinical data registries, that are also certified under Section 3001(c)(5) of [the Public Health Service] Act and such registries shall be capable of transmitting, receiving, and accepting data from other certified health information technology.” The Coalition strongly supports the requirement that health information technology must be able to share data with clinician-led clinical data registries as a condition of certification of such technology. This is precisely the kind of federal requirement that is necessary to ensure such registries have efficient and cost-effective access to clinical outcomes data from the EHRs of their participating health care providers. It will go a long way toward preventing EHR vendors from blocking or impeding such access.

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The Coalition strongly supports the definition of clinician-led clinical data registry, which accurately reflects the principal characteristics of most physician-led clinical outcomes registries. We appreciate the opportunity to have had input into the development of this definition.

The Coalition is concerned, however, about the language that requires clinician-led clinical data registries to be certified. First, there is no provision in Section 3001(c)(5) of the Public Health Service Act for certifying clinical data registries. That provision applies only to the certification of health information technology.

Second, we are concerned that this open-ended certification requirement could carry over into other federal programs, such as the qualified clinical data registry (QCDR) reporting option under the Physician Quality Reporting System. In addition to being deemed by the Centers for Medicare and Medicaid Services as a QCDR, many registries are also Qualified Registries and certified by ONC as a Certified EHR Technology (CEHRT) for purposes of collecting and reporting clinical quality measures. Adding an undefined certification requirement onto the existing QCDR, Qualified Registry, and CEHRT requirements could serve as an administrative hurdle for registries, detracting attention from their quality and patient outcome improvement work. We understand that ONC may need to establish some technical standards or criteria to ensure that clinician-led clinical data registries are capable of receiving data from EHRs. We think the following revised language would address this need:

**6. LEVERAGING HEALTH INFORMATION TECHNOLOGY TO IMPROVE PATIENT CARE.**

(a) REQUIREMENT RELATING TO REGISTRIES.—To be certified in accordance with title XXX of the Public Health Service Act, health information technology (as defined by section 3000(5) of the Public Health Service Act (42 U.S.C. 300jj(5))) shall be capable of transmitting ~~to, and~~ receiving, and accepting data from registries, including clinician-led clinical data registries, in accordance with standards established by the Office of National Coordinator, that are also certified under section 3001(c)(5) of such Act (42 U.S.C. 300jj-11(c)(5)) and such registries shall be capable of transmitting ~~to, and~~ receiving, and accepting data from ~~other~~ certified health information technology in accordance with such standards.

Third, it is not clear what type of data a clinician-led clinical data registry would be transmitting to a health information technology. Clinical data registries share data reports with their participating health care providers, but generally not with EHR vendors.

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Thus, while the Coalition understands there may be a need to include a requirement in this section that clinician-led clinical data registries be capable of receiving and accepting data from certified health information technologies, we respectfully request that the registry certification requirement be replaced by the compliance with ONC standards language we have proposed and that the Committee clarify the type of data it expects registries to share with health information technologies.

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Thank you again for the opportunity to submit these comments. The Coalition greatly appreciates the work of the Committee and staff in developing the Draft Bill. It represents a major step in the right direction by giving clinician-led clinical data registries efficient access to EHR data of their participating health care providers. It also sends a strong message to EHR vendors that if they indiscriminately block such access, they will face potential prosecution and civil monetary penalties. If you have any questions about these comments, please contact Rob Portman at [rob.portman@ppsv.com](mailto:rob.portman@ppsv.com) or 202-872-6756.

Respectfully submitted,

- AMERICAN ACADEMY OF DERMATOLOGY ASSOCIATION
- AMERICAN ACADEMY OF NEUROLOGY
- AMERICAN ACADEMY OF OPHTHALMOLOGY
- AMERICAN ACADEMY OF PHYSICAL MEDICINE AND REHABILITATION
- AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS
- AMERICAN COLLEGE OF EMERGENCY PHYSICIANS
- AMERICAN COLLEGE OF RHEUMATOLOGY
- AMERICAN GASTROENTEROLOGICAL ASSOCIATION
- AMERICAN JOINT REPLACEMENT REGISTRY
- AMERICAN SOCIETY OF ANESTHESIOLOGISTS/ ANESTHESIA QUALITY INSTITUTE
- AMERICAN SOCIETY OF CLINICAL ONCOLOGY
- AMERICAN SOCIETY OF NUCLEAR CARDIOLOGY
- AMERICAN SOCIETY OF PLASTIC SURGEONS
- AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY
- AMERICAN SOCIETY FOR RADIATION ONCOLOGY
- AMERICAN UROLOGICAL ASSOCIATION
- AMERICAN COLLEGE OF GASTROENTEROLOGY
- NORTH AMERICAN SPINE SOCIETY
- SOCIETY OF INTERVENTIONAL RADIOLOGY
- SOCIETY OF NEUROINTERNTIONAL SURGERY
- SOCIETY FOR VASCULAR SURGERY
- THE SOCIETY OF THORACIC SURGEONS