

Health Record Banking Alliance

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Via Electronic Mail: Secretary@HHS.gov

Hon. Alex M. Azar II
Secretary, Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

We write to refute assertions in a February 3, 2020 letter, widely distributed, signed by health system chief executive officers. The letter asks you, in effect, to eviscerate rules proposed by ONC to implement the 21st Century Cures Act.

The CEOs' letter claims the proposed rules are unnecessarily burdensome and pose unacceptable privacy risks. However, and to the contrary, the new rules fulfill explicit requirements in the Cures Act that ONC must meet in order to make health records exchangeable and to empower patients with digital access to, and control of, their records.

A detailed legal analysis, based on the Cures Act's text and explaining each of these technical mandates, is set out in 2017 rulemaking comments from the Health Record Banking Alliance (http://www.healthbanking.org/uploads/9/6/9/4/9694117/hrba_comments_on_cures_act_rule_making_20170824.pdf). ONC's proposed rules satisfy each of the Cures Act's explicit, textual engineering and policy specifications, both separately and in combination, as HRBA's analysis urged ONC to do. Any implication in the February 3 CEOs' letter that ONC's rules are incompatible with the Cures Act is thus demonstrably wrong.

The proposed rules' central innovative engineering mechanism is a national exchange standard for digital health records. It will be mandatory for clinical enterprises seeking Federal funding. It bears reiterating: ONC's promulgating the exchange standard is a Cures Act requirement. The initial standard comprised of eight templates will be updated regularly via ONC rulemaking to keep pace with technological and medical innovations.

Vendors of Electronic Medical Record systems will write initial output and input interfaces to meet the digital exchange standard's specifications. Then, for the first time, health records stored in EMR systems around the country will be readily exchangeable and accessible to patients nationwide, and to their clinicians when the patients grant access.

These benefits will be transformative. Pertinent health data will be reliably available at the point and time of care nationwide; outcomes will improve, yet care will cost less; clinician burdens will be reduced because of easier access to normalized, searchable patient records; and patients will be able (often with the help of consultants such as medical record social workers) to better manage their health and their interactions with the health system. To cite a prominent example of benefits from the digital exchange standard, veterans moving from DOD to Veterans Administration jurisdiction will be able to transfer records easily, quickly, and reliably.

The CEOs' letter complains that ONC should only require EMR systems to exchange standardized data (presumably data included in the eight templates of the initial version of the exchange standard). No such limit is necessary. EMR systems interfaced via the exchange standard can also

exchange a variety of structured reports in use now, plus free text and other useful data that is not yet normalized in the initial eight exchange standard templates. The data exchanged via such structured reports and free text can be enormously useful for care and patient engagement.

In all events, the Cures Act specifies that the standard must enable exchange of a *complete copy* of patients' medical records *without special effort on the part of the user*. The CEOs' plea to limit mandated exchange only to data included in the exchange standard's initial set of eight templates, by definition excluding currently available structured reports and free text among other data categories not initially covered, runs afoul of Congress's specific statutory instructions.

The exchange standard will quickly enable patients to gather and store their medical records in secure data repositories called Health Data Banks, or HRBs. Patients will *own and control* the "lifetime" medical record compilations in HRB accounts. They can elect to grant controlled access to all or part of their records using HRBs as communications hubs. For example, patients may furnish all or part of their records, identified or de-identified, gratis or for payment, as *the patients themselves* may decide, to researchers working on projects of vital interest to those patients because of personal or family diseases or conditions.

Conversely, new information flows will enable medical researchers to notify HRBs of ongoing research initiatives. HRBs can then notify account holders who want to be told of particular categories of research projects. This will vastly expand medical researchers' access to data they need, enabling use of machine learning, artificial intelligence, and other "big data" techniques to speed and improve research results, while reducing data acquisition and overall research costs.

The CEOs urge you to limit use of the data exchange standard because of "scare tactic" fears that some patients will misuse data and create privacy problems for themselves. They also cite narrow proprietary interests expressed by at least one EMR vendor. None of the CEOs' arguments overcomes the prodigious practical benefits a national exchange standard will bring to healthcare in the U.S. None of their arguments undercuts ONC's extensive cost-benefit calculations, required under the Administrative Procedure Act, that support the proposed rules as submitted to OMB.

And the CEOs' arguments cannot overcome the fact that a national health data exchange standard, designed to be used by and to empower patients, is mandated by the 21st Century Cures Act.

Sincerely yours,

The Health Record Banking Alliance

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