

21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (2019-02224)

Excerpts from more than 2,000 Comments on the NPRM

ONC's proposed regulations are unduly burdensome to the industry

American Academy of Family Physicians: "The AAFP has deep concern that this [privacy] exception will add significant burden to health care providers in that they must be the arbiters between state and federal (and among federal) laws." (HHS-ONC-2019-0002-1652)

American College of Emergency Physicians: "We are very concerned about the additional burden being placed on providers, from investing in and adopting new technology to understanding all of the new definitions and exceptions around information blocking." (HHS-ONC-2019-0002-1433)

American College of Surgeons: "The ACS is concerned that this proposed definition of EHI is too vague, subjective, and potentially expansive for purposes of information blocking enforcement... To limit confusion and regulatory burden, we recommend that the information blocking restrictions in this rule only apply to the data classes in the USCDI." (HHS-ONC-2019-0002-1854)

American Medical Association: "The AMA is concerned about the potential increase of administrative burden the proposed rule places on the practice of medicine... The increase in administrative tasks is unsustainable, diverts time and focus away from patient care, and leads to additional stress and burnout among physicians." (HHS-ONC-2019-0002-1914)

Medical Group Management Association: "The approach proposed by ONC is far too complex. It would significantly increase administrative burden for physician practices, cause industry confusion regarding what data can be disclosed and when, and increase the risk for sensitive health information to be shared inappropriately or not shared when needed." (HHS-ONC-2019-0002-1297)

ONC has broadly interpreted congressional intent and overstepped its statutory authority

Allscripts: "Patents, copyrights, trade secrets and other intellectual property are property, property that cannot be taken without due process. **Compulsory licensing has happened in the past in very specific situations, but always via an act of Congress. Congress, in drafting the 21st Century Cures Act, did not choose to take that extreme step, and we believe this proposal is antithetical to the fundamental principles of IP in this country.**" (HHS-ONC-2019-0002-1754)

American Hospital Association: "In addition, we are opposed to the agency's interpretation of what may be included in the definition of electronic health information, specifically regarding price information. **It goes well beyond what Congress intended and would seriously harm patients, hospitals and other health care providers.**" (HHS-ONC-2019-0002-1814)

College of Health Information Management Executives (CHIME): "We are very worried that **the EHI definition proposed by ONC is overly broad, exceeds what was intended by Congress, and would be administratively complex to meet.**" (HHS-ONC-2019-0002-0674)

Electronic Health Record Association: "When you consider that "interoperability elements," as defined in the NPRM, refers to "any means by which EHI can be accessed, exchanged, or used", this amounts to virtually any piece of technology that engages EHI on some level. Conversely, the "purpose" for which a competitor may wish to access those "elements" is not reined in at all. This is imbalanced and unfair. The natural result of these proposals moving forward would be lawsuits contesting the validity and arguing the **overreach** of the regulation." (HHS-ONC-2019-0002-1468)

Federal Trade Commission staff: "Our goal in providing technical assistance has been to **help ensure that the final rule does not inadvertently distort competition or inhibit conduct that is affirmatively procompetitive and consumer friendly.** We set out below some additional areas where the information-blocking rule and accompanying exceptions could be further refined to help minimize unintended consequences." (HHS-ONC-2019-0002-1923)

Health Innovation Alliance: "**These proposed rules extend beyond the scope and Congressional intent of the Cures Act.** The ONC proposed rule envisions a significant expansion of the National Coordinator's regulatory purview and fashions the agency as a regulator instead of a coordinator. If the ONC proposed rule was finalized as written, ONC would have **broad new authority** to regulate health IT manufacturers inside and outside of the Promoting Interoperability program." (HHS-ONC-2019-0002-1731)

IBM: "The proposal to extend ONC's regulatory reach to any of a certified developer's noncertified products would also create an unlevel playing field among health IT developers and discourage innovation investment." (HHS-ONC-2019-0002-1723)

ONC should not interfere with market-based pricing

Electronic Healthcare Network Accreditation Commission: "EHNAC believes that the health competition which currently results in the development of an excellent rate of health data processes and products will be thwarted, if the development companies cannot make some sort of profit." (HHS-ONC-2019-0002-1776)

Federal Trade Commission staff: "Consider (a) clarifying when market pricing is not deemed information blocking, and (b) providing additional leeway for market pricing and certain ordinary refusals (or failures) to deal under the 'recovering costs reasonably incurred,' 'responding to requests that are infeasible,' and the 'licensing of interoperability elements on fair and reasonable terms' safe harbors." (HHS-ONC-2019-0002-1923)

Health IT Advisory Committee: "[T]he HITAC believes the net force of the proposed rule will be to raise prices (by raising compliance burdens, such as accounting controls, pricing controls, and other pricing compliance activities) and limit the supply for value-added interoperability services." (HHS-ONC-2019-0002-1614)

Indiana Health Information Exchange (IHIE): “Such prohibition disincentivizes actors from improving security, functionality, and finding solutions to non-standardized implementations beyond the minimum necessary.” (HHS-ONC-2019-0002-1783)

Integrating the Healthcare Enterprise USA: “...the proposed fee structure may engender complexities that lead to less innovation, increased administrative burden, and a focus on cost recovery rather than creation of improved ways to improve data access.” (HHS-ONC-2019-0002-1513)

Partners Healthcare: “It is important for health IT developers, healthcare providers and/or data providers to innovate. We believe profit spurs innovation and competition and is an important factor in the advancement of health IT.” (HHS-ONC-2019-0002-1691)

The Sequoia Project: “We are concerned that requirements for very granular costs and fee accounting will significantly increase the cost of doing business and of data exchange.” (HHS-ONC-2019-0002-0428)

ONC should revise the Conditions of Certification to respect intellectual property law and investments

Change Healthcare: “HIT vendors can create unique, creative, and aesthetic user interfaces based on user-studies at great expense and allowing unfettered access to such screens can stifle innovation and allow malicious actors to compromise the security of systems by providing these malicious actors easy access to the UI organization blueprint.” (HHS-ONC-2019-0002-1552)

Healthcare Information and Management Systems Society (HIMSS): “It is also important to note the possibility exists of “bad actors” receiving screen shots and then using that information to develop malware or other harmful IT that could be incorporated into the healthcare ecosystem.” (HHS-ONC-2019-0002-1842)

Healthcare Leadership Council: “[ONC] must allow developers of certified health IT to protect legitimate intellectual property interests.” (HHS-ONC-2019-0002-1806)

ONC should publish a second information blocking NPRM or an IFR

American Academy of Allergy Asthma and Immunology: “These proposals do not tackle challenges that providers have raised about health information technologies for several years, and in fact, create a whole new host of challenges that will have significant, unintended consequences for patients and providers. To that end, we strongly urge the Administration to delay these proposed requirements, or at a minimum, issue the provisions as interim final and continue to accept comments from the public.” (HHS-ONC-2019-0002-1591)

American College of Obstetricians and Gynecologists: “ACOG also recommends that ONC consider issuing a Supplemental Notice of Proposed Rulemaking to seek further comments on the information blocking provisions in the proposed rule.” (HHS-ONC-2019-0002-1349)

American Medical Association (AMA): “The AMA also recommends that ONC consider issuing a Supplemental Notice of Proposed Rulemaking (SNPRM) to seek further comments on the information blocking provisions the proposed rule.” (HHS-ONC-2019-0002-1914)

American Psychiatric Association (APA): “The APA requests that the timeline be extended to a 36-month period, and that an interim final rule be released in advance of the final rule. The scope of this Rule is vast and touches every patient and provider in the United States. An interim final rule, with comment period, as well as additional implementation time after the final rule is released, would provide developers, patients, and physicians the opportunity to acclimate to the new regulation.” (HHS-ONC-2019-0002-1768)

Baylor Scott & White Health: “To that end, the Proposed Rule should be implemented as an interim final rule, so stakeholders can continue to provide feedback to ONC.” (HHS-ONC-2019-0002-1635)

ONC and OIG should defer information blocking enforcement and provide a grace period with focus on clarity of guidance and education

American Academy of Family Physicians: “The AAFP strongly recommends HHS phase in penalties for information blocking through the implementation of a temporary safe harbor for a consecutive 24-month period after the rule is in effect.” (HHS-ONC-2019-0002-1652)

Direct Trust: “Given the broad nature of the definition of information blocking and the narrowness of many of ONC’s proposed exceptions, DirectTrust anticipates that the nuances regarding information blocking practices will come out through subsequent enforcement actions. There is a real risk of entities making spurious complaints and data holders expending significant resources to defend against these complaints.” (HHS-ONC-2019-0002-1512)

Electronic Health Records Association: “A time period of enforcement discretion should be established for this necessary guidance to be propagated and for claims to be investigated in an educational manner, without financial penalties.” (HHS-ONC-2019-0002-1468)

Florida Hospital Assn: “Given the vast array of actors (the definition of health care provider alone is very expansive) and differing needs for understanding expectations as they exchange EHI among themselves, patients and other parties in compliance with the information blocking rule, FHA believes that a significant period of non-enforcement is required to ensure adequate time for all regulated actors to adapt to and understand what is required for compliance with this new framework.” (HHS-ONC-2019-0002-1627)

Johns Hopkins Medicine: “ONC should institute a significant grace period during which it offers guidance and educational assistance to those accused of information blocking. Such an approach would avoid unnecessary and costly litigation and allow for a better understanding of the types of activities that may constitute information blocking and what documentation is required to defend against such an allegation.” (HHS-ONC-2019-0002-1760)