



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of Policy Planning
Bureau of Economics
Bureau of Competition

RIN 0955-AA01

Department of Health & Human Services
Office of the National Coordinator for Health Information Technology
Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule

The staff of the Federal Trade Commission (“FTC” or “Commission”) Office of Policy Planning, Bureau of Economics, and Bureau of Competition (“FTC staff” or “we”)¹ appreciate the opportunity to comment on the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule, RIN 0955-AA01 (“NPRM”).²

We recognize the potential benefits of interoperability and of easier sharing of health care information.³ Both can foster innovation and competition in health information technology (“HIT”) and health care diagnosis, delivery and treatment. This benefits consumers financially and in better health care outcomes. We support ONC’s efforts to achieve these important objectives.

As the NPRM acknowledges, FTC staff provided informal technical assistance to ONC staff during the drafting process.⁴ We appreciate the open dialogue between the agencies’ staffs as ONC worked to accomplish the various policy goals identified by Congress in the 21st

¹ These comments reflect the views of FTC staff. They do not necessarily represent the views of the FTC or of any Commissioner; the Commission has, however, voted to authorize staff to submit these comments.

² 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Criteria, 84 Fed. Reg. 7424, 7424 (proposed Mar. 4, 2019) (to be codified at 45 CFR Parts 170 and 171) [hereinafter NPRM].

³ See, e.g., Fed. Trade Comm’n Staff Comment Before the Office of the National Coordinator for Health Information Technology, regarding Its Draft Shared Nationwide Interoperability Roadmap for Health Information Technology Systems (Apr. 2015), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-office-national-coordinator-health-information-technology-regarding-its-draft/1504-roadmaphealth.pdf.

⁴ NPRM at 7523.

Century Cures Act, including, but not limited to, fostering competition and innovation in HIT, and promoting consumer welfare.⁵ We look forward to continuing our close cooperation.

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. These suggestions may help clarify the final rule so that the exceptions do not inadvertently prohibit “activities that are innocuous, or even beneficial.”⁶

1. We acknowledge the considerable work the Department and ONC have done to identify and clarify exceptions to the information blocking prohibition; however, consider whether additional and more fully developed examples of permissible conduct, as observed in HIT and EHI use and development, could clarify safe harbors for conduct that does not harm competition or consumer welfare.
2. Consider adjusting the definition of EHI, so that it applies more narrowly to the information that is the focus of the statute, such as the information needed for patient treatment and HIT interoperability.
3. 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,”⁷ “responding to requests that are infeasible,”⁸ and the “licensing of interoperability elements on fair and reasonable terms”⁹ safe harbors.
4. Consider narrowing the proposed definition of “developers of certified HIT” so that regulatory restrictions apply to certified HIT, but not for all of its products, services, conduct, or practice, “including practices associated with any of the developer or offeror’s health IT products that have not been certified under the Program.”¹⁰

We hope that these comments are helpful as you consider revisions to the NPRM, and we would be glad to provide additional technical assistance if beneficial to finalizing the proposed rule.

⁵ Pertinent provisions of the 21st Century Cures Act provide that HHS may consult with FTC staff “in defining practices that do not constitute information blocking because they are necessary to promote competition and consumer welfare.” NPRM at 7523 (citing Section 3022(a)(5) of the Public Health Services Act).

⁶ NPRM at 7509.

⁷ NPRM at 7538.

⁸ NPRM at 7542-44.

⁹ *Id.* at 7544 et seq.

¹⁰ NPRM at 7510 (emphasis in text).