



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

Office of Policy Planning
Bureau of Economics
Bureau of Competition
Bureau of Consumer Protection

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 Final Rule

The staff of the Federal Trade Commission Office of Policy Planning, Bureau of Economics, Bureau of Competition, and Bureau of Consumer Protection (“FTC staff”)¹ write to express our appreciation to the Office of the National Coordinator for Health Information Technology and the Department of Health and Human Services for their consideration of FTC staff’s comments on the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule. We write to offer our perspective on certain changes in the Final Rule² to provisions of the information blocking regulations upon which FTC staff commented previously.³ We believe that several of those changes are salutary and will likely further ONC and FTC’s joint goals of fostering procompetitive innovation in health IT while protecting patient privacy.

First, the definition of electronic health information (“EHI”) has been streamlined in the Final Rule so that it applies more narrowly to information of concern to the relevant provisions of the authorizing statute. Second, as a related matter, the Final Rule’s new “content and manner” exception should facilitate near-term compliance with the Rule’s requirements regarding EHI. Third, the Final Rule clarifies and streamlines the concepts of “exchange, access, and use.” We appreciate ONC’s thoughtful responses to FTC staff’s comments on these issues.

FTC staff also appreciates ONC’s clarification that the Final Interoperability Rule does not alter the FTC’s role in protecting the privacy and security of consumers’ personal

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 Program (to be codified at 45 CFR Parts 170 and 171) [hereinafter Final Rule].

³ FTC staff’s comments can be found at https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-department-health-human-services-regarding-21st-century-cures-act-interoperability/v190002_hhs_onc_info_blocking_staff_comment_5-30-19.pdf. As noted therein, FTC staff also provided informal assistance to ONC in the course of the rule making process. *Id.* at 1.

information. As the nation’s leading consumer protection agency, the FTC enforces (among other statutes) the FTC Act, which prohibits, *inter alia*, unfair or deceptive acts or practices in or affecting commerce.⁴ Using its deception authority, the FTC may bring an enforcement action against, for example, a health IT app developer whose promises—whether in the app’s privacy policy, user interface, FAQs, or elsewhere—depart from its practices.⁵ Using its unfairness authority, the FTC could also challenge a particular use or disclosure of health information as unfair if it causes or is likely to cause substantial injury to consumers that is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition.⁶

FTC staff recognize the complex regulatory and enforcement charge that ONC and the Department have sought to implement in the information blocking provisions of the Final Rule. Our formal and informal input to ONC has been based on our experience and expertise in competition and consumer protection matters generally, and in competition and consumer protection in the health IT space, where the FTC and the ONC have long worked to benefit health care consumers. We look forward to ongoing cooperation between our agencies to that end.

⁴ 15 U.S.C. § 45(a) declares unlawful “[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce” and empowers and directs the FTC to prevent most persons, partnerships, or corporations from using such methods.

⁵ *See, e.g., Compl., Pact, Inc., No. 2:17-cv-1429* (W.D. Wash. Filed Sept. 21, 2017), <https://www.ftc.gov/system/files/documents/cases/1523010pactcomplaint.pdf> (alleging that mobile health app developer misled consumers about payments and billing related to achieving health and fitness goals).

⁶ 15 U.S.C. § 45(n)