

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

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 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/

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."

- 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 P at 7509 -12 .y
 - 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," "responding to requests that are infeasible," and the "licensing of interoperability elements on fair and reasonable terms" 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, P at7538 -12 onduct, 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.

P at7542y 4o

⁵ Pertinent provisions of the 21st Century Cures Act provide that HHS may con(ss). -0.6(a)-19.8 fr "nd o
ra.8 -8 (c.8 -8 (tic.8 -8 ec.8 -8 s)-2.5 (th54 (a.8.7 (nd))78 (o).
Pat20.9 700059 http20.9 tat20.9 c (H)112 ealt20.9 t 20.9 hs-551 Af