ONC EXERCISES ENFORCEMENT DISCRETION WITH RESPECT TO IMPLEMENTATION OF RANDOMIZED SURVEILLANCE
Program Guidance #17-02
Issued and Effective Date: September 21, 2017

The Department of Health and Human Services’ Office of the National Coordinator (ONC) for Health Information Technology announces that it is exercising enforcement discretion with respect to the implementation of randomized surveillance by ONC Authorized Certification Bodies (ONC-ACBs). Regulatory requirements at 45 CFR 170.556(c)(2) dictate that ONC-ACBs conduct randomized in-the-field surveillance for, at a minimum, two percent of the health IT certifications they have issued. As of September 21, 2017, however, ONC is exercising enforcement discretion. ONC will not, until further notice, audit ONC-ACBs for compliance with randomized surveillance requirements or otherwise take administrative or other action to enforce such requirements against ONC-ACBs, nor will it consider lack of implementation of these requirements by an ONC-ACB to be a violation of its compliance requirements under 45 CFR 170.566, the Principles of Proper Conduct for ONC-ACBs, or good standing under the ONC Health IT Certification Program (Program).

This exercise of enforcement discretion will permit ONC-ACBs to devote their limited resources to certifying health IT to the 2015 Edition, which will support its greater availability for providers participating in the Centers for Medicare & Medicaid Services’ Quality Payment Programs. It will also permit ONC-ACBs to focus on their ongoing responsibilities to conduct reactive surveillance (e.g., surveillance based on provider complaints), including in-the-field reactive surveillance of certified health IT.

ONC-ACBs should continue good faith execution of any active and ongoing randomized surveillance to ensure product compliance with the Program.