

Office Of Inspector General Issues Policy Reminder On Information Blocking And The Federal Anti-Kickback Statute

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The federal anti-kickback statute (42 USC § 1320a-7b(b), the “Statute”) prohibits individuals and entities from receiving or soliciting any remuneration for the referral of services reimbursable under any federal health care program. The Statute defines remuneration broadly to include kickbacks and rebates but also to include the purchasing or leasing of any products reimbursable under a federal health care program. Violators of the Statute can face civil monetary damages, program exclusion, criminal penalties, and liability under the False Claims Act.

To avoid liability under the Statute, businesses may choose to comply with certain exceptions referred to as “safe harbors” (42 CFR § 1001.952). One of these safe harbors relates to electronic health records and states that, under certain circumstances, “remuneration” under the Statute shall not include nonmonetary remuneration in the form of software, information technology, or training which is “necessary and used predominately to create, maintain, transmit, or receive electronic health records.”

To illustrate the importance of the safe harbor protections, the Department of Health and Human Services’ Office of the Inspector General (the “OIG”) has used the example of a hospital seeking to provide software to a physician practice. As a potential referral source for the hospital, this arrangement would violate the Statute and prevent the hospital from utilizing valuable software.

To remove barriers to the adoption of electronic health records while also reducing the risk that these arrangements will be used to reward the generation of federal health care business, the Statute imposes a number of requirements that must be met before the safe harbor protections are applied.

One such requirement relates to information blocking and prevents the donor from taking any action that would limit or restrict the use, compatibility, or interoperability of the items or services with other electronic systems. (42 CFR § 1001.952(y)(3)). As part of National Health IT Week, the OIG issued a policy reminder regarding how this information blocking may affect safe harbor exceptions.

The OIG takes the position that the donation of products with limited or restricted interoperability due to actions taken by the donor fail to meet the safe harbor requirements. For example, any arrangement in which the donor has restricted interoperability in an attempt to prevent a competitor from interfacing with a donated system, or charging these competitors high interface fees, would not meet the requirements for safe harbor protection.

Providers of software, information technology, and training services must take note of this policy reminder and ensure they take no actions that would restrict the interoperability or compatibility of their products and services with the products and services of others. Failure to comply with this requirement will preclude these providers from claiming safe harbor protections, thereby exposing them to liability under the Statute.

The full policy reminder can be found here: <http://oig.hhs.gov/compliance/alerts/guidance/policy-reminder-100615.pdf>

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