PUBLICATION

CMS Advisory Opinion 2017-01 Approves Pop-up Alerts to Physicians Through Online Laboratory Portal

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A clinical laboratory has received a green light from CMS to offer pop-up notifications alerting physicians of various potential issues (Laboratory Alerts) through its web-based portal for ordering and reporting results of diagnostic tests. CMS reviewed the proposal to offer the Laboratory Alerts in Advisory Opinion 2017-01, issued in September 2017, and determined that the Laboratory Alerts do not constitute *remuneration* (42 C.F.R. § 411.351) creating a *compensation arrangement* that implicates the physician self-referral law (the Stark Law).

The laboratory proposing to offer the Laboratory Alerts (Laboratory) currently provides referring physicians with free access to an online portal through which the physicians can order tests and communicate with the Laboratory through secure messaging. The proposed Laboratory Alerts would pop up through the portal with information related to the test then being reported to the physician. The Laboratory Alerts might recommend that the physician order repeat or additional tests, and all recommendations would be based on industry-standard, peer-reviewed guidelines. The Advisory Opinion cites the example that a Laboratory Alert might recommend follow-up testing in 90-days based on the result of a particular test. The Laboratory Alerts would not include any information not directly tied to the test results with which it was provided, such as general clinical information or drug interaction warnings.

The Laboratory Alerts would only remain on the portal until the physician ordered the follow-up testing (if recommended), but never longer than two weeks. The physician would also have the ability to turn off a particular alert rule or set of rules (grouped by disease condition) if the physician chose not to receive the Laboratory Alerts.

CMS determined that the Laboratory Alerts do not create a *compensation arrangement* under the Stark Law because they fit within an exception to the definition of *remuneration*. The Stark Law defines a *compensation arrangement* as "any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity" furnishing designated health services. 42 U.S.C. § 1395nn(h)(1). The Stark Law regulations define *remuneration*, in turn, as "any payment *or other benefit* made directly or indirectly, overtly or covertly, in cash or in kind." 42 C.F.R. § 411.351 (emphasis added). The statutory and regulatory definitions of *remuneration* include several exceptions, though, and "[t]he provision of items, devices, or supplies that are *used solely to* collect, transport, process or store specimens for the entity providing the item . . . , or *order or communicate the results of tests or procedures for such entity*" does not constitute remuneration. 42 U.S.C. § 1395nn(h)(C)(ii) (emphasis added).

CMS's analysis turned on the fact that the Laboratory Alerts would be used solely in connection with ordering or communicating the results of the diagnostic procedures. The Advisory Opinion referenced language from a 1998 CMS proposed rule in which the agency stated that the term *solely* means the donated item must be used "solely for the purposes listed in the statute" and that CMS believes a donated item will not meet this requirement "if it is used for any purposes besides these." 63 Fed. Reg. 1659, 1694 (Jan. 9, 1998). Additionally, CMS referenced its position taken in the 1998 proposed rule that the donated item can be used only for the entity that donated the item. 63 Fed. Reg. 1694 (Jan. 9, 1998). CMS affirmed in 2013 that these

principles do apply to limited-use laboratory interfaces used to store and communicate diagnostic test results. 78 Fed. Reg. 78751, 78759 (Dec. 27, 2013).

In Advisory Opinion 2017-01, CMS took the position that the proposed Laboratory Alerts would not be used for any purpose other than ordering or communicating diagnostic test results for the Laboratory. Specifically, CMS cited the following factors in its analysis:

- Physicians would receive Laboratory Alerts when test results are communicated via the online portal.
- The Laboratory Alerts would only contain information related to the specific test results reported (such as recommending an additional test that would provide definitive identification if a test result reveals a possible abnormality).
- The purpose of the Laboratory Alerts would not be to provide a physician with general information that may or may not bear on a particular patient's test results.
- The Laboratory Results would be used solely in connection with ordering and communicating test results for the Laboratory.

CMS also acknowledged that the Laboratory had built in critical safeguards to prevent overutilization of its testing services. These safeguards would be required to avoid duplication and medically unnecessary services, CMS stated, because the Laboratory Alerts would "assist physicians in the deliberative process of determining which additional tests, if any, to order" from the Laboratory. CMS specifically referenced the following safeguards that the Laboratory had certified would be in place:

- The recommendations in the Laboratory Alerts would be based on industry-standard, peer-reviewed guidelines.
- The Laboratory Alerts "are not overly intrusive, and they do not override the physician's independent judgment."
- If a Laboratory Alert recommended more than one additional test, there would not be a "select all" button for the physician.
- The physician could turn off the Laboratory Alerts for particular disease conditions.
- The Laboratory Alerts would not incentivize physicians to order additional tests for the purpose of accessing information because the information that would be in the Laboratory Alerts is available without charge from other sources.

Based on the use of the Laboratory Alerts *solely* in connection with ordering and communicating test results for the Laboratory, and the safeguards in place to prevent overutilization of diagnostic testing, CMS concluded that the Laboratory Alerts would not constitute *remuneration* resulting in a *compensation arrangement* implicating the Stark Law.

Baker Donelson's Comments

CMS emphasized multiple times in Advisory Opinion 2017-01 that its analysis related *only* to whether the Laboratory Alerts provided through the online portal constituted *remuneration* and that it was not opining on whether online portals themselves, which laboratories commonly offer to referring physicians, constitute *remuneration*. The facts of the Advisory Opinion did not include a full description of the portal's functionality, stating only that the portal "is used for electronic test order management and secure messaging between [the Laboratory] and Referring Physicians." Presumably, the analysis of whether the Laboratory's (or any other laboratory's) portal constitutes *remuneration* for purposes of a Stark Law *compensation arrangement* would also turn on whether the portal is used *solely* to order or communicate test results.

CMS Advisory Opinion 2017-01 is especially noteworthy because of the rarity of CMS Advisory Opinions compared to OIG Advisory Opinions: Advisory Opinion 2017-01 is only the 15th CMS Advisory Opinion since 1998.