

STATE OF TENNESSEE
OFFICE OF THE
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Opinion No. 13-16

Donations for Electronic Health Records Software by Clinical Laboratories

QUESTIONS

1. Pursuant to Tenn. Code Ann. § 68-29-129(7), may a clinical laboratory licensed by the State of Tennessee lawfully make a monetary donation to a physician to cover up to 85% of the cost of software designed to manage the physician's electronic health records (EHR) when the physician's office that receives the EHR donation either continues an existing referral arrangement with the donating laboratory or subsequently initiates an arrangement for referral of specimens to the donating laboratory for analysis?

2. If such donations are permissible under Tenn. Code Ann. § 68-29-129(7), would either an increase in specimen referrals or a subsequent initiation of specimen referrals by the physician recipient who orders laboratory services from the donating laboratory be a violation or a potential violation of the above section and thus be subject to investigation by the Tennessee Medical Laboratory Board?

OPINIONS

1. No. Tenn. Code Ann. § 68-29-129(7), which is part of the Tennessee Medical Laboratory Act, prohibits any person from soliciting the referral of specimens to such person's (or to any other) medical laboratory or from contracting to perform medical laboratory examinations of specimens "in a manner that offers or implies an offer of rebates to a person or persons submitting specimens, other fee-splitting inducements, participation in any fee-splitting arrangements, or other unearned remuneration." This provision would prohibit a licensed medical laboratory from making any monetary donation to a physician to cover the cost of software designed to manage the physician's electronic health records (EHR) when the physician's office that receives the EHR donation either continues an existing referral arrangement with the donating laboratory or subsequently initiates an arrangement for referral of specimens to the donating laboratory for analysis.

2. The response to question one pretermits the need to answer question two.

ANALYSIS

1. The Tennessee Medical Laboratory Act, codified at Tenn. Code Ann. §§ 68-29-101 to -138 (hereinafter “TMLA”) is intended, among other things, “to protect the public health, safety, and welfare of the people of this state from the hazards of improper performance by medical laboratories.” Tenn. Code Ann. § 68-29-102(a). The TMLA at Tenn. Code Ann. § 68-29-129 enumerates various prohibited acts. Specifically, Tenn. Code Ann. § 68-29-129(7) provides that it is a violation of the TMLA for any person to:

Solicit the referral of specimens to such person’s or any other medical laboratory or contract to perform medical laboratory examinations of specimens in a manner that *offers or implies an offer of rebates* to a person or persons submitting specimens, other fee-splitting inducements, participation in any fee-splitting arrangements, *or other unearned remuneration*.

(emphasis added).

The prohibition of Tenn. Code Ann. § 68-29-129(7) is unambiguous, and thus the plain meaning of the statute must be followed. *See, e.g., Garrison v. Bickford*, 377 S.W.3d 659, 663 (Tenn. 2012) (stating the rule of statutory construction that, if the language of a statute is unambiguous, then a court is required to “apply the plain meaning of the words used in the statute” and to presume that the General Assembly intends to give each word its full effect). This “anti-kickback” provision prohibits any explicit *or implicit* financial incentive to solicit a contract to perform medical laboratory examinations of specimens. Thus even the implication of an offer by a medical laboratory or other entity listed under Tenn. Code Ann. § 68-29-129(7) of a rebate, fee-splitting inducement, fee-splitting arrangement or “other unearned remuneration” to a person or persons submitting specimens is prohibited. Accordingly, a medical laboratory licensed by the State of Tennessee may not lawfully make a monetary donation to a physician to cover the cost of software designed to manage the physician’s electronic health records (EHR) when the physician’s office that receives the EHR donation either continues an existing referral arrangement with the donating laboratory or subsequently initiates an arrangement for referral of specimens to the donating laboratory for analysis.

The qualified federal “safe harbor” for EHR donations by clinical laboratories at 42 CFR § 1001.952(y) does not preempt state anti-kickback laws such as Tenn. Code Ann. § 68-29-129(7). This federal safe harbor rule, which is scheduled to sunset on December 31, 2013, does allow certain medical professionals to receive EHR software donations under defined circumstances without violating a federal anti-kickback statute. 42 C.F.R. § 1001.952(y). *See also* OIG Advisory Opinion No. 12-19, 2012 WL 7148095 (Nov. 30, 2012). However, the legal authority for the EHR safe harbor does not extend to preempt State anti-kickback laws. *See* 71 Fed. Reg. 45114 (stating that the legal authority for the EHR donation safe harbor is derived from section 1128B(b)(3)(E) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, which does not provide authority to preempt state anti-kickback laws). *See also* Wash. Att’y Gen. Op. 7, 2012 WL 7148193 at *5 (Nov. 20, 2012) (reaching same conclusion in finding that Washington’s anti-kickback provisions were not preempted by federal law).

2. The second question is pretermitted by the above response to question one.

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