Beware the pitfalls of EHR licenses, donations

Adoption of electronic health records (EHRs) has yet to hit “critical mass” in the health-care industry. When asked why they have not implemented an EHR, most physician practices cite the high cost of purchasing the software, as well as the costs associated with adapting office workflow to the new technology.

Until recently, many physician practices believed that it would be less expensive to continue using paper records. That calculus has changed for many practices in the wake of federal initiatives. The prospect of Health Information Technology for Economic and Clinical Health Act-related payments for achieving “meaningful use” of EHRs, coupled with the sunset of the Stark exception and the anti-kickback statute safe harbor for EHR donations in 2013, is spurring practices to adopt EHRs rather than purchasing them directly or by receiving them from a donor.

If your practice receives or plans to receive donated software, however, proceed carefully to ensure that the agreements you sign comply with the federal requirements and that you understand the significance of your EHR license agreements.

Federal Requirements for Donated Software

In general, entities that refer federal healthcare business to physician practices are not permitted to give a practice free EHR software; doing so normally would violate the Stark statute and anti-kickback statute. In 2005, however, federal regulations applying to each were revised to allow donation of nonmonetary remuneration in the form of EHR software and certain associated services, provided that the donation met certain regulatory requirements. If you are considering entering into a license agreement wherein the software is being donated, review the agreements closely to determine whether the donation meets these requirements:

- A written contract. A written contract between the donor and the recipient practice must describe the full range of items and services being donated, the donor’s costs, and the recipient’s payment to the donor.

This document is not necessarily a true license agreement, which would specify that your practice is being granted the right to use the software (by a party with the ability to permit such use) and which also would outline a range of terms, conditions, and duties such as how technical support is handled, any use restrictions on the software, how and when the software will be modified or updated, and how the data you enter into the software will be handled during the term of the license and after termination.

The donation agreement may include some or all of these terms, but it is not required to do so. In addition, the vendor of the software (which is not the donor) may provide your practice with a separate license agreement. Regardless of whether the EHR vendor provides you with this document, make certain that you at least have an agreement in place between your practice and the donor; the agreement with the vendor is not required under the federal regulations, but the donation agreement is.

- Nonmonetary donation. Next, the donation must be nonmonetary. In other words, the donor cannot simply pay you for software you already purchased. The donor may donate the software itself, as well as related services (such as maintenance and EHR training services). The donation may not, however, include personnel to staff your practice.

You must also pay at least 15% of the donor’s costs for the EHR software. This requirement implies that the donor must first purchase the software and then donate it to the practice, at which point the practice pays the donor at least 15% of the cost for the EHR.

When examining a license agreement for a donated EHR, carefully consider the percentage of the donor’s costs that you pay. Bear in mind that the regulations merely require that you pay the donor at least 15% of the donor’s costs; nothing stops the donor from increasing that amount. Moreover, the donor is not required to pay for ongoing fees such as those covering support and maintenance. The donation agreement should specify...
the up-front and ongoing costs to you, however.

**“Interoperable” software.**

To meet federal requirements, the donated software also must be “interoperable” within the meaning of the regulations. Both the donation agreement and the license agreement (if they are separate documents) should affirmatively state that the software is interoperable.

**Not “equivalent” software.**

To be safe, your practice also may not receive from the donor software “equivalent” to software that it already has. The term “equivalent” has not been defined in the federal regulations. When examining the functionality of the EHR software, however, make sure it does not duplicate the functionality of your current software.

**Additional requirements.**

The donation of the software also may not be a requirement for your practice to continue doing business with the donor, and the donation must not be related to the volume or value of any referrals between your practice and the donor. In addition, the software must contain an electronic prescribing component, it cannot be restricted to use with only patients from specific payers, and the donor cannot restrict the interoperability of the software. The agreement with the donor should state all of these facts.

Depending on the nature of the EHR donation, your practice may face different hurdles regarding the license agreement(s). If the donor simply is donating the software to your practice and has no other involvement in software-related services (such as ongoing technical support, offsite storage of electronic records, or training services) or use of the software, then you will need a separate agreement with the EHR vendor outlining such duties.

If the donor will provide some of the services, but not all of them, then you may end up either in an arrangement where the donor is the only entity with which you have a contract (and where the donation and license terms appear in the same document), or an arrangement where you have a donation/license agreement with the donor and a separate license with the EHR vendor.

**COVER YOUR NEEDS**

If you have only a license agreement with the donor, be sure that the agreement addresses your practice’s ongoing needs. Either the donation/license agreement should list the EHR vendor as a signing party or your practice needs to have a separate license agreement with the EHR vendor; otherwise, regardless of what the donation/license agreement says, you won’t be able to enforce its provisions against the vendor.

When technical support services are split between the donor and the EHR vendor (for example, simple technical support is provided by the donor, but complex support is provided by the EHR vendor), the documentation should address explicitly what happens if either the donor or the EHR vendor can no longer provide such services and whether either party will step in and continue to provide the services to your practice. Also be sure that the agreement addresses what will happen if the laws relating to EHRs change.

Likewise, pay very close attention to how the agreement(s) address your data. You should always own the data you enter into the EHR software, and any documentation controlling the use of the software should say as much. If the agreement(s) terminate for any reason, your data should be returned to you.

Do not let your data be held hostage. You have an obligation under the Health Insurance Portability and Accountability Act, and likely under state medical licensure laws, to retain the data. Make certain that the agreement(s) address whether the data are stored in a format readable by other EHRs (although this should be less of a problem if the EHR is “interoperable”), and make certain that all data elements will transfer to a new system if necessary.

If you store your data offsite either in an arrangement where you have an agreement only with the donor or where you have agreements with the donor and the EHR vendor, then the agreement(s) should address what happens to your data if either the donor or the EHR vendor goes out of business. If the EHR vendor goes out of business, can the donor ensure that your data will be protected? If the donor goes out of business, will the EHR vendor continue to provide you with data storage services? The agreement(s) should address these contingencies.

The author is a health law attorney with Alice G. Gosfield and Associates PC, Philadelphia, Pennsylvania. Law Consult deals with questions on common professional legal issues. Unfortunately, we cannot offer specific legal advice. If you have a general question or a topic you would like to see covered here, send it to medec@advanstar.com.