

## Chapter 2

# Downstreamed Physician EHR License Agreements: Understanding the Ebb and Flow

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### § 2:1 Introduction

The shift to paperless offices is still developing throughout health care. For physician practices, electronic health records (EHRs) and health information technology (HIT) offer the potential to reduce errors and expenses, and increase efficiency. Obtaining access to EHR software is a looming chal-

lenge for many physician practices who must balance the high cost of EHRs against the promise of a better tomorrow. As part of an ongoing effort by the federal government to spur EHR adoption, regulations permit hospitals to share the cost of an EHR with a physician practice. However, this approach with its introduction of a third party to the relationship will necessarily raise additional complications not otherwise present in a standard EHR license between a practice and a software developer.

Yet, this “downstreamed” license arrangement is not unique to federal regulatory schemes. Any physician practices that have purchased an EHR from a vendor which did not develop the software itself, as well as physician practices which have joined health information exchanges (HIEs), face a similar arrangement. Beginning with the policy context, this chapter will focus on three common models of downstream arrangements: (1) the vendor sub-license arrangement; (2) the HIE participation arrangement; and (3) the federal donation arrangement. Examining the various complications and concerns arising from the nature of each of these arrangements, this chapter will identify and distinguish the significance of contract terms taken from actual agreements, and the practical issues they may create.

## § 2:2 Federal policy developments

First proposed by President Bush in his 2004 State of the Union address and subsequently issued as an executive order, the President’s goal has been the establishment of a national electronic health information infrastructure by 2010.<sup>1</sup> In August of 2006, federal regulations governing the Stark exception and federal anti-kickback statute safe harbors for donations of EHR software from hospitals to physician practices were finalized.<sup>2</sup> This move by federal authorities, coupled with the May, 2007 IRS ruling on EHR donations by not-for-profit hospitals, represented another

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### [Section 2:2]

<sup>1</sup>State of the Union address, January 20, 2004, at <http://www.whitehouse.gov/news/releases/2004/01/20040120-7.html>; Exec. Order No. 13335 (April 27, 2004). See <http://www.whitehouse.gov/news/releases/2004/04/20040427-4.html>.

<sup>2</sup>42 C.F.R. § 411.357(w); 42 C.F.R. § 1001.952(y), respectively.

step in promoting the creation of such an infrastructure.<sup>3</sup> The theory underlying the exception and safe harbor was that by permitting hospitals to donate the technology, the federal government could alleviate much of the financial burden on physician practices and thereby spur adoption. This liberalization, however, did not create the anticipated major groundswell in response.

Other efforts to increase adoption have been initiated since. On October 31, 2007, the Department of Health and Human Services (HHS) announced a five-year demonstration project to encourage small and medium-sized physician practices to adopt EHRs. The project would link higher Medicare payments to the use of EHRs that meet specific quality measures. Although payment would be tied to performance on the measures, an increased bonus would be available “based on how well integrated the EHR is in helping manage patient care.”<sup>4</sup> The project is in its infancy, but it evidences the link between HHS’s intent to improve quality in health care through the use of EHRs.

Reports do indicate that adoption is expanding.<sup>5</sup> States such as Arizona are also entering the fray, working to promote the development of state-wide electronic exchanges of health information.<sup>6</sup> However, although raw numbers are increasing, adoption rates are still relatively low. National estimates are that EHR adoption in physician offices is as low as ten to fifteen percent.<sup>7</sup> Sixty-four percent of the physicians queried in a December, 2006 survey conducted by

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<sup>3</sup>Memorandum Re: Hospitals Providing Financial Assistance to Staff Physicians Involving Electronic Health Records (May 11, 2007), at <http://www.irs.gov/pub/irs-tege/ehrdirective.pdf>.

<sup>4</sup>HHS Announces Project to Help 3.6 Million Consumers Reap Benefits of Electronic Health Records. <http://www.hhs.gov/news/press/2007pres/10/pr20071030a.html>.

<sup>5</sup>See “Doc E-Records Could Hit 30 Percent By ‘11,” United Press International (July 11, 2007), at [http://www.upi.com/Health\\_Business/Briefing/2007/07/17/doc\\_erecords\\_could\\_hit\\_30\\_percent\\_by\\_11/5521/](http://www.upi.com/Health_Business/Briefing/2007/07/17/doc_erecords_could_hit_30_percent_by_11/5521/). Reporting that a study by the Millenium Research Group found that almost 18 percent of physicians had an electronic medical record system in 2006, and that this figure could rise to 30 percent by 2011.

<sup>6</sup>See Vesely, “Bringing EHRs to the Desert,” *Modern Healthcare*, pp. 6-7, 16 (Sept. 10, 2007).

<sup>7</sup>Vesely, “Bringing EHRs to the Desert,” *Modern Healthcare*, pp. 6-7, 16 (Sept. 10, 2007).

*Medical Economics* magazine responded that they had not yet purchased an EHR.<sup>8</sup> The major reason for such low adoptions has been the high expense of implementing an EHR.<sup>9</sup> When an EHR can cost as much as thirty thousand dollars for a practice, it represents a major capital investment, even with a good expected return.<sup>10</sup>

The Stark exception and anti-kickback safe harbor attempt to remedy this situation, by permitting hospitals to donate EHR software, provided certain requirements are met. If the regulations are satisfied, a physician practice could pay as little as fifteen percent of the hospital's costs for the software. Thus, a \$30,000 EHR could drop in price to as low as \$4,500. However, one of the major complications of such an arrangement is the contractual relationships that must be established among the relevant parties. Unlike a traditional EHR license, with the practice purchasing directly from the developer of the software, the Stark and anti-kickback regulations necessitate “downstreamed” licenses.

The Stark and anti-kickback regulated donations however are not the only methods of downstreaming software licenses in the health care setting. Downstreaming varies from mere three-party sub-licenses, to partial participation in HIEs, to idiosyncratic custom-crafted relationships. However, as EHRs and related technologies are more widely adopted, physician practices will be faced with such arrangements more often. Understanding the nature of the underlying relationships and their structural considerations will help in navigating the legal issues that will arise in the license agreement.

### § 2:3 Forms of downstreaming—In general

At its most basic, “downstreaming” simply means that

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<sup>8</sup>“Malpractice Risk and EHRs: How Physicians View It,” joint study by Medical Economics and The Doctors Co., p. 5, at <http://www.memag.com/memag/data/articlestandard/memag/222007/429882/article.ppt#5>.

<sup>9</sup>A survey conducted by the American Osteopathic Association (AOA) found that the greatest barrier to EHR adoption was “lack of capital resources to invest in an EHR.” *Assessing Electronic Health Record Use by Members of the American Osteopathic Association*, p. iii (Feb. 2007).

<sup>10</sup>The AOA survey reported a median purchase and implementation cost of \$20,000 per full-time equivalent physician, with monthly software and hardware maintenance costs running approximately \$250 per full-time equivalent physician. *AOA Survey*, p. ii (Feb. 2007).

there are three parties in the license agreement, rather than the usual two: the developer of the software, the party delivering the software to the practice, and the end-user practice itself. The nature of the party delivering the software to the end-user and how the software will be used, of course, raise different legal issues. The three specific methods of downstreaming addressed here—(1) vendor sub-licenses; (2) HIE agreements; and (3) donations of EHRs made under the Stark exception—raising subtly different legal issues and practical peculiarities due to their different structures and purposes. The downstreaming methods and their effects upon and manifestations in contractual language will be examined from the perspective of the end-user physician practice, rather than from the institutional point of view. Moreover, this chapter is not intended to be a primer on RHIOs, HIEs, or other similar entities, nor on the specifics and nuances of the Stark exception and antikickback safe harbor. While these issues will be addressed, they will only be discussed in the context of how they impact contract language.

#### § 2:4 Forms of downstreaming—Vendor sub-licenses

A vendor sub-license is the simplest of the three models addressed here. The vendor who sells the software to a physician practice may not be the entity which created the software. The vendor may simply be an authorized reseller of a larger company's software. It may have rebranded the software with its own name, or it may have maintained the original name of the software. The vendor may assume all relevant duties under the agreement, or may split duties between itself and the developer.

A vendor may provide product support and maintenance, but may rely on the developer entirely for the actual creation of periodic software updates. The vendor may have no role in the development of such updates, and may only be responsible for passing them along to the practice when they are released by the developer. Likewise, services such as off-site data storage might be provided by the developer, rather than the vendor.

By contrast, a vendor might, for all intents and purposes, be treated in the license agreement as the only entity involved. Once the software is sold by the developer, the

vendor may be the sole source of services for the practice. All support, updates, and services may be provided solely by the vendor, with the physician practice having no interaction whatsoever with the developer.

Despite these concerns, the vendor sub-license represents the simplest of the three approaches, it is direct and linear. Many of the additional concerns found in other models (such as contractual complications from regulatory requirements, post-termination data control issues, etc.) will not apply.

### § 2:5 Forms of downstreaming—Health Information Exchanges (HIEs)

HIEs are generally structured both in legal terms and in terms of software functionality, to permit multiple otherwise unrelated or loosely related medical service providers to exchange health information among themselves, thereby facilitating the treatment of patients.<sup>1</sup> In so doing, HIEs may vary in size and scope, may provide additional services such as quality assessments, but at their core will transmit patient data among providers. The HIE must therefore have a software component that allows for the exchange of such data, which will in turn require a license agreement.<sup>2</sup>

HIE contracts may be between a separate legal entity and HIE participants, or between HIE participants and a single participant who operates the HIE.<sup>3</sup> For example, the HIE may be a larger-scale regional or state-wide network organized as an independent corporate entity, such as the Regenstreif Institute, Inc., a non-profit institution affiliated

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#### [Section 2:5]

<sup>1</sup>For a more in-depth discussion of HIEs, RHIOs, and similar organizations, see Rosati and Lamar, “The Quest for Interoperable Electronic Health Records” (July 2005) and Lamar, “Electronic Health Record Contracts in the RHIO Context—A Practical Guide to Multiparty Arrangements,” Health Law Handbook, 131-63 (Gosfield, ed. 2007).

<sup>2</sup>As a point of clarification, this chapter does not attempt to navigate the distinctions between RHIOs and HIEs. In general, a RHIO, as its name suggests, is more regionally focused, whereas an HIE may not necessarily be limited to a specific region. Functionally, for purposes of this chapter, the two are interchangeable.

<sup>3</sup>Lamar, “Electronic Health Record Contracts in the RHIO Context—A Practical Guide to Multiparty Arrangements,” Health Law Handbook, 136-38 (Gosfield, ed. 2007).

with Indiana University, which operates an HIE in Indiana, consisting of multiple hospitals in the Indianapolis area. Alternatively, the HIE may be a smaller network created by a large physician group practice with multiple office sites, which wishes to share health information with other treating providers.

The HIE may act as a data warehouse, storing and updating all of the data. In this case, it is acting as the hub of a wheel, with the providers acting as the spokes, allowing participating providers to “dial in” to a central database, upload their updated information on the patient, and then download whatever other data has been uploaded by other providers. Alternatively, the HIE may operate on a peer-to-peer basis, where the HIE acts merely as a “matching service.” In this setting, the providers maintain data on their own systems, while the HIE maintains an index of where information on patients resides. When the providers query the HIE about the location of information, all the HIE does is inform the providers of the locations, and the providers then connect directly to each other.

Regardless of the HIE’s architecture, it will be the entity with which all participating providers contract and from which they obtain the software necessary to participate. With respect to the software, it is unlikely to be the creation of the HIE itself. Instead, the HIE usually is licensing the software from a developer for distribution to the practices. At the very least, the HIE may have worked with the developer to design software specifically suited to the HIE’s needs. To the extent that the HIE is licensing the software from the developer and passing it on to the participating providers, it is downstreaming the software.

### **§ 2:6 Forms of downstreaming—Stark/anti-kickback statute donation model**

The Stark and the federal anti-kickback regulations generally permit a hospital to pay for most of the costs of an EHR on behalf of a physician practice. The regulations are harmonized in terms of their requirements, although the Stark regulations obviously focus more on donations to physicians, while the anti-kickback safe harbor focuses on donations to federal health care providers in general. Both regulations place requirements on the software itself, including

that the donated software be “interoperable;”<sup>1</sup> that there are no limits placed on the use, compatibility, or interoperability of the software with other EHR or electronic prescription systems; that the software includes an electronic prescription (E-Rx) component or can interface with an E-Rx system; and that the donated software is not functionally or technologically equivalent to what the physician practice already possesses. The regulations specify that the donor may not have actual or constructive knowledge of the practice having equivalent software.

“Equivalency” is a nebulous concept, which has not been defined in the regulations. In the proposed rule for Stark, CMS provided an example of equivalency, illustrating that it would be impermissible to give a physician a hand-held device able to transmit E-Rx information if the physician already had a device capable of doing so and to run the new software.<sup>2</sup> In the final rule, CMS did not elaborate on a definition of “technically or functionally equivalent,” but stated that determinations of equivalency would not require the hiring of technical experts.<sup>3</sup> Moreover, CMS explained that while equivalent technology could not be donated, donations of upgrades or updates to existing technology were permissible.<sup>4</sup> The ultimate impact of this requirement of the regulations might seem simple at first blush, but actually can conceivably pose a more difficult problem for Stark donations. Without a clear definition of “equivalency” (nor of what constitute “upgrades” rather than a donation of “equivalent” technology), contractual language requiring parties to

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**[Section 2:6]**

<sup>1</sup>Meaning that the software can communicate and exchange data accurately, effectively, securely, and consistently with different systems. 42 C.F.R. § 411.351. A system will be deemed interoperable if it has been certified by a certifying entity recognized by the Department of Health and Human Services (HHS) not more than twelve months prior to receipt by the physician practice. 42 C.F.R. § 411.357(w)(2).

<sup>2</sup>70 Fed. Reg. 59184 (Oct. 11, 2005).

<sup>3</sup>71 Fed. Reg. 45154 (Aug. 8, 2006).

<sup>4</sup>71 Fed. Reg. 45154 (Aug. 8, 2006). Such upgrades could “enhance the functionality of the physician’s existing technology, including upgrades that make software more user-friendly or current,” and permits standardization of systems among donors and physicians, as long as such standardization enhances the functionality of the electronic health records systems.

guarantee that their technology is not equivalent may present a lurking problem if CMS eventually provides a clearer definition with which the parties cannot comply. For the time being, parties must rely on their best judgment to ensure that they can meet the regulatory requirements, and simply hope that CMS maintains what appears to be a “common sense” approach to equivalency.

The donation must also be controlled by an agreement signed by the donor hospital and recipient physician practice, which specifies what items and services are being provided, the donor’s costs for such items and services, and the contribution by the physician practice. The agreement must also specify all of the EHR items and services provided by the donor. The recipient cannot require the donation before it will work with the donor, and the conditions for donation by the donor cannot be based on volume or value of the business referred or otherwise generated by the recipient.<sup>5</sup> Most importantly, the physician practice must pay at least 15 percent of the donor’s costs for the items and services provided.<sup>6</sup>

The two largest issues facing physician practices in the context of downstreamed Stark/anti-kickback regulated licenses are: (1) the contractual structure developed by the donor; and (2) the cost for the services. Two different models of Stark/anti-kickback downstreaming seem to be prevalent thus far. The first model is linear—the developer has a license agreement with the donor, while the donor has a sublicense agreement with the recipient practice. This places the physician practice in contractual privity with the donor, but not with the developer. It presents the simpler of the two models, however, because it only uses a single contract. The advantage of simplicity in contracting, however, may be offset by the fact that donors may be unwilling to enter into such an arrangement; doing so requires that they engage in far more management and oversight of the physician practice’s use of the software than the donor may want to.

The second model has more of a “V” shape in visual terms—the physician practice contracts with the donor for

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<sup>5</sup>The regulations describe numerous methods by which this may be shown. However, these are not the focus of this chapter.

<sup>6</sup>The donor cannot loan the 15 percent to the practice. 42 C.F.R. § 411.357(w)(4).

purposes of satisfying the Stark/anti-kickback requirements, and also contracts with the developer for the actual software and services themselves. The developer may also have a contract with the donor, but this is not “passed through” to the physician practice. This model is more complex for physician practices, but helps alleviate some of the concerns donors may have with respect to managing the practice’s use of the software. In addition, it may help the practice for purposes of ensuring continued operation of the software. Unlike the first model, there is a direct contractual relationship between the practice and the developer. Thus, any services provided by the developer become enforceable under the terms of the contract itself, rather than requiring litigation and claims surrounding laws of quasi-contracts and intended third-party beneficiaries.

From a contracting perspective, most of the regulatory requirements are addressed in the agreement between the recipient practice and the donor, rather than the practice and the developer. The typical approach thus far appears to be representations and warranties, or less imposing requirements or statements that effect the regulatory requirements. For example, language might read “Each party will comply with applicable laws and regulations relating to this Agreement.” This broad approach to regulatory compliance may be more palatable for the physicians reading the agreement, but does not deal with the specific requirements of the regulations the way other language might. For example,

In accordance with 42 C.F.R. § 1005.952(y) and 42 C.F.R. § 411.357(w), the amounts paid by Practice upon execution of this Agreement and prior to the receipt by Practice and its Physicians of the items and services under this Agreement represent 15 percent or more of Corporation’s total cost for the items and services to be provided in this Agreement.

This clause, along with other clauses similarly focused on specific requirements of the regulations, is both more explicit and more appropriate to a Stark donation model. Clearly spelling out the obligations of the parties in light of the regulatory requirements has the double benefit of removing ambiguity and putting all parties on notice of their regulatory obligations. However, while these requirements typically appear in agreements between the donor and recipient practice, they may still inform the contract language between the practice and the developer in a “V” shaped model.

**§ 2:7 Contract issues—In general**

Some problems are common to all of the major forms of downstreaming. We address these with special attention to the specific ways in which such problems manifest across different forms. Several problems reappear across the multiple different forms of downstreaming, just as they do across multiple different non-downstreamed EHRs. Inserting a “middleman” into the arrangement may create different duties, and place different liabilities on the parties than would otherwise exist in an arrangement between only two parties. Issues such as “pass-through” documents, controlling access to data, HIPAA issues, support clauses, disclaimers of liability, and data control all may play out differently in a downstreamed relationship.

**§ 2:8 Contract issues—Pass-through documents**

Downstreamed EHR licenses, like many agreements in health care, may include pass-through documents. Like managed care contracts that hold providers to the provisions of provider manuals, handbooks, and/or other external documentation not always included or incorporated into the agreement, a downstreamed software license may impose additional duties and penalties on a practice, elaborate in external documents on existing duties differently from what is stated in the main license agreement, or may limit the responsibilities of the developer or downstreaming entity.

Pass-through documents in downstreamed licenses may include software user manuals, use policies, handbooks, or even a separate agreement to which the user will be bound. The pass-through documents may impose additional requirements and restrictions on the end user, or may construe the duties of the downstreaming entity or the superior entity differently than as worded in the base contract.

Some contracts may include the pass-through documents as exhibits. For example, in one Stark donation model agreement, the end-user practice must:

[acknowledge and agree] that it is required to acquire and maintain, and is acquiring, a license for each provider [defined as a physician, nurse practitioner, physician assistant, or similar provider able to bill in their own name and who accessed the software at least twice in the past 90 days] consistent with the requirement imposed on [the

Hospital] pursuant to the Practice Management and EHR Systems Agreement between [the Hospital] and [the Developer of the software.]

Similarly, a different vendor sub-license references a “Project Agreement,” which itself outlines additional duties of both parties, and elaborate on the scope of services and products to be provided. The Project Agreement is incorporated into the main document by reference, but is not actually attached as an exhibit. Additional Project Agreements can be entered into, and all Project Agreements are “on the specific terms and conditions” of the main agreement.

In instances where the pass-through documents are not included, the end-user should obtain and review the pass-through documents prior to signing. It may be helpful to request that the downstream entity represent and warrant that the relevant documents requiring compliance have been provided to the end-user prior to signature. When the pass-through documents are included as an exhibit, it is important to ensure that the terms cannot be changed unilaterally or at least that the downstream entity will notify the end-user sufficiently in advance of any impending changes. Likewise, practices should request that language be added requiring that any amendments to either the main agreement or the pass-through documents be provided to the practice in writing in advance of their effective date.

Whether they are attached as exhibits or simply referred to in the base contract, it is crucial to read the pass-through documents closely to see where they differ with the base contract, and whether they interpret language from the base contract differently than expected. If there is a conflict in the terms, both the base contract and the pass-through document should be examined for a supremacy clause. If no such clause exists, one should be added either during the negotiation phase, or as an amendment after signing.

In certain cases, the majority of conditions imposed on the use of the software are contained in the pass-through documents rather than the base contract. For example, some agreements include lengthy use policies or user handbooks which place substantial requirements on the end-user, and to which the end-user is bound by the terms of the base agreement itself. The base agreement may be relatively circumscribed and simple on its face, but the lurking implica-

tions of the use policy may be significant and onerous. In one Stark donation model agreement, an entire thirty-plus page System Use Policy is incorporated into the agreement. The System Use Policy includes requirements and information on maintenance and support, committee memberships that must be entered into, etc.

Some pass-through obligations may simply be incorporated into the contract between the downstream entity and the end-user. For example, as a practical matter, a hospital donating an EHR to a physician practice under the Stark exception likely does not actually care if the physician practice modifies the EHR or decompiles it. However, the EHR developer has placed requirements on the hospital that it must not allow the end-users to modify or decompile the software, thus the hospital is obligated to pass such requirements on to the end-user.

### § 2:9 Contract issues—Use restrictions

Many software licenses control the scope of the license based on how many individuals are permitted to use the software. For example, many non-downstreamed licenses will price the software based on the number of individual users. With downstreamed licenses, controlling access to the software and how it is used may raise additional issues, based on the nature of the agreement.

A downstreamed vendor sub-license will be the least problematic. Vendor sub-licenses usually adopt the same form of access control as a non-downstreamed commercial license by simply requiring the end-user to pay a higher fee for adding new users. An example of “Scope of Use” language in a vendor sub-license is as follows:

Permitted Users and Facilities may have access to the [software] for Client’s internal use only and solely for purposes of viewing and processing data resulting from or related to clinical procedures or financial transactions performed at the Permitted Facility or for Client in a manner consistent with this Agreement and for which the [software] was designed.

Monthly payments for the software here are determined on a per-user basis. Material defaults under the agreement are grounds for termination, but the parties are given sixty days to cure the breach. Adding a Permitted User and fail-

ing to pay additional amounts would constitute a breach. However, the vendor presumably would permit the Client to simply pay the necessary increase and any outstanding balance, and continue providing services at the new, increased rate. With HIE and Stark donation models, the matter of access to and use of the software is not as simple.

For a Stark donation model, adding more users may involve additional calculations for purposes of satisfying regulatory requirements regarding the 15 percent practice contribution requirement. As a result, some donation models may adopt a tiered approach to controlling the number of users. For example, in one Stark donation model, a section titled “What Customer Pays” outlines that payment includes an initial set-up fee, tiered by group size, complexity, and number of sites. Payment also includes monthly fees, which are subject to adjustment based on changes in the number of authorized users. Recipient practices are further required to notify the donor in writing of the total number, type, and location of its current authorized users, and must keep the donor informed of any changes to this list.

An alternative to this approach may be for donor hospitals to only cover expenditures based on the initial 15 percent calculation, and to leave all additional costs to the practice. In this way, the donor would not have to address any potential problems raised by adding new users or adding new functionality. The donor could donate its share of the initial costs and include a clause in its agreement with the recipient that all additional fees are to be paid by the recipient. While this type of language was not found in any of the Stark donation model agreements reviewed for this chapter, it is certainly conceivable that donor hospitals might include such language to alleviate the need for complicated calculations. An even simpler approach is to price the license on a per-practice basis, rather than a per-user basis, thereby avoiding any potential problems with a need to recalculate the 15 percent contribution by the practice. Both approaches, however, may still require the practice to notify the hospital of who its authorized users are, so as to maintain proper confidentiality controls. This issue is of special import for HIEs and Stark donation models which include information exchange components.

For HIEs and Stark models with HIE aspects, in addition to the abovementioned potential problems, the participants

will need to limit access to only authorized users so as to protect the confidentiality of the information circulated on the network. HIE agreements may include extensive use restrictions, permitting only authorized personnel to access the HIE via the downstreamed software, as well as requiring use of the HIE only for specific purposes. For example, one agreement limits use of the HIE “to locate [patient data including demographic information, medical results, URLs and IP addresses for the data’s location, etc.] and to retrieve [such data].” Participants in the HIE are prohibited from using the HIE for any reason other than these or as permitted by the HIE organization itself. This HIE also limits access based on a maximum number of concurrent users from the participant. Other HIE agreements explicitly prohibit users from granting access to third parties, use of the information on the HIE network for research and/or marketing purposes, and use of the information to process data for others.

### § 2:10 Contract issues—HIPAA issues

Even in non-downstreamed agreements, HIPAA can be a concern requiring, at the very least, a business associate agreement between the practice and the licensor. With downstreamed software agreements, HIPAA can become a major obstacle that must be dealt with by contract, depending on the nature of the relationships involved. It will therefore be necessary to have a clear understanding of how and by whom protected health information (PHI)<sup>1</sup> will be used, so as to properly address the HIPAA concerns.

In a vendor sub-license, HIPAA concerns are less of an issue. If the vendor is the sole source of services and the developer plays no role in the transaction beyond having created the software and licensed it to the vendor, there is no need for the end-user to have any kind of business associate relationship with the developer. However, if both the developer and the vendor are providing services to the end-user, such as data storage, claims processing, or technical support that will grant the developer access to PHI, the end-

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#### [Section 2:10]

<sup>1</sup>PHI is defined in the HIPAA regulations as “individually identifiable information” which is transmitted or maintained electronically or in any other format. 45 C.F.R. § 160.103.

user. For example, in one vendor sub-license, the vendor provides technical support, but data backups are stored offsite at the developer's data warehouse. However, the end-user only has a direct contractual relationship with the vendor, and not with the developer. In such circumstances, the vendor might become a business associate, while the developer becomes a subcontractor of the vendor for purposes of providing data storage. Using this approach, the end-user physician practice could bind the developer to the same terms and conditions of the business associate agreement with the vendor, because the vendor would have the obligation to ensure that its subcontractors complied with the agreement.

In an HIE model, the organization of the HIE may require additional business associate agreements and specific authorizations, but the crucial question will be for what purposes the PHI is used, especially following termination by a participant in the HIE. If the PHI is being used primarily for treatment, payment, or operations (*i.e.*, two practices exchanging PHI to coordinate care for a common patient; participating practices send claims data to the HIE entity which submits them for payment on behalf of the practices; etc.), it will not require a specific authorization from the patient, but may require business associate agreements.<sup>2</sup> Most HIE agreements anticipate this issue and limit use as described in § 2:9.

The typical HIPAA business associate agreement requires that, following termination of the underlying agreement, the business associate will destroy or return all PHI provided by the covered entity. If this is not possible, the business associate is usually required to maintain the PHI under the same safeguards as applied while the business associate agreement was in force. With HIEs, however, matters are somewhat more complicated, due to the roles the various parties play.

An HIE organized on a peer-to-peer model will have an

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<sup>2</sup>Generally speaking, HIPAA permits nearly unlimited disclosures of PHI between covered entities for both treatment and payment purposes (the exceptions being information such as HIV status, mental health PHI, or drug or alcohol addiction PHI). 42 C.F.R. § 164.506(a), (c). However, with operations, HIPAA will only permit unlimited disclosures where there is a relationship between the covered entities in question and the patient who is the subject of the PHI. 42 C.F.R. § 164.506(c).

easier time complying with the HIPAA requirements. Under the peer-to-peer model, PHI is actually not maintained by the HIE entity itself. Instead, the PHI is all stored locally by the various participating covered entities. The HIE (via the software) merely acts like a search engine, which can tell the participants where PHI is located. Because no data is stored locally, when a participant terminates, the HIE need merely delete all references in its search engine to the terminating participant, and the HIE, as the business associate, will meet its obligation to delete PHI following termination. Assuming the covered entities that accessed the PHI had a relationship with the patient, the participants need not return or destroy the PHI, although they must still comply with the usual obligations of a covered entity.

With a centralized server model, the HIE will have to delete all PHI belonging to the terminating participant from its database. Again, assuming that the participants who accessed the terminating participant's PHI were covered entities with a relationship with the patient, they will not have to delete the PHI from their own records, nor will the HIE have to delete the PHI from the participants' records, to the extent such PHI has been duplicated in the remaining participants' records.

Both of these approaches, however, turn on the requirement that the participants only use the PHI for treatment, payment, or operations, and that they have a relationship with the patient in question. If participants access PHI for other uses, that will raise considerable complications for all parties involved, both because there may not be a business associate agreement between the specific participants in question, and for purposes of post-termination control of the data.

With Stark donation models, many arrangements are intended to allow exchange of information between the donating entity and the recipient practice. At the same time, additional services may be provided by the software developer. For example, recipient practices may be required to at least allow the donating entity to access patient records for those patients whom the two entities have in common. The developer of the software may also need access to the system itself (and thus will incidentally be able to see PHI) by virtue of the support services it provides or during installation. In this sense, the Stark donation model can

raise similar issues as the vendor sub-license and as the HIE agreement.

### § 2:11 Contract issues—Support clauses

Whenever a practice obtains software, ensuring continuing software support will be critical. In a downstreamed license agreement, support duties may be provided by the downstreaming entity alone, by the software developer, by both entities, or by the developer with the downstreaming entity requiring the developer to provide such support. It is critical to understand both the scope of support provided, and the source of the support so as to enforce the end-user's rights and guarantee continued smooth operation of the software.

Support services across each of the three major models may be provided by the downstreaming entity alone. For example, a vendor sub-license agreement might indicate that telephone support would be provided by the vendor, who would also implement any patches or updates created by the developer. A similar model used by an HIE states that the HIE will “exercise reasonable efforts to cause the Technical Vendor to maintain the [software] such that it shall be available and functional in accordance with [the terms of an Exhibit attached to the Agreement.]” The terms of the agreement between the HIE and the end-user practice include what amounts to a separate agreement with the Technical Vendor in the form of the Exhibit. The Exhibit lays out obligations of the Technical Vendor which include technical support for minor problems, “problem correction” for critical flaws in the software, and other services to ensure constant availability of the web-based software.

Similar approaches have the downstreaming entity acting as the sole point of contact for support services, or as the middleman between the practice and the developer. For example, one Stark donation model contract states that the donating entity would:

provide to Practice . . . (i) limited technical assistance via telephone available during [Donating Entity]'s business hours to diagnose the source of System failure or other problem; (ii) in the event that [Donating Entity] is unable to diagnose or remedy the failure or other problem, facilitation of communication between [Developer] and Practice

designed to diagnose and correct the failure or other problem; and (iii) upgrades to System as may be provided to [Donating Entity] by [Developer.]

In agreements such as these, support duties are split between the downstream entity and the developer itself to varying degrees. A similar support clause in an HIE agreement has the HIE providing the practices with substantially more support in the form of telephone, web, and e-mail technical support, diagnosis and correction of errors both at the participating practices' request and on the HIE's own initiative, and the performance of software modifications for a fee. However, creation of software updates and new versions was obviously left to the developer.

Finally, the downstream entity might wash its hands entirely of any support obligations. In one donation model agreement, the donating hospital completely removes itself from providing any support services to the recipient practice. Instead, the practice has an entirely separate agreement directly with the developer, under which the developer provided extensive support services for an annual fee.

The different approaches to providing support offer different advantages and disadvantages. It is important for end-user practices to determine which method best suits their needs. One disadvantage of a direct relationship with the developer is that it will require multiple contracts to be signed—including both an agreement between the end-user and the downstream entity, and an agreement between the end-user and the developer. Physician practices may find this burdensome. However, such an arrangement provides the most reliable support service from what should be the most knowledgeable source.

By contrast, an arrangement where all or most of the services, except updates to and new releases of the software, are provided by the downstream entity offers simplicity in the contracting process, but may not provide the practice with support services from those sufficiently experienced with the software. The decision in this case will rely on due diligence and determining the downstream entity's level of competence with resolving support issues. If the downstream entity can provide competent support, this may be the most efficient method, since it provides support from, presumably, local sources familiar to the practice.

Finally, an arrangement where support services are split

between the downstream entity and the developer, such as where the downstream entity provides “first tier” support and the developer provides support for more complex problems, offers its own pros and cons. As with the arrangement where the practice receives the bulk of its support from the downstream entity, this arrangement allows for simplicity in the negotiation process and only requires the practice to review a single contract. However, such an arrangement may prove infeasible or at least inconvenient when actually implemented. The practice runs the risk of hearing “That’s not our department. Call the other support line.” In addition, instead of placing a single call for support, the practice may be required to make multiple calls to different support centers. The practice might have to call the downstream entity first, only to determine that the problem is more severe than originally understood, necessitating a call to the developer’s own support line, where the practice might have to undergo yet more delays while the developer confirms that the problem is indeed severe enough to warrant its intervention.

### § 2:12 Contract issues—Disclaimers

All EHR or software license agreements include disclaimers of liability and warranties. Language is usually printed in boldface, capital letters, or some other obvious font to visually distinguish it from the surrounding clauses. Under a standard developer/end-user software license, the disclaimer of liability/warranties acts to protect the developer from being sued by the end-user if, for example, a software error in a computerized physician ordering system results in the death of a patient. In such circumstances, the disclaimer of liabilities will be worded such that the end-user can only obtain recompense at most for the cost for the software, rather than special damages such as consequential or punitive damages.

Similarly, most licenses disclaim specific warranties such as the warranty of merchantability, warranty of fitness for a particular purpose, or warranty of non-infringement. The disclaimers may also be worded to include “catch-all” language that disclaims all other warranties either express or implied. Downstreamed licenses are no exception in this regard, although they may differ in their construction based on the relationships between the parties involved.

In vendor sub-licenses, the disclaimers of warranties and limitations on liabilities may only apply to the vendor itself, and may make no mention of the developer at all. For example, a disclaimer might read:

THE APPLICATION SERVICES TO BE PROVIDED UNDER THIS AGREEMENT SHALL BE PERFORMED WITHOUT WARRANTY FROM [VENDOR] TO CLIENT OR ANY THIRD PARTY, SPECIFICALLY AND WITHOUT LIMITATION. THERE SHALL BE NO IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY AS MAY OTHERWISE BE APPLICABLE TO THE APPLICATION SERVICES TO BE PERFORMED OR PRODUCTS TO BE PROVIDED BY [VENDOR] HEREUNDER.

In the above language, the vendor is disclaiming warranties applicable to the services and products it provides. Similar language in the license applies to limitation of liability. However, neither the disclaimer of warranties nor the limitation of liability applies to the developer in any way. Thus, it is conceivable that an end-user could sue the developer for flaws in the software. However, if the document includes pass-through language covering disclaimers, the end-user will only have those legal recourses available under the contract. Disclaimers of warranties and limitations of liability do not differ significantly for other downstreaming models. In both the HIE model and the donation model, the disclaimers of warranties and limitations of liability only apply to the downstreaming entity, and do nothing to shield the developer.

### § 2:13 Contract issues—Data ownership and control

Data ownership and control should be a major concern for physician practices. Because data, even when de-identified, has commercial value, practices should seek to maintain control and ownership of as much of the data they generate as possible.<sup>1</sup> The use of EHRs and other practice management software provides practices with the tools necessary to

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#### [Section 2:13]

<sup>1</sup>For more on data control via contractual provisions, *see* Shay, “A Primer on Electronic Health Record License Agreements,” Health Law

create and monitor data more effectively. Depending on the nature of those tools and the terms of the license agreement, physician practices may give up more control than what they might otherwise prefer. Downstreamed license agreements will likewise pose additional concerns for physician practices.

Two key concerns applicable to all three models are: (1) the issue of offsite data storage; and (2) post-termination disposition of data. Many EHRs and practice management software packages allow for the storage of data at a location other than the practice's offices. While this may be convenient for a physician practice, it will naturally require close scrutiny of data use provisions in the license agreement, as well as the establishment of a business associate agreement between the practice and the entity providing offsite storage if the data involved is PHI. These issues will also affect how the data is dealt with after termination. Each of the three models for downstreaming must contend with these issues, but may deal with them differently due to the underlying nature of the relationships.

In a vendor sub-license relationship, the key question will be whether the vendor itself is providing the offsite storage, or whether the developer provides the storage. If the developer is providing offsite data storage, the physician practice must look closely at the terms of the agreement to determine how such services are handled. Ideally, the contract with the vendor should explicitly state that developer will provide the data storage services, and that the vendor shall ensure the developer does so, or that the vendor shall provide for alternative data storage services in the event that the developer is no longer able or willing to provide them. Thus, even though the developer is the entity providing the services, it is essentially treated as the subcontractor of the vendor and it is the vendor's duty to ensure data storage continues uninterrupted. Without this type of language, the developer could decide to stop providing the services and the physician practice would have to rely on quasi-contract theories to enforce the terms of the sublicense agreement, to which the developer is not a party.

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Handbook, 444-46 (Gosfield, ed. 2006). Data ownership clauses vary from license to license, and practices should carefully examine such clauses to determine which approach will most benefit the practice.

The simpler solution is where the vendor provides data storage services itself. Similar to the subcontractor language, this places the duty on the vendor itself to ensure uninterrupted data storage services. However, in this scenario it is the vendor who actually provides the service.<sup>2</sup> For example, the vendor sub-license might state that the vendor “will provide certain data center hardware and software to provide [offsite data storage and data processing services] to Client,” and further indicating that certain hardware (such as routers, ethernet cables, or other similar hardware) would be provided to the practice to facilitate the rendering of such services.

Regardless of which entity provides the data storage services, the physician practice should carefully examine the sub-license agreement to determine if and how its data may be used by the vendor and/or the developer. Some protection of the practice’s data may come via the terms of a confidentiality clause. For example, the clause might prohibit either party from using, disclosing, copying, distributing, selling, or otherwise making available to anyone other than the parties (or their employees, agents, attorneys, or independent contractors) “Confidential Information.” This naturally begs the question of what is considered “Confidential Information.” The definition may include some data that the practice wishes to keep strictly confidential, such as financial information, business plans or practices, PHI, or other such information. Depending on the breadth of the confidentiality clause, the practice may be able to prohibit all unauthorized use of its data.

However, even if the sub-license includes a broad confidentiality clause, a vendor sub-license may still include language that specifically permits the vendor and/or the developer to make use of some of the practice’s data. For example, a vendor sub-license states that both the vendor and the developer were permitted to use “blinded data” that did not identify a specific individual. The terms of the “Access to Data” clause in this case granted the vendor and developer

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<sup>2</sup>Of course, this is no guarantee that the vendor will not subcontract the services out to another entity altogether. If this is a concern for the physician practice, the practice should ask that language be added prohibiting the subcontracting of this and any other duties the practice wants to ensure are provided directly by the vendor.

an irrevocable, nonexclusive, transferable, perpetual license to use such data for “any purpose permitted by law, including, without limitation, comparative data analysis and the development, marketing and distribution of other products or services.” As compensation for this license of data, the practice would be permitted to access the comparative data “and other related services and products.”

The implication of this language is that the practice forever loses exclusive control over its deidentified data, but gains access to the comparative data provided by the developer and vendor. Practices must determine whether such an exchange is worthwhile. While the value-added comparative data might be attractive, is it worth giving up control of data that obviously has commercial value? If the practice wants to commercialize its data, granting a license to another party to use and commercialize the data will undoubtedly diminish its value for purposes of further distribution. This may not eliminate all of the data’s value, but the practice must still decide whether the contract language is worthwhile on balance. In addition, the effect of termination of the agreement is nil. By virtue of having granted an irrevocable, perpetual license to use the “blinded data,” the practice has no ability to recapture the data.

With Stark/anti-kickback downstreaming, data ownership is less of an issue for the practice. In both linear and “V” agreements, the downstream agreement typically will include provisions which specify that the data is owned by the practice itself. For example, in a “V” model agreement, the developer contract with the practice states, “As between Customer and [Developer], all patient demographics, medical records and [PHI] created by or stored in the [Software] is and shall be solely owned by the Customer.” The confidentiality clause stated that each party’s confidential information would remain the exclusive property of that party. Moreover, neither party was permitted to disclose the confidential information without authorization (except when required to by law, or when confidential information could be shown to have come from a legitimate alternate source). Taken together, and in the absence of any language granting the developer permission to use de-identified information, the agreement provides considerable protection for the practice’s data. Linear agreement models also include language that protects the confidentiality of PHI, although they do not

always discuss non-PHI data. Post-termination disposition of data in both models also typically favors the practice, with confidential information usually being returned to the practice upon termination of the license.

In instances both where non-PHI data is not discussed, and where it is specified as being the practice's information, it is in the practice's interests to inquire as to whether de-identified PHI or other data will be used by both the downstream entity and the developer. If there is any question regarding the use of this data and the practice wants to ensure that it retains as much control as possible, the practice should request that language be added explicitly prohibiting the downstream entity, the vendor, and any other entities from using, disclosing, or commercializing the data in de-identified form. The practice could still challenge the unauthorized use of the data without this language, but such an argument would be more difficult than if the contract clearly states that the data cannot be used.

The only instance in which Stark/anti-kickback statute models become more complex is when they also include provisions relating to a HIE. HIE models present a particularly difficult proposition for purposes of data use and control, both in terms of controlling data use during the term of the agreement, and in terms of recapturing disclosed data following termination. By their very nature, HIEs require that practices disclose at least the relevant PHI on a given patient; this is the very purpose of the HIE. However, this raises a host of issues surrounding HIPAA, as well as additional concerns regarding disclosure of other data.

Most HIE agreements clearly address the HIPAA issues raised by the sharing of data across multiple physician practices or other providers. HIE agreements typically include provisions requiring practices to sign additional security or HIPAA agreements, usually attached as exhibits to the main agreement. These agreements often limit the use of data (usually PHI) to uses related to treatment, payment, or operations, and may require the participating provider to have a treatment relationship with the patient to gain access. In some cases, the agreement specifically states that non-PHI data will not be part of the information shared. For example:

[HIE] agrees that no data (including aggregate data on a Participant level basis) concerning a Participant will be

provided to other Participants or published in an identifiable form without the written permission of the affected Participant. Such data includes, but is not limited to, patient volume, charges to patients or third-party payors and similar reimbursement data, and Participants' practice patterns.

Most agreements do not discuss whether or how deidentified data would be used. Practices should inquire about this prior to signing the license agreements.

A separate and far more complex question is how to handle post-termination disposition of data. Non-PHI data can be returned or destroyed following termination. But in many cases, depending on the nature of the HIE's architecture, PHI data cannot be returned. Some agreements do contemplate the return of PHI data following termination. For example:

[HIE] may use [Participant's] Patient Data as long as [HIE] complies with the provisions of this Agreement, until a patient's consent (if applicable) to such use of Patient Data is no longer in effect, until [HIE] discontinues use of the [HIE data exchange], or until this Agreement expires or is terminated as provided herein, whichever is shorter.

The implication of this language is that, following termination, the HIE would no longer access the participant's patient data. Such language lays the foundation for a post-termination nightmare scenario where other practices which have already accessed and used the data conceivably must somehow disengage the terminating participant's data from their own and return or destroy it. Most agreements adopt clearer language, indicating that the terminating participant is no longer required to *continue* providing access to its PHI, but that any PHI provided previously (especially PHI that has already been incorporated into another participant's records) will remain accessible to participants in the HIE. This is especially relevant to central-server model HIEs, although it can also apply to peer-to-peer models.

### § 2:14 Contract issues—Termination and transition

Termination and transition language are among the most critical provisions of any license agreement, whether traditional or downstreamed. The two primary questions for

any physician practice are: (1) what are the conditions under which the parties may exit the agreement; and (2) what are their respective duties following termination. The answers to these questions are every bit as important as their duties during the course of the license. Even in traditional software licenses, the termination language and post-termination duties can be problematic for physician practices, especially with regard to post-termination data control issues. Downstreamed licenses can present certain additional complications by virtue of their multi-layered nature, with each of the three different models discussed in this chapter having their own specific complications.

With vendor sub-licenses, termination provisions may be relatively straightforward. Parties typically may terminate for breach upon prior written notice. The amount of advance warning required varies from agreement to agreement and may include a cure period. Some breaches may result in immediate termination. Both parties should be able to terminate for breach. Causes for breach will also often be spread throughout the document, sometimes in the specific section dealing with the duty the breach of which will be grounds for termination. All of this is true in both traditional licenses and in sub-licenses. Where things become more complicated, however, is in the split among duties and in the ability of a party to enforce those duties.

For example, the vendor may be providing technical support to the practice, while the developer provides off-site data storage. If the practice has no direct contractual relationship with the developer, the vendor/practice agreement will need language guaranteeing that the developer continues to satisfactorily maintain and provide access to the data. Yet, without a direct contractual relationship, the practice will have no privity of contract with the developer and thus, no means to enforce the contract against the developer if there is a breach. Even if there is a clause in the agreement between the developer and the vendor stating that the vendor will continue providing support, the practice will have to file a lawsuit against the developer based on the theory that the practice was an intended third-party beneficiary to the developer/vendor license, and thus can enforce against the developer.

Filing a lawsuit, regardless of its chances of success, may not be in the practice's interests due to the expense and time

involved. A better solution is to request contract language that will help protect the practice from such issues. One option is to request that the developer and practice sign an addendum to the agreement which states that, even if the vendor terminates its relationship with the developer, the developer will continue to provide services to the practice. This will create explicit contractual privity between the developer and the practice. However, it may require the practice to pick up the cost of payment to the developer for the ongoing services. If the agreement between the vendor and practice remains in effect, the practice could ask that language be added to the license indicating that the vendor will either pay the developer directly for the services or reimburse the practice, although the vendor may not be willing to do either.

Another option is to add language stating that the services provided by the developer are unique; thus, any termination of the developer/vendor agreement which does not allow for ongoing services will result in termination of the vendor/practice agreement. If a practice has purchased the software from the vendor specifically because it includes services provided by the developer, the unwillingness or inability of the developer to continue to provide those services should permit the practice to terminate.

Once terminated, a key concern is the post-termination disposition of data. Some vendor sub-licenses require the practice to return or delete the software from their system, and return any associated documentation (such as software manuals) upon termination of the license. If this is the case, the license should include language permitting the practice to transition the accumulated data to another software system. In general, this will mean converting the data into another generally readable format, and providing the converted data to the practice on storage media. If the software is CCHIT certified, the practice should only need the vendor to provide it with the copies of its data.<sup>1</sup> If the license has terminated due to a breach by the vendor, or if the license is terminated because the vendor/developer agree-

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**[Section 2:14]**

<sup>1</sup>CCHIT certification implies interoperability in accordance with the definition of “interoperable” found in the Stark exception and anti-kickback safe harbor for donated EHR software. *See* § 2:2, note 10. Lists of

ment has terminated, the license should specify that such transitional services shall be provided at the vendor's expense. The termination language should also specify that, even if the license terminates due to the practice's breach, post-termination transition services will still be provided, albeit at the practice's expense.

HIE licenses often include similar, relatively simple provisions regarding termination like those seen in the vendor sub-license model. Like the language found in vendor sub-licenses, the HIE license's termination provisions will include grounds for terminating: (1) without cause upon prior written notice; (2) for cause; and/or (3) for other reasons including illegality of the agreement or bankruptcy. Where things become more complicated, however, is with respect to what constitutes a breach. Because HIEs are oriented around the sharing of confidential information, the parties are often subject to additional duties the breach of which will be grounds for termination. Whereas both a vendor sub-license and an HIE license will include grounds for termination such as an end-user's failure to pay for ongoing services, or reverse-engineering or unauthorized modification of the software, an HIE license will include duties such as the proper maintenance, access, and use of confidential information and/or PHI. Typically, these duties are spread throughout the body of the agreement. The termination language may refer to them specifically, or may be worded more generally. For example:

A significant breach of another Participant's duties of confidentiality under ARTICLE V of this Agreement with regard to Information stored on the Network by the withdrawing Participant, or a significant breach of [HIE]'s duties under Article VII or Article VIII [relating to HIPAA uses and disclosures for research purposes, and business associate obligations, respectively] with regard to Information stored on the Network by the withdrawing Participant (provided that the Participant has allowed a reasonable time for [HIE] to cure any such significant breach).

By contrast, another HIE agreement merely describes grounds for termination for cause to include circumstances

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currently certified ambulatory and inpatient EHRs can be found at <http://www.cchit.org/choose/index.asp>.

where one party determines that the other party was not performing its duties in accordance with the terms of the agreement. Regardless of the specificity of the termination clause language itself, end-users in an HIE will have to ensure that they appropriately comply with the ongoing use and confidentiality requirements. Such requirements should also apply to the HIE itself. Regardless of whether the HIE is a centralized server or a peer-to-peer model, the HIE should be required to terminate the access of any other participant who misuses or improperly discloses the practice's data. The HIE's failure to do so should constitute grounds for termination of the license by the practice.

Donated EHRs include many of the complications associated with both vendor sub-licenses and in some cases with HIEs if the parties choose to participate in one. However, some aspects of certain donated EHR arrangements may be relatively simple. For example, concerns regarding binding a developer to perform its duties will be easily resolved with a "V" shaped arrangement. Because the practice has a direct contractual relationship with the developer, all expectations regarding duties and their continued performance can be dealt with directly. Linear donation models, however, will still suffer the same complications as a vendor sub-license.

Both donation models will have to contend with complications raised by the nature of the Stark and anti-kickback regulations. Chief among these complications is the question of payment. As stated above, the regulations require that a recipient practice pay at least fifteen percent of the donor's costs for the EHR. In situations where the donor does not pay all of its 85 percent of the costs before the practice signs, when the donor terminates its agreement with the developer while there are payments outstanding, the practice may find itself between the proverbial rock and hard place. The practice may either agree to let the license lapse, or may choose to assume the donor's share of the payments and continue receiving services from the developer. Alternatively, if the donor's portion of the payment was simply the initial costs, and the practice is responsible for all ongoing maintenance payments, there may be no practical impact on the practice's payment obligations.

Such an arrangement may be more or less difficult from a practical perspective based on how the parties relate. For example, in a "V" shaped relationship, if the practice obtains

all of its services from the developer and the only ongoing obligation of the donor is to continue paying its share of the license costs, a clause can simply be included in the developer/practice license stating that any termination of the developer/donor license shall require the practice to assume the donor's payments or terminate the developer/practice license. In a "V" shaped relationship, the donor/practice agreement would obviously require a counterpart clause stating that: (a) if the developer/donor license is terminated, the practice shall assume the donor's payment obligations; and (b) any termination of the developer/practice license shall result in a termination of the donor/practice license. Alternatively, the developer/donor agreement could include a simple clause stating "The expiration or earlier termination of this Agreement shall not affect any [practice end-user license] then in effect and shall not relieve, release or discharge either party hereto from any obligation, debt or liability that may have previously accrued and that remains to be performed upon the date of termination."

In a linear relationship, depending on the extent of the services provided by the donor (if any), it may be infeasible for the practice to continue the license. The developer may be unwilling to step into the donor's shoes with respect to ongoing services, or the practice may not want the developer to do so. In either case, the cost associated with the donor's portion of payments for the license may prove too high for the practice, and it may simply be better to terminate the agreement. None of the linear donor/practice agreements reviewed for this chapter included language relating to how to handle such a scenario.

With respect to post-termination obligations, the same issues that apply to vendor sub-licenses and HIE arrangements can apply to Stark/anti-kickback donation arrangements. Obviously, the same post-termination data transition issues that apply in a vendor sub-license will apply to a linear donation model, and may actually be simpler in a "V" shaped model. Practices will still need to ensure that data is returned or destroyed or, if this is not possible, that confidentiality is maintained.

## § 2:15 Conclusion

Downstreamed EHRs may not be the federal government's

hoped-for solution to enhancing EHR adoption, but the underlying approach to delivering an EHR to a physician practice will likely persist. Certainly vendor sub-licenses and HIE arrangements do not appear to be falling out of favor among health care providers. Whereas many of the larger physician practices across the country may have already adopted an EHR, the smaller practices still must contend with the license negotiation process. These practices may have to contend with the complicated contractual landscape presented by a downstreamed EHR. Thus, it is crucial for these practices to understand the nature of the relationships involved, as well as the potential pitfalls lurking in a downstreamed relationship. With a clear understanding of the implication of contract language and prudent negotiation, smaller physician practices can navigate the sometimes murky waters of a downstreamed EHR.