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HEALTH LAW VITALS

A Healthcare Newsletter from Haynes and Boone, LLP

NOVEMBER 2016

QUICK SHOTS

Penalties under the False Claims Act nearly doubled as of August 1, 2016, to a minimum of $10,781 per claim and a maximum of $21,563 per claim. **Read more.**

U.S. Supreme Court resolves circuit split regarding the implied certification theory under the False Claims Act. **Read more.**

CMS releases **final rule** establishing emergency preparedness requirements for Medicare and Medicaid providers and suppliers. **Read more.**

HHS releases new security risk assessment tool to help small-and medium-sized health care providers conduct risk assessments of their organizations. **Read more.**

HHS guidance on cloud computing and HIPAA compliance for cloud services providers and their customers. **Read more.**

Haynes and Boone announces new Health and Welfare blog. **Read more.**

Seventh Circuit Requires Objective Standards in Medical Necessity Cases

Jeremy D. Kernodle and Taryn McDonald

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The Seventh Circuit recently held that a relator's subjective evaluation of medical necessity, standing alone, is not a sufficient basis for a fraud claim under the False Claims Act (FCA). In *U.S. ex rel. Presser v. Acacia Mental Health Clinic, LLC*, the nurse-relator alleged that a number of her employer's practices and policies were not medically necessary, including (1) mandating patients be assessed by at least four different individuals before provided with medication; (2) requiring that patients undergo mandatory drug screening during each visit; and (3) requiring patients to come to the clinic in person in order to obtain prescription refills or speak with physicians.[1] In support of her claims, the relator cited to her own personal view and experience, but provided "no medical, technical, or scientific context" explaining why the clinic's policies and procedures constituted medically unnecessary care.

The Seventh Circuit held that the relator's own personal opinion that such policies and procedures were unnecessary was not enough to state a claim under Federal Rule of Civil Procedure 9(b). The relator did not reference policies or practices at other clinics, regulations, or other publications to support her conclusion. Further, the relator failed to put the clinic's activity into relevant context. Without additional context as to why the policies and practices were inappropriate, the court found the allegations to be too indefinite. The court pointed out that many relators could state that the clinic's activities were contrary to their own personal experience, but it is possible that those relators might not see the entire picture, might simply have a subjective disagreement, or might be affected by personal bias. Emphasizing that the "heightened possibility of mistake or bias supports the need for a higher standard of specificity for fraud," the court affirmed the lower court's dismissal of the medical necessity-related claims.

The implications of the Seventh Circuit's opinion are significant for FCA defendants facing similar claims. Under *Presser*, relators not only must

provide context as to why particular policies and practices are inappropriate or unnecessary, but also must support their theory with something more than their own personal opinion or experience in the industry. Such requirements present a substantial hurdle for FCA relators and should protect defendants against claims by relators who might simply have a difference of opinion or lack full information.

[1] The relator also alleged the clinic misused a certain billing code, the only claim that the Seventh Circuit allowed to move forward.

New Guidance on EHR Contract Negotiation Should Facilitate Implementation

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Twelve years ago, the Department of Health and Human Services (HHS) established the Office of the National Coordinator for Health Information Technology (ONC) and called for the nationwide implementation of electronic health records (EHRs), or, in essence, a paperless healthcare system, within a decade. Use and functionality of EHRs have increased rapidly since then, buoyed by the financial incentives offered for healthcare providers that demonstrate meaningful use of EHRs pursuant to the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH). But large-scale adoption and application of EHRs still present certain challenges. For example, acquiring a new EHR system or updating an old one may require conversion of existing medical records, changes in the way documentation is handled, and new training of employees. Such activities often result in increased workload and costs and potentially lost revenue caused by disruptions associated with system conversion and integration with existing infrastructure.

These challenges and consequences can be exacerbated if providers do not obtain favorable agreements with EHR vendors, especially with cloud-based EHR systems in which providers often

UPCOMING EVENTS

ABA 39th Annual Forum on Franchising

Menu Labeling - Cheese Fries for 700 Calories, Please

Suzie Trigg

November 2-4, 2016 | Miami, Florida

2016 Texas Association of Health Plans - Managed Care Conference & Trade Show

Modernizing Medicaid: What's New in Medicaid Managed Care Rules, Part 1: Overview of New Federal Rules

Michelle Apodaca

November 15, 2016 | Dallas, Texas

pay vendors a subscription fee to use the system rather than purchasing and installing the software themselves.[2] To this end, the ONC recently released a new guidance document entitled *EHR Contracts Untangled: Selecting Wisely, Negotiating Terms, and Understanding the Fine Print* (the "Guide"). The Guide addresses issues healthcare providers must consider when navigating the EHR implementation process and negotiating key vendor contract provisions.

The first steps in providers' selection of an EHR system involve identification and prioritization of their technical and operational requirements and comparison of possible EHR systems and types. The ONC's Guide explains why these steps are important for providers' comprehension and communication of their needs to potential EHR vendors, which, in turn, serve as a framework for negotiating reasonable contract terms.

The Guide stresses that providers should not rely on a vendor's demonstration of its product or the claims and statements made in a vendor's marketing materials. Instead, providers must ensure that the EHR contract's express terms reflect their needs, since the contract alone defines and limits parties' rights and obligations. For example, a good contract will spread the responsibility for preventing and mitigating different safety risks among both parties, while also expressly referencing the specific amount and type of training provided by the vendor for its provider customers. The ONC previously released a guide explaining key EHR contract terms in 2013, and *EHR Contracts Untangled* supplements the agency's resources to translate legal and contract terms into easy-to-understand language for providers.

The ONC's Guide also emphasizes that providers should negotiate certain express warranties to create legally enforceable rights with respect to core EHR system performance expectations. This is important to ensure a vendor support when a provider faces problems such as system unavailability at critical times, a slow or unresponsive system affecting the ability to provide medical services, or the unavailability of important data. In addition, providers should attempt to obtain guaranties that the vendor's system allows sharing and seamless integration of data from the provider's other sources—also known as interoperability—without the vendor being able to block the exchange of patient data or terminate system access.

The Guide covers different types of EHR systems, and explains the difference between on-site deployment (requiring providers to pay for ongoing costs to support and manage on-site data servers) and software-as-a-service (SaaS) deployment (typically requiring providers to pay a fixed monthly subscription cost). SaaS EHR solutions are growing in popularity, as they allow vendors to make upgrades and repairs without the provider's involvement while simultaneously allowing providers and staff members to access the system from remote locations.

But SaaS EHRs also mean the vendor stores all patient data and documentation. The Health Insurance Portability and Accountability Act (HIPAA) requires covered entities and business associates to enter into contracts with their business associates to ensure that protected health information is appropriately safeguarded (Business Associate Agreements).[2] The Guide, however, points out the value of negotiating terms related to data rights and information security as part of the EHR contract rather than relying solely on the provisions of Business Associate Agreements. This means contracts with vendors should include terms concerning the provider's exclusive ownership of data stored in, created by, or received by the EHR; control over the vendor's ability to de-identify and commercialize data; and the vendor's approach to data backup and disaster recovery. The contracts may

also cover what would happen if a vendor is acquired by another entity, goes out of business, or otherwise encounters hurdles that affect its ability to deliver continuous service.[3] More generally, EHR contracts should cover transition issues and how a provider can continue operation of its system and retain immediate access to all data in a variety of emergency scenarios.

Finally, the ONC's Guide explains how intellectual property (IP) provisions in an EHR contract not only protect providers but also outline the extent to which providers can customize or enhance their systems. The Guide emphasizes that EHR vendors should warrant that their software does not infringe on any patent, copyright, trademark, trade secret, or other IP right of any third parties. Vendors should also indemnify providers from all costs associated with infringement of such third party rights, as damages awarded in IP cases involving EHR software can reach millions of dollars.[4] Relatedly, EHR contracts should include terms concerning limitations of liability and damages, management of risks, contract termination, and dispute resolution.

EHR Contracts Untangled provides valuable guidance for healthcare providers that are adopting an EHR system for the first time or upgrading and replacing existing technology. As EHR implementation and use continue to grow, the Guide will assist providers with better communicating their health information requirements to potential vendors, negotiating favorable contract terms, managing risks, and addressing security and intellectual property issues.

[1] *See* Sam Narisi, **Watch out for these common EHR contract pitfalls**, HEALTHCARE BUSINESS & TECHNOLOGY (Aug. 13, 2013)

[2] A "business associate" is an entity or individual that performs certain functions or activities on behalf of a "covered entity" (*e.g.* health providers and insurers). 45 C.F.R. § 160.103.

[3] Jenny Jackson et al., *Negotiating the EHR Vendor Contract*, 96 BULL. AM. COLL. SURG. 12, 14 (2011).

[4] For example, a jury awarded medical software giant Epic Systems $240 million in compensatory damages and $700 million in punitive damages in a lawsuit against Indian IT provider Tata Consultancy Services for unauthorized access and use of confidential information and trade secrets. Epic alleged that Tata employees hired as consultants to help a Kaiser Permanente medical center implement an Epic EHR used their temporary access to Epic's databases to download confidential source code and data and then used this information to benefit Tata's competing EHR software. See Epic Sys. Corp. v. Tata Consultancy Servs. Ltd., No. 14-cv-748-wmc, 2015 WL 7301245 (W.D. Wis. Nov. 18, 2015).

The Sandbox Bully: Health Savings Accounts, Onsite Clinics, and Telemedicine

Christopher A. Beinecke

Christopher Beinecke

Employers, particularly those employers that feel they are running out of room to further pare down medical plan design(s) or shift cost-sharing to employees, are increasingly looking toward alternatives like telemedicine and onsite clinics to help lower the cost of their group health plans.

Telemedicine is relatively easier to implement than an onsite clinic. Onsite clinics require a sufficient concentration of participants (which can include employees and their dependents) in a given location to be effective. Having a sufficient concentration of participants is less of an issue for healthcare systems, which also have the advantage of being able to operate an onsite clinic as an own-use facility. *Note: It is possible for multiple employers to share an onsite clinic with clever separate accounting and administration, but that is beyond the scope of this article.*

For all of their advantages, health savings accounts (HSAs) do not easily co-exist with many other benefits. This article focuses on the

HSA-compatibility issues employers face when implementing telemedicine and/or an onsite clinic in conjunction with a high deductible health plan (HDHP) with an HSA and potential solutions.

HSA "Eligibility"

In order for an individual to be eligible to make or receive HSA contributions, he or she must be covered under an HDHP and not have any other disqualifying coverage. Other disqualifying coverage includes many arrangements that do not qualify as an HDHP and that pay for medical expenses, including most forms of traditional health insurance, Medicare, and general purpose healthcare flexible spending accounts and health reimbursement arrangements that can reimburse an individual's medical expenses (including the expenses of a covered spouse or dependent).

Through what is best described as scattered guidance, there are a number of exceptions to this *other disqualifying coverage* rule:

- Coverage for preventive services (including within the HDHP itself);
- "Permitted insurance," including property and casualty insurance that pays benefits for accident or injury, workers' compensation, insurance for a specified illness or disease (e.g. cancer, diabetes, asthma), and indemnity coverage;
- "Permitted coverage," including dental, vision, accident, disability, and long term care coverage;
- Employee assistance program, disease management, and wellness coverage that do not provide significant medical care benefits;
- Arrangements that provide medical benefits only after the statutory minimum deductible for an HDHP has been met (which also means coverage under more than one HDHP does not create an HSA eligibility conflict), known as "post-deductible benefits;" and
- Services for which the individual has paid fair market value (effectively meaning that there was no other disqualifying coverage with respect to the service(s)).

An arrangement may fit under more than one exception.

Pain Points

It is a fairly common misconception that maintaining other disqualifying coverage affects eligibility under the HDHP itself. It does not, although dual coverage may create a coordination of benefits issue between the HDHP and the other disqualifying coverage. Instead, other disqualifying coverage causes the individual to be ineligible to make or receive HSA contributions. Eligibility is determined on the first of each month.

An employer generally has no obligation to police the eligibility status of its employees outside its own knowledge and only a limited ability to force a recovery of HSA contributions when: (i) the individual was never eligible for an HSA contribution, (ii) an amount contributed was in excess of the statutory annual limit, or (iii) there is clear case of administrative error.

An individual who has made or received an ineligible contribution must take a corrective taxable distribution for the ineligible contribution plus any related earnings before their personal income tax return due date for that year (generally April 15th of the following year) or pay a 6 percent excise tax on the ineligible amount. The excise tax is not a one-shot penalty that absolves the ineligible amount and continues each year until the corrective distribution is taken. Admittedly, unless the individual self-reports, the IRS needs to be aware of the ineligible contribution in order to penalize the individual.

Note: Other disqualifying coverage does not generally affect HSA contributions the individual was eligible for or his/her ability to use those funds to reimburse for qualifying medical expenses.

Telemedicine, Onsite Health Clinics, and HSA Eligibility Solutions

It is reasonable to assume that many telemedicine and onsite health clinic benefits will be considered other disqualifying coverage and cause an HSA eligibility issue without some sort of solution to resolve the conflict:

1. Limit the scope

   The benefits could be limited in scope to services that do not interfere with HSA eligibility such as preventive services, dental or vision care, first aid (in the case of the clinic), or other services deemed insignificant care by the IRS such as immunizations and providing non-prescription pain relievers.

   This solution falls into the category of legally correct but not particularly useful, as limiting the scope of telemedicine and/or onsite health clinic benefits in this manner can defeat the purpose of meaningfully lowering the cost of the employer's health plan.

2. Provide only post-deductible benefits

   If the benefits are restricted to an HDHP participant until after he or she has met their HDHP deductible, there is no HSA conflict. This solution also falls into the category of legally correct but not particularly useful and can be both difficult and impractical to administer.

3. Charge fair market value for the services

   If the HDHP participants pay the fair market value (FMV) for the services received, there is no HSA conflict. While unpleasant, this is often the most practical solution to implement. There is no guidance explicitly directing how to calculate FMV for these benefits, which should make several approaches reasonable:

   (a) Use the Medicare reimbursement rate for the given service;

   (b) Use the in-network usual, customary, and reasonable charge for the given service; and

   (c) Develop standard rates for services/bundles of services based on the expected cost of providing them through the telemedicine or onsite health clinic benefit.

Flat rates are very common for telemedicine and clinic "visits" with additional charges for labs, tests, or prescriptions. An employer (particularly a healthcare system) may determine a discount is appropriate when determining the appropriate rates to take into account the lower cost of providing the services through an onsite clinic or via telemedicine compared to general medical facilities. It is also not unusual for third-party administrators to have developed standard rates for services using the methods described above that employers can implement. If there is a monthly cost for access to the telemedicine or onsite health clinic benefit, that could be factored into the FMV fee calculation.

HSA contributions can be used to offset the cost of services for the telemedicine and onsite health clinic benefits, and employers can provide HSA seeding contributions to assist. No fee needs to be charged for limited scope services (*e.g.*, preventive, dental, vision, etc.). Although it adds a layer of administrative complexity, it is also true that the clinic does not need to charge anything once the individual has met the HDHP deductible for the year.

If point-of-service charges are limited to HDHP participants, it does raise a potential nondiscrimination issue under the Tax Code.

However, if there is a reasonable mix of both highly and non-highly compensated participants in the HDHP and other medical plan options, this should not present a problem.

We recommend that the costs for telemedicine and onsite health clinic benefits that are fully integrated with medical coverage (e.g., you must be a participant in the medical coverage to use the telemedicine and/or clinic benefit) accumulate toward the individual's out-of-pocket maximum limit in that medical coverage. An employer could choose to exclude these costs from the corresponding deductible.

We'd like to hear your feedback and suggestions for future newsletters. Please contact:

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