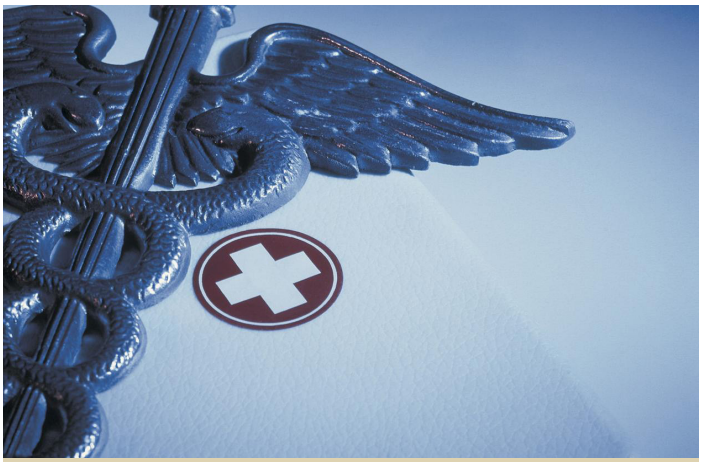

August 2015 • Volume 5, Number 3

IN THIS ISSUE

DW HEALTHCARE BLOG
http://www.dwhealthlawblog.com/

DICKINSON WRIGHT'S

HEALTHCARE **LEGAL**NEWS

RESPONDING TO SUBPOENAS AND OTHER REQUESTS FOR PERSONAL HEALTH INFORMATION: TAKE THEM AT FACE VALUE

by Billee Lightvoet Ward, Of Counsel
Grand Rapids, 616.336.1008
Kalamazoo, 269.276.9444
bward@dickinsonwright.com

Healthcare providers and other HIPAA covered entities receive requests for protected health information ("PHI") from a variety of sources on a daily basis. Such requests can range from informal requests made during the course of conversation with a patient or family member, to written requests or demands served by law enforcement personnel or through a formal legal process. For more common requests, such as when a patient requests access to his or her PHI, covered entities typically have established procedures for documenting the request and responding in a manner that complies with HIPAA and applicable state laws. Although requests for PHI in the form of subpoenas, requests for production and other legal documents may be less common, it is no less important for covered entities to know what is (and is not) required of them in responding to such requests.

The general principle under HIPAA is that covered entities may use or disclose PHI only as permitted or required under the HIPAA Privacy Rule or as authorized in writing by the patient (or his/her personal representative) who is the subject of the PHI. HIPAA contains various exceptions to this general principle that provide the boundaries within which PHI may be used or disclosed in specific situations. In the context of litigation or other legal proceedings, if a covered entity is a party to the proceeding, the covered entity is generally permitted (with certain exceptions and limitations) to use or disclose PHI for purposes of the proceeding as part of the covered entity's healthcare operations. It is often the case, however, that covered entities receive requests or demands for PHI in relation to legal proceedings to which they are not parties. In those situations, if the patient's authorization cannot be obtained, HIPAA permits covered entities to disclose PHI under certain conditions. Because HIPAA distinguishes between requests that are authorized by an order of a court or administrative tribunal, and subpoenas or other requests that are not accompanied by such an order, it is crucial to make this determination from the face of the documents received.

Judicial and Administrative Proceedings: Disclosures Pursuant to Court Order

HIPAA permits covered entities to disclose PHI in the course of any judicial or administrative proceeding "in response to an order of a court or administrative tribunal, provided that the covered entity

discloses only the protected health information expressly authorized by such order." See 45 C.F.R. 164.512(e)(1). A court order may require production of Tom Smith's medical records from January 1, 2000-December 31, 2000, for example. In responding to such an order, the covered entity must be attentive to the language on the face of the order and ensure that it limits disclosure of PHI only to what is specified in the order. Only Tom Smith's medical records should be produced, but production should include his full medical records from the year 2000. The covered entity must fully comply and respond to the order in a timely fashion or risk being held in contempt of court.

Judicial and Administrative Proceedings: Requests Not Accompanied by a Court Order

When a covered entity receives a subpoena, discovery request, or other request that is not accompanied by a court order, the covered entity must ensure that additional protections are in place before disclosing the PHI. These protections are referred to as "satisfactory assurances" and can come in the form of: (1) written assurance that good faith attempts have been made to notify the patient; or (2) written assurance that the parties have agreed to or requested a qualified protective order. See 45 C.F.R. 164.512(e)(1)(ii).

1. **Notice to the Patient.** To allow for disclosure of the requested PHI, the covered entity may obtain a written statement and accompanying documentation from the requesting party that: (A) the party has made a good faith attempt to provide written notice to the patient; (B) the notice included sufficient information about the legal proceeding to permit the patient to raise an objection to the court; and (C) the time to object has passed, and the patient did not object or any objections have been resolved and the disclosure is consistent with such resolution. See 45 C.F.R. 164.512(e)(1)(iii).

2. **Qualified Protective Order.** Another option that allows the covered entity to disclose the requested PHI is to obtain a written statement and accompanying documentation that the parties to the proceeding have agreed to a qualified protective order and presented it to the court or the party requesting the PHI has requested a qualified protective order from the court. The qualified protective order must prohibit the parties from using or disclosing the PHI for any purpose other than the legal proceeding and require the parties to return the PHI to the covered entity or destroy the PHI at the end of the proceeding. See 45 C.F.R. 164.512(e)(1)(iv).

A covered entity is permitted to disclose the requested PHI if, in lieu of obtaining satisfactory assurances from the requesting party, the covered entity makes reasonable efforts on its own to provide the required notice to the patient or seek the qualified protective order. See 45 C.F.R. 164.512(e)(1)(vi).

Additional Considerations:

When a covered entity receives any request for PHI in the context of litigation or other legal proceedings, HIPAA should be considered at the forefront. It can be helpful to remember that, for purposes of HIPAA, disclosure in response to such requests is *permitted* but not required; although there may be other statutes, court rules and practical considerations that also apply and may warrant or compel disclosure. In the process of assessing its response, the covered entity should also consider whether de-identified information would be responsive to the request. De-identifying PHI, or obtaining a HIPAA-compliant authorization from the patient, can significantly reduce potential HIPAA liability exposure. If PHI must be disclosed, covered entities must make reasonable efforts to limit such PHI to the minimum necessary to accomplish the intended purpose of the request.

It can sometimes be difficult for covered entity personnel to determine whether a subpoena or other request constitutes a court order or is simply a subpoena for records. Legal documents sometimes have a tendency to look alike, and the difference can depend on who is signing the document (a judge versus an attorney, for example). Additionally, subpoenas, civil investigative demands, and similar requests that arise in judicial and administrative proceedings may also be served in the context of a law enforcement inquiry or health oversight activity. The HIPAA Privacy Rule contains specific requirements for disclosures in those contexts, so careful consideration must be given to each request to determine which HIPAA exception applies. In addition, each covered entity should have clear and compliant policies and procedures that outline the internal processes for handing responses to subpoenas and other requests for PHI. If there are questions or uncertainties that arise, covered entities should consult with an attorney who is well-versed in HIPAA and applicable state privacy laws to ensure that all applicable legal requirements are met.

QUI TAM LAWSUITS AND THE STATUTE OF LIMITATIONS

by Keith C. Dennen, Member
Nashville office
615.780.1106
kennen@dickinsonwright.com

In *Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter*, 575 U.S. _____) (2015), Justice Alito stated "[t]he False Claims Act's qui tam provisions present many interpretive challenges." Lawyers and judges who struggle with those challenges understand the truth of that statement. The United States Supreme Court recently resolved two of those issues.

1. Does the Wartime Suspension of Limitations Act toll the statute of limitations? No, that act only tolls criminal proceedings.

2. Does the "First to File" Rule bar subsequent lawsuits if the first action is dismissed? The "First to File" Rule bars a "qui tam" action during the pendency of the first action and, upon its conclusion, another relator may file a lawsuit involving similar facts.

False Claim or "qui tam" lawsuits have proliferated as whistleblowers and their legal counsel have discovered the financial benefits of being the "qui tam" relator. Although "qui tam" lawsuits have become synonymous with healthcare, Congress enacted the False Claims Act

in 1863 due to the "rampant fraud" being committed by suppliers to the Union Army during the Civil War. Congress recognized that it was impossible for the federal government to police this industry effectively because of the sheer number of contractors. Therefore, Congress provided a process in which a private citizen with knowledge of fraud (called a relator) could file a lawsuit on behalf of the government. To incentivize the filing of these lawsuits, the False Claims Act permitted the relator to obtain a percentage of the ultimate recovery by the government.

The False Claims Act contains an express statute of limitations (31 U.S.C. § 3730). That statute requires a lawsuit to be filed within six (6) years of the violation, but no later than three (3) years after the date that the United States should have known about the violation. In *Kellogg Brown*, the question was whether another statute -- the Wartime Suspension of Limitations Act – tolled the running of the statute of limitations. The Supreme Court held that it did not. Instead, the Court held that the express language of the Wartime Suspension of Limitations Act made that act applicable only to criminal prosecutions and not to cases involving "civil claims."

The False Claims Act also includes a provision that bars an action if it is filed after another action -- the "first to file" bar. Specifically, the False Claims Act provides that "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). In *Kellogg Brown*, two qui tam lawsuits were filed that alleged substantially similar facts. The *Kellogg Brown* lawsuit was the second lawsuit filed. Therefore, the trial court dismissed that lawsuit as being barred by the "first to file" bar. While an appeal was pending, the first lawsuit was dismissed. The relator refiled his lawsuit, but the court dismissed the lawsuit once again stating that the "First to File" bar applied. The Supreme Court rejected this argument noting that the express language of the statute provided that the first-to-file bar ceases once the earlier action is dismissed.

For healthcare providers, the *Kellogg Brown* decision removes one source of uncertainty and creates another source of uncertainty. The False Claims Act statute of limitations will not be tolled during time of "war" regardless of the definition of "war", but the settlement or dismissal of a qui tam action will not necessarily bar another individual from filing a lawsuit on the same grounds. The Supreme Court noted that the dismissal of the first filed action may have "claim preclusion" effect if the action is decided on its merits; however, the Court relegated that issue to another day. Healthcare providers should consider the impact of this decision during settlement discussions for qui tam cases.

OIG FRAUD ALERT REGARDING PHYSICIAN COMPENSATION ARRANGEMENTS: WHAT YOU NEED TO KNOW

by Jessica L. Russell, Associate and Emily Procyk, Summer Associate
Troy office,
248.433.7503
jrussell@dickinsonwright.com

On June 9, 2015, the Department of Health and Human Services' Office of the Inspector General ("OIG") issued a new fraud alert regarding physician compensation arrangements, with a particular emphasis on medical director arrangements. The OIG urged physicians to "carefully consider the terms and conditions of medical directorships and other compensation arrangements before entering into them," so as to avoid violation of the Anti-Kickback statute.

This Fraud Alert serves as a reminder to physicians that prior to entering into compensation arrangements, they should verify that the payments reflect fair market value for the services provided and are not calculated based on the volume or value of the physician's referrals of patients covered by a federal healthcare program or other business generated between the parties. This latest fraud alert mentions medical directorships in particular because of the concern that schemes exist to compensate referring physicians improperly through positions that require few actual duties. However, medical directorships are just one type of physician compensation arrangement that could violate the Anti-Kickback statute.

The Anti-Kickback statute is both a civil and criminal statute that prohibits the exchange (or offer to exchange) of anything of value to induce or reward the referral of patients participating in a federal healthcare program. The statute establishes penalties for parties on both sides of the prohibited transaction ranging from a fine per violation of up to $25,000 to imprisonment for up to five years. A successful conviction under the Anti-Kickback statute requires proof that a defendant intended to engage in illegal activity, though not necessarily proof that a defendant knew the activity violated the Anti-Kickback statute specifically.

The OIG has adopted various "safe harbors" to the Anti-Kickback statute, which create a presumption of legality for arrangements that meet their criteria. Structuring physician compensation arrangements to comply with a specific safe harbor – such as the employment or the personal services and management contracts safe harbor – can help ensure that physicians, their employers, and other parties paying for physician services avoid the Anti-Kickback statute's significant penalties.

Impact on Physicians:

This is the third fraud alert in three years in which the OIG has focused on individual physician behavior. The alert was spurred by settlement agreements the OIG recently reached with 12 individual physicians accused of entering into questionable compensation arrangements. The OIG pointed to three major violations of the Anti-Kickback statute by these physicians: (1) the payments received by the physicians took into account the physicians' volume or value of referrals and the payments did not reflect the fair market value for the services the physicians performed; (2) the physicians themselves did not provide the actual services required under the agreements; and (3) some of the physicians had entered into arrangements in which a healthcare entity affiliated with the party paying for the physicians' services also paid the salaries of the physicians' office staff, which constituted additional improper remuneration.

The Fraud Alert puts individual physicians on further notice that compensation arrangements could have Anti-Kickback implications if they are not carefully structured. Because the Anti-Kickback statute is an intent-based statute, issuance of a fraud alert makes proof of intent a smaller hurdle for the government. Physicians should also be aware of the OIG's continuing focus on individual physicians along with large healthcare groups and other healthcare providers. Physicians should thus be careful to structure their compensation arrangements so that they fit within a safe harbor to the Anti-Kickback statute and avoid arrangements that are considered "red flags," such as bonuses based on patient referrals and certain percentage-based payment arrangements.

Impact on Hospitals and Other Healthcare Providers:

Compensation arrangements in violation of the Anti-Kickback statute implicate both parties to the agreement. As a result, hospitals and other healthcare providers must also ensure that medical director agreements and other physician compensation agreements are structured in compliance with the Anti-Kickback statute. Meeting the requirements of the personal services and management contract safe harbor to the Anti-Kickback statute is one way to avoid liability. Compliance with that safe harbor requires that the contract between the healthcare provider and a physician meet the following requirements:

1. The agreement is set out in writing and signed by the parties.

2. The agreement covers all of the services the physician provides to the principal for the term of the agreement and specifies the services to be provided by the physician.

3. If the agreement is intended to provide for the services of the physician on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.

4. The term of the agreement is for not less than one year.

5. The aggregate compensation paid to the physician over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other federal healthcare programs.

6. The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any state or federal law.

7. The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

OIG guidance has also suggested several best practices that providers and hospitals should employ for physician compensation arrangements, including maintaining time logs and other accounts of services performed by physicians, implementing and maintaining a compliance program, and ensuring there is a legitimate business justification for any arrangement with a physician.

When entering into a compensation arrangement, both parties must ensure that the physician's compensation reflects the fair market value of the services provided and is not determined in any way by the number or value of patient referrals. Compensation can include anything of value and is not limited simply to a paycheck. To avoid Anti-Kickback liability, physicians and healthcare providers should carefully structure physician compensation arrangements in such a way that they meet the requirements of an applicable safe harbor.

DICKINSON WRIGHT OFFICES

Detroit
500 Woodward Ave.
Suite 4000
Detroit, MI 48226
Phone: 313.223.3500

Columbus
150 E. Gay St.
Suite 2400
Columbus, OH 43215
Phone: 614.744.2570

Las Vegas
8363 West Sunset Rd.
Suite 200
Las Vegas, NV 89113
Phone: 702.382.4002

Lexington
300 W. Vine St.
Suite 1700
Lexington, KY
Phone: 859.899.8700

Nashville
424 Church St.
Suite 1401
Nashville, TN 37219
Phone: 615.244.6538

Phoenix
1850 North Central Ave.
Suite 1400
Phoenix, AZ 85004
Phone: 602.285.5000

Reno
100 West Liberty
Suite 940
Reno NV 89501
Phone: 775-343-7500

Toronto
199 Bay St., Suite 2200
Commerce Court West
Toronto ON M5L 1G4
Phone: 416.777.0101

Washington, D.C.
1875 Eye St., NW
Suite 1200
Washington, DC 20006
Phone: 202.457.0160

Ann Arbor
350 S. Main St.
Suite 300
Ann Arbor, MI 48104
Phone: 734.623.7075

Grand Rapids
200 Ottawa Ave., NW
Suite 1000
Grand Rapids, MI 49503
Phone: 616.458.1300

Lansing
215 S. Washington Square
Suite 200
Lansing, MI 48933
Phone: 517.371.1730

Music Row
54 Music Square East
Suite 300
Nashville TN 37203
Phone: 615.577.9600

Saginaw
4800 Fashion Square Blvd.
Suite 300
Saginaw, MI 48604
Phone: 989.791.4646

Troy
2600 W. Big Beaver Rd.
Suite 300
Troy, MI 48084
Phone: 248.433.7200