Health Law Developments

The Newsletter of the Health Law Section
State Bar of Georgia
June 2015

From the Chair

Greetings Health Law Section Members,

The Executive Committee has been busy planning activities on behalf of the Section this year and we are excited about our upcoming events.

The Health Law Section recently co-sponsored the Georgia ICLE Fundamentals of Health Law Program. Thanks again to program chair Rob Meadows along with everyone who participated for another successful program.

The Section will also be sponsoring the annual Advanced Health Law Program on Friday, October 30, 2015, at the Four Seasons in midtown Atlanta. We hope that you will be able to join us. The Executive Committee is currently planning the program and is excited to include a wide range of current topics.

We would like to thank all of the authors who contributed to the Spring 2015 Health Law Section Newsletter, and we are grateful for their contributions. In this most recent edition:

- Amy Fouts, Laurice Rutledge Lambert, and Jennifer Whitton offer their perspectives on Congress's repeal and replacement of the sustainable growth rate formula for physician reimbursement;
- Randy Dalby, Emma Cecil, and John K. Larkins provide commentary on the relationship between the Stark Law, the federal Anti-Kickback Statute, and the federal False Claims Act;
- Jill M. Girardeau and Yami Mackenzie provide their insights regarding the implications of health information technology under the Stark Law and the Anti-Kickback Statute; and
- Rebecca Merrill examines the courts' increasing reliance on HIPAA as the standard of care in common law negligence actions.

We also would like to thank Brian Stimson for his leadership and time spent recruiting authors and editing and publishing the newsletter.

The Executive Committee strives to prepare meaningful, substantive programs for the section and provide members with information relevant to the practice of health care law in Georgia. We invite you to submit articles, reports, and proposals for presentations that would be informative to the membership. Additionally, please be on the look-out for future notices about upcoming events including a social event this summer for section membership.

It is an honor to serve as Chair of the Health Law Section this year. Please let me know if you have any ideas or suggestions that might help us better serve you.

Best regards,

Mark S. Kashdan

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Health Law Developments **is looking for authors of new content for publication.**

If you would like to contribute an article or have an idea for content, please email Brian Stimson at Brian.Stimson@alston.com

The opinions expressed within *Health Law Developments* are those of the authors and do not necessarily reflect the opinions of the State Bar of Georgia, the Health Law Section or the Section's Executive Committee.

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The False Claims Act on Steroids: The Impact of the Stark and Anti-Kickback Laws on Health Care Fraud Complaints

by John D. "Randy" Dalbey[1], Chilivis Cochran Larkins & Bever LLP

With the incredible focus by the United States government on alleged healthcare fraud, and the potentially huge financial recoveries under the federal False Claims Act (FCA), ever-increasing numbers of FCA complaints are being filed against healthcare providers each year.[2] Many of us probably think of these FCA complaints in the traditional sense – those alleging that a provider billed for services not rendered, double billed, upcoded, or unbundled claims. Increasingly, however, violations of both the federal Stark Law, 42 U.S.C. § 1395nn, and the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b), are being alleged as the basis of "false claims" under the FCA. The likely effect will be a continuing increase in the number of potential complaints, and the amounts of potential recovery.

BACKGROUND

The FCA prohibits "knowingly"[3] presenting a "false claim" for payment by the government, "knowingly" making a false statement "material to" such a false claim, and "knowingly" retaining funds that the recipient or holder knows it is not entitled to receive or retain.[4] Moreover, the FCA allows private citizens, known as "relators," to file suits alleging violations of the FCA.[5] When a relator files an FCA complaint, they must file under seal so that the government may investigate the claims and determine if it wants to intervene and take over the lawsuit.[6] If the government intervenes and ultimately obtains a recovery, then the relator receives between 15 percent and 25 percent of the recovery; if the government does not intervene, and the relator elects to proceed with the lawsuit and ultimately obtains a recovery, then the relator receives between 25 percent and 30 percent of such recovery.[7] Recoveries can be massive, as the FCA also provides for treble damages against the defendant and a penalty of between $5500 and $11,000 for each claim submitted,[8] as well as payment of the relator's attorneys' fees.[9] This article will not discuss all healthcare-related FCA claims and defenses;[10] instead, it will focus on those FCA claims that are based on alleged violations of the Stark Law or the AKS.

FCA CLAIMS BASED ON ALLEGED STARK LAW OR AKS VIOLATIONS

The Stark Law prohibits a physician from referring patients to an entity for certain "designated health services"[11] payable by Medicare if the physician or a member of his or her immediate family has a financial relationship with the entity, unless an exception applies.[12] The AKS is a criminal statute that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs.[13] Remuneration is broadly interpreted and includes the transfer of anything of value or the flow of benefits, directly or indirectly, overtly or covertly, in cash or in kind, that may influence referrals.[14]

How does a "false" claim or statement result from physician self-referrals or the payment or receipt of payment for referrals? After all, the patient will have received services that are covered by Medicare or Medicaid and for which Medicare or Medicaid is obligated to pay. An FCA case based upon purported violations of the AKS typically alleges that the provider, in submitting a claim to Medicare or Medicaid for payment for those services, falsely certified that the claim complies with all federal statutes.[15] A "false certification" alleged to form the basis of an FCA claim may be either express or implied. An "implied" certification means that the provider, simply by submitting the claim, implicitly certifies that the claim is in compliance with the Stark Law and the AKS.[16] Courts have treated FCA claims based on false certifications of compliance with the Stark Law and the AKS as falling into both categories.[17]

Importantly, the FCA was amended in 2009 to impose liability for false statements that are "material" to a claim.[18] The FCA now defines "material" as anything "having a natural tendency to influence, or being capable of influencing, the payment or receipt of money or property."[19] A false statement could thus be considered "material" even if it had no impact on the government's decision to pay. While the courts have not explicitly so held, it seems fairly clear that a "false certification" of compliance with the Stark Law or the AKS is a false statement that is "material" to a false claim, particularly since courts have held with "near unanimity" that a certification of compliance with the Stark Law or the AKS is a condition of payment of a claim.[20]

In 2010, the AKS was amended to expressly provide that a claim "resulting from" a violation of the AKS is a "false claim" for purposes of the FCA.[21] Although the meaning of "resulting from" is not entirely clear, at least one court has found that, in amending the AKS to include this language, "Congress gave absolutely no indication that it intended to amend the definition of the word 'false' in the FCA, or to limit the FCA's reach where kickbacks were concerned."[22]

See False Claims on page 4

False Claims from page 1

In light of the foregoing, there is little support for an argument that violations of the Stark Law or the AKS are insufficient to support an FCA claim.

STARK LAW + AKS = FCA CLAIMS ON STEROIDS

The Stark Law's prohibition against self-referrals and the AKS's prohibition against payments to induce referrals are both interpreted broadly.[23] Both statutes then contain protective safe harbor provisions that are limited in scope. They also authorize the U.S. Department of Health & Human Services to promulgate regulations containing additional safe harbor provisions. This regulatory regime, combined with the FCA, presents great risk for health providers.

First, the Relator's bar typically maintains that outside of the safe harbors, every transaction between two health care providers may lead to FCA liability. Many courts interpret the "safe harbors" as affirmative defenses that must be pleaded, and proven by the provider invoking them.[24] Unless the relator inadvertently alleges facts showing that the defendant complied with a safe harbor, the defendant may have difficulty winning a Rule 12(b)(6) motion to dismiss that is based on a safe harbor. A shrewd pleader may be able to evade dismissal by simply alleging that no safe harbor has been met. When this happens, the defendant must incur the cost and inconvenience of defending against the claim.

Moreover, the damages for which a provider may be held liable on such a claim can be staggering, since damages are not measured by the usual concept of loss to the plaintiff.[25] Instead, damages for an FCA claim based on a Stark Law or AKS violation are essentially punitive, in that their measure appears to be every dollar paid to the provider from the time of the violation.[26] These damages are then *trebled*, with the per-claim fines and penalties stacked on top.[27] Such a measure of damages also makes proving the amount of damages easier, since there is no need to prove the falsity, or amounts, of individual claims (either directly or statistically).

The lure of such large damages undoubtedly provides a huge incentive for the filing of FCA claims based on Stark Law and AKS violations. Because the FCA protects employees against retaliation,[28] large numbers of whistleblower FCA complaints are now being filed by current and former high-ranking employees of large healthcare providers.[29] This trend is easy to understand, since nearly every transaction or relationship between and among healthcare providers potentially implicates the Stark Law or the AKS, any damages may be enormous and capable of fairly straight-forward proof, and whistleblowers are protected against adverse employment actions. Yet another incentive is the rule that only the "first [relator] to file" an FCA complaint can share in the recovery.[30] It is no wonder, then, that some lawyers who defend FCA cases believe that an ever-increasing number of whistleblower complaints are being pursued by private attorneys after the government declines to intervene.

CONCLUSION

Certainly, the waters of the healthcare industry are a dangerous place for providers to swim. But as always, careful planning and close analysis of compliance with the Stark Law and the AKS when entering into financial relationships or transactions with other providers are essential to minimizing this risk.

1 The author wishes to thank Emma Cecil, Esq. and John K. "Jake" Larkins, Esq., for their assistance.

2 In FY 2008, the number of healthcare-related FCA cases filed by relators nationwide was 231; in FY 2013 that number was over 500. Taxpayers Against Fraud Statistics, *available at*: http://www.taf.org/resource/fca/statistics (last visited May 4, 2015).

3 "Knowingly" under the FCA means that "a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required." 31 U.S.C. § 3729. While the False Claims Act imposes liability only when the claimant acts "knowingly," it does not require that the person submitting the claim have actual knowledge that the claim is false.

4 31 U.S.C. § 3729(a).

5 31 U.S.C. § 3730(b).

6 *Id.*

7 31 U.S.C. § 3730(d).

8 31 U.S.C. § 3729(a)(1).

9 31 U.S.C. § 3730(d). Since 2012, FCA claims that included allegations of illegal kickbacks were settled against GlaxoSmithKline for approximately $2 billion, Justice Department Recovers Nearly $5 Billion in False Claims Act Cases in Fiscal Year 2012, *available at*: http://www.justice.gov/opa/pr/justice-department-recovers-nearly-5-billion-false-claims-act-cases-fiscal-year-2012 (last visited May 4, 2015); against Abbott Laboratories for just under $1 billion, *id.*; against Johnson and Johnson and two subsidiaries for approximately $1.1 billion, Justice Department Recovers Nearly $6 Billion from False Claims Act Cases in Fiscal Year 2014, *available at*: http://www.justice.gov/opa/pr/justice-department-recovers-nearly-6-billion-false-claims-act-cases-fiscal-year-2014 (last visited May 4, 2014); and against Omnicare for $116 million, *id.*

10 Likewise, this article will not attempt to address claims made under the Georgia False Medicaid Claims Act, as that Act is substantially similar in material respects to the FCA.

11 Designated health services, or "DHS," include laboratory services, physical therapy, occupational therapy, radiology and imaging, radiation therapy, durable medical equipment, prescription drugs, hospital, home health, and a number of other services. 42 U.S.C. § 1395nn(h)(6).

12 42 U.S.C. § 1395nn(a).

13 42 U.S.C. § 1320a-7b(b).

14 *Id.*

15 For instance, the CMS Form 1500 on which a provider submits a claim states that the provider's signature certifies that the claim complies with "all applicable Medicare and/or Medicaid laws, regulations and program instructions"; and the Medicare enrollment forms, CMS 855 and 855i, state that the provider "understand[s] that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with [Medicare] laws… (including, but not limited to, the Federal anti-kickback statute and the Stark law)…." CMS 1500, available at: http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS1188854.html?DLPage=1&DLFilter=1500&DLSort=0&DLSortDir=ascending (last visited May 4, 2015).

16 *See, e.g., United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 59-60 (D. Mass. 2011); *United States ex rel. Pogue*

v. Diabetes Treatment Ctrs. of Am., 565 F. Supp. 2d 153, 158-60 (D.D.C. 2008) (discussion of FCA claims based on alleged AKS violation); *United States ex rel. Schubert v. All Children's Health Sys., Inc.*, No. 8:11-CV-1687-T-27EAJ, 2013 WL 1651811, at *3 (M.D. Fla. Apr. 16, 2013) (citing cases recognizing the "implied certification" theory of FCA liability).

17 *See United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.*, No. 6:09-cv-01002-ORL-31, 2012 WL 921147, at *4 (M.D. Fla. Mar. 19, 2012).

18 31 U.S.C. § 3729(a)(1)(B).

19 31 U.S.C. § 3729(b)(4).

20 *Pogue*, 565 F. Supp. 2d at 160. Of course, the implied certification must impact a condition of payment, such that the government would not have paid had it been aware of the violation. *See, e.g., United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 269 (5th Cir. 2010) ("[A] false certification of compliance, without more, does not give rise to a false claim for payment unless payment is conditioned on compliance."); *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001) ("[A] claim under the Act is legally false only where a party certifies compliance with a statute or regulation as a condition to governmental payment."); *United States ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000) ("[A] false certification of compliance with a statute or regulation cannot serve as the basis for a *qui tam* action under the False Claims Act unless payment is conditioned on that certification.").

21 42 U.S.C. §1320a-7b(g).

22 *See United States ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp.3d 323, 331-32 (S.D.N.Y. 2014) (rejecting defendant's argument that the 2010 AKS amendment created a strict "but for" causation requirement on a transaction-by-transaction, claim-by-claim basis, such that AKS violations can only give rise to legally "false" claims where the decision to provide medical treatment is caused by a kickback scheme).

23 *See, e.g.*, *United States ex rel. McDonough v. Symphony Diagnostic Servs., Inc.*, No. 2:08-CV-00114, 2014 WL 3906461, at *7 (S.D. Ohio Aug. 12, 2014) (noting that "the AKS's broad definition of remuneration as 'anything of value' could embrace relator's theory of illegality based upon defendant's pricing of its Part A services below costs); *Ameritox, Ltd. v. Millennium Labs., Inc.*, No. 8:11-CV-775-T-24-TBM, 2014 WL 1456377, at *3 (M.D. Fla. Apr. 14, 2014) (noting the "broad definition of remuneration" under the AKS); *United States v. Halifax Hosp. Med. Ctr.*, No. 6:09-CV-1002-ORL-31, 2014 WL 68603, at *3 (M.D. Fla. Jan. 8, 2014) (noting that the Stark Law places a "broad prohibition on compensation arrangements between health care entities and referring physicians"); *Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 678 (N.D. Ill. 2006) ("Remuneration, for purposes of the AKS, is defined broadly, meaning 'anything of value.'"); *United States v. Shaw*, 106 F. Supp. 2d 103, 114 (D. Mass. 2000) (citing 42 C.F.R. Part 1001, 56 Fed. Reg. 35952–01 (July 29, 1991) ("Congress's intent in placing the term 'remuneration' in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever.")).

24 *United States ex rel. Willis v. Angels of Hope Hospice*, Inc., No. 5:11-CV-041 MTT, 2014 WL 684657, at *11 (M.D. Ga. Feb. 21, 2014) ("[T]he employment exception to the AKS is an affirmative defense on which [defendant] has the burden of proof."); *United States ex rel. Osheroff v. Tenet Healthcare Corp*., No. 09-22253-CIV, 2012 WL 2871264, at *7 n.11 (S.D. Fla. July 12, 2012) (stating that the "financial relationship" element of a Stark violation "is subject to numerous exceptions that may be raised by Defendants as affirmative defenses"); *Baklid-Kunz*, 2012 WL 921147, at *5 ("[Stark] exceptions would appear to be affirmative defenses that must be raised by the Defendants."). *See also United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 98 (3d Cir. 2009) (holding that defendant failed to meet burden to demonstrate its right to an exception under the Stark Act).

25 In an FCA case based on an alleged violation of the Stark Law or the AKS, the patient typically has received Medicare or Medicaid-covered services that are paid pursuant to a set fee schedule – thus, there arguably is no "loss" to the government.

26 *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008); *United States ex rel. Freedman v. Suarez-Hoyos*, 781 F. Supp. 2d 1270 (M.D. Fla. Mar. 18, 2011).

27 In *Rogan*, the verdict against the defendant was $64 million, affirmed on appeal. Without expressly so deciding, the Court indicated that this verdict appeared not to violate the "excessive fines" clause of the Eighth Amendment. *Id.* at 454.

28 31 U.S.C. § 3730(h).

29 *United States ex rel. Barker v. Columbus Reg'l Healthcare Sys.*, No. 4:12-cv-108 (M.D. Ga. 2012) (filed by defendant's current administrative director); Second Am. Compl. ¶ 8, *United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.*, No. 6:09-CV-1002-ORL-31 (M.D. Fla. Feb. 18, 2011), 2011 WL 10885443 (filed by hospital's Director of Physician Services); *United States ex rel. Williams v. Health Mgmt. Assocs. Inc., Tenet Healthcare, et al.*, No. 3:09-CV-130 (M.D. Ga.) (filed by HMA's former CFO); *United States ex rel. Miller v. Health Mgmt. Assocs. Inc., et al.*, No.10-3007 (E.D. Pa.) (filed by former CEO and CFO of hospital); *United States ex rel. Nurkin v. Health Mgmt. Assocs. Inc., et al.*, No. 2:11-cv-14-FtM-29 (M.D. Fla.) (filed by former CEO of hospital); *United States ex rel. Jacqueline Meyer & Cowling v. Health Mgmt. Assocs. Inc., et al.*, No. 0:11-cv-01713-JFA (D.S.C.) (filed by former Regional Client Administrator and former hospital CEO); *United States ex rel. Paul Meyer v. Health Mgmt. Assocs. Inc., et al.*, No. 11-62445 cv-Williams (S.D. Fla.) (filed by HMA's former director of compliance).

30 31 U.S.C. § 3730 (b)(5).

A Permanent Doc Fix? – New Legislation Repeals Unpopular SGR and Moves Towards Merit-Based Payments

by Amy Fouts, Laurice Rutledge Lambert and Jennifer Whitton, McKenna Long & Aldridge LLP

On April 16, 2015, President Obama signed into law the Medicare Access and CHIP Reauthorization Act of 2015 (H.R. 2), more commonly known as the "doc fix" bill (the Act).[1] The Act, in part, repeals Medicare's widely unpopular sustainable growth rate (SGR) formula for physician reimbursement and replaces it with a new payment model based on performance and quality.[2]

The new reimbursement model will provide modest increases to physician payments annually from 2015 through 2019, at which time payments will be frozen at the rates in effect on Jan. 1, 2019, and remain static until 2025. The static rates are the result of two new incentive models that provide physicians and other eligible professionals the opportunity to earn incentive payments based on (1) meeting certain quality performance measures established and reported under the "Merit-based Incentive Payment System" (MIPS); and (2) participating in alternative payment models (APMs). The key provisions of these new Medicare physician payment models are outlined below.

Out with the "Old" Medicare SGR Payment System

The Medicare SGR formula was established by Section 1848(f) of the Social Security Act (the SSA), as amended by Section 4503 of the Balanced Budget Act of 1997, which specified a formula for establishing yearly SGR targets for physicians' services under Medicare.[3] The SGR was originally intended to control the growth in aggregate Medicare expenditures for physician services.[4] In practice, the SGR has routinely resulted in drastic cuts to physician payments, which have largely been avoided by Congress' routine "SGR patches," each of which has frozen physician payments for the term of the patch. Since the SGR's enactment and including the current "doc fix," Congress has enacted a total of seventeen patches costing an estimated $169.5 billion.[5]

In With the "New" Pay-For-Value Payment System

Under the Act, certain physicians and other health care professionals will be eligible for merit-based incentive payments under the MIPS. The MIPS applies to payments for Medicare items and services furnished by physicians and other eligible professionals on or after Jan. 1, 2019. Notably, the MIPS consolidates incentives from three current Medicare programs: (1) the Electronic Health Record (EHR) Meaningful Use Incentive Program, which entails meeting certain requirements in the use of certified EHR systems; (2) the Physician Quality Reporting System, which incentivizes professionals to report on quality of care measures; and (3) Value-Based Payment Modifier, which adjusts payments based on quality and resource use in a budget-neutral manner. Under the Act, these three programs will sunset prior to the implementation of the MIPS in 2019.

The Act has also eliminated one of the barriers to the use of merit-based incentive programs by amending the Civil Monetary Penalties Law (CMP Law) to allow for greater use of "gainsharing programs." Gainsharing programs allow hospitals and physicians to reduce inefficiencies and waste by focusing on those services that provide the best patient outcomes at the lowest cost. Under the original CMP Law, any hospital or critical access hospital could not knowingly make a payment directly or indirectly to a physician as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's care.[6] The Act amends the CMP Law by adding the phrase "medically necessary" after "reduce or limit," thereby allowing hospitals and physicians to create merit-based incentive programs as long as the programs do not induce physicians to reduce or limit medically necessary services.[7] This change reduces the chilling effect that the prior CMP Law had on merit-based programs and aligns the CMP Law with the broader statutory and regulatory move towards greater use of coordinated care.

Who Is Eligible For Participation In the MIPS?

The MIPS applies only to "MIPS Eligible Professionals," which is defined to include physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and groups that include such professionals. The MIPS will require the reporting of certain quality measures by MIPS Eligible Professionals and offer bonuses or penalties based on whether a MIPS Eligible Professional scores above or below certain thresholds based on those quality measures. It is important to note, however, that the MIPS requirements and payment methodology will not apply to MIPS Eligible Professionals who participate in APMs, individuals who are partial qualifying APM participants (and meet all other requirements under the Act), or MIPS Eligible Professionals who do not exceed certain low-volume threshold measurements set forth in the Act.

How Are Mips Eligible Professionals Evaluated?

The Act establishes four performance categories

under the MIPS, each of which factor into a MIPS Eligible Professional's composite performance score and are weighted as follows:

1. *Quality* (30 percent of the composite performance score);
2. *Resource use* (30 percent of the composite performance score);
3. *Clinical practice improvement activities* (15 percent of the composite performance score); and
4. *Meaningful use of certified EHR technologies* (25 percent of the composite performance score).

Within these four performance categories, the Act contemplates that a list of quality measures will be established and updated annually. MIPS Eligible Professionals and the Department of Health and Human Services (HHS) will use these quality measures to assess performance within each category and report performance under the quality measures. Stakeholders and certain professional organizations are invited to propose quality measures to be considered by HHS for selection. For each listed quality measure, the Secretary will establish certain performance standards. These performance standards will take into account historical performance standards, improvement and the opportunity for continued improvement.

Based on the performance standards for each quality measure within a particular performance category, each MIPS Eligible Professional will receive a composite performance score ranging from zero to 100. For each year of the MIPS, a "Performance Threshold" will be computed by HHS that equals the mean or median of the composite performance scores for all MIPS Eligible Professionals with respect to a prior performance period and will be reassessed every three years. MIPS Eligible Professionals' payments under the MIPS will be based on a MIPS adjustment factor that is determined by comparing the composite performance score of a MIPS Eligible Professional to the applicable Performance Threshold.

MIPS Eligible Professionals with composite performance scores at, or above, the applicable Performance Threshold will receive a "0," or positive payment adjustment factor, for such year, and those MIPS Eligible Professionals with composite performance scores below the applicable Performance Threshold will receive a negative payment adjustment factor. Payment incentives and penalties under this new system will range from a maximum of four percent penalty or bonus in 2019 to a nine percent penalty or bonus for 2022 and subsequent years. Additionally, from 2019 through 2024, MIPS Eligible Professionals whose composite performance scores are exceptional, meaning their score reaches or exceeds an "additional" Performance Threshold,[8] are eligible to receive even greater incentive payments. MIPS Eligible Professionals who fail to report on an applicable measure or activity that is required to be reported will be treated as achieving the lowest potential score applicable to such measure of activity.

What About Practitioners Already Participating In Apms?

The Act also amends Section 1833 of the SSA, by creating a new provision for incentive payments based on participation in an APM. This program signifies another step in Medicare's effort to move away from fee-for-service payment models and encourages physician participation in collaborative, pay-for-performance models. "Qualifying APM Participants" already participating in an APM as of 2019 are eligible to be paid an incentive amount equal to five percent of the estimated aggregate payment amounts for covered professional services[9] rendered for the preceding year, in addition to the amount of payment that they would otherwise earn for such covered professional services in the current year. An APM means any of the following payment models:

- a model under Section 1115A of the SSA, other than a health care innovation award;
- the shared savings program under Section 1899 of the SSA;
- a demonstration under Section 1866C of the SSA; or
- a demonstration required by Federal law.

Qualifying APM Participants are eligible professionals[10] for whom participation in an APM accounts for an increasing share of the eligible professional's practice, beginning at a 25 percent share for 2019 and 2020 and increasing to a 75 percent share from 2023 onward.[11]

Navigating the Changing Healthcare Landscape

The trend towards implementing pay-for-performance models under Federal health care reimbursement systems has become increasingly common since the passage of the Affordable Care Act (the ACA) and it seems likely that over the next decade, quality and outcome driven care will largely replace traditional fee-for-service care. According to current HHS Secretary, Sylvia Burwell, "[a] majority of Medicare fee-for-service payments already have a link to quality or value. [HHS's] goal is to have 85 percent of all Medicare fee-for-service payments tied to quality or value by 2016, and 90 percent by 2018."[12]

Pre-existing quality reporting programs established by the ACA have laid the groundwork for the Act's merit-based payment model. The Hospital Inpatient Value-Based Purchasing (VBP) Program, Hospital Readmissions Program and Healthcare Acquired Conditions Reporting Program are all current and ongoing efforts that link federal health care dollars to performance and quality. The Hospital Inpatient VBP Program, in particular, has a similar premise to the MIPS, in that hospitals are rewarded or penalized depending on their performance in response to minimum quality thresholds.[13]

Given the framework of the payment models established by the ACA and the bipartisan Act, health care providers and practitioners will need to begin (or continue) collaborating and shifting their delivery models towards clinical integration that rewards quality and performance over quantity. This shifting paradigm will hinge on investment in health care information technology, evaluation of affiliated health insurance plan products and the adoption of care models applicable to all governmental and private pay beneficiaries. Although providers are happy to say goodbye to the SGR formula, many are apprehensive about the unfamiliar and untested performance-based model that lies ahead.

1 Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10 (2015).
2 The Act includes other significant provisions such as a two-year extension of the CHIP program, new restrictions on Medigap coverage of Part B deductibles, tying Part B premiums to beneficiary income levels and various program integrity measures. This paper does not address these provisions.
3 *Estimated Sustainable Growth Rate and Conversion Factor for Medicare Payments in 2015*, Centers for Medicare and Medicaid Services, Apr. 2014, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SustainableGRatesConFact/Downloads/sgr2015p.pdf.
4 *Id.*
5 Barbara L. McAneny, MD, Chair, AMA Board of Trustees, American Medical Association, A Permanent Solution to the SGR: The Time is Now, Before the H. Committee on Energy & Commerce Subcommittee on Health, Jan. 21–22, 2015.
6 SSA, 42 U.S.C. § 1128a(b)(1) (2012).
7 The Act, Pub. L. No. 114-10, § 512(a)(1) (2015).
8 The additional Performance Threshold is a score that is equal to the 25th percentile of the range of possible performance scores above the applicable Performance Threshold, or a score that is equal to the 25th percentile of the actual composite performance scores for MIPS Eligible Professionals with composite performance scores at or above the applicable Performance Threshold for the applicable performance period.
9 "Covered professional services" are defined by Section 1848(k)(3) of the SSA as "services for which payment is made under, or is based on, the fee schedule established under this section and which are furnished by an eligible professional."
10 Section 1848(k)(3) of the SSA defines an eligible professional as a (i) physician, (ii) practitioner (defined as a physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse-midwife, clinical social worker, clinical psychologist, or a registered dietitian or nutrition professional), (iii) physical or occupational therapist, (iv) a qualified speech-language pathologist or (v) a qualified audiologist.
11 Note, the definition of Qualifying APM Participant also contemplates other more nuanced avenues of qualification and contains requirements not fully addressed herein.
12 Sylvia Burwell, *Setting Value-Based Payment Goals—HHS Efforts to Improve U.S. Health Care*, 372 New Eng. J. Med. 897 (2015).
13 SSA, 42 U.S.C. § 1886(o)(3)–(5) (2012).

HIPAA Gains Traction as the Standard of Care in Common Law Negligence Cases

by Rebecca J. Merrill, Dentons US LLP

Legal pundits have long predicted an uptick in negligence lawsuits premised on the standards set forth in the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (HIPAA).[1] Their predictions are now ringing true, as a growing number of federal and state courts are concluding that HIPAA supplies the standard of care in common law negligence actions for damages resulting from health privacy breaches. The capstone of this legal trend is *Byrne v. Avery Center for Obstetrics & Gynecology, P.C.,* 102 A.3d 32 (Conn. 2014). This article surveys the case law over time and across geographies, up to and including *Byrne.* In addition, this article explains why health care providers must remain vigilant when handling personal health information (PHI) after *Byrne*.

Key Cases Leading up to Byrne

***Harmon v. Maury County, TN*, Case No. 1:05 CV 0026, 2005 WL 2133697 (M.D. Tenn. Aug. 31, 2005)**

Harmon is one of the earliest cases addressing the use of HIPAA as a standard of care in a state negligence action. The plaintiff in *Harmon* sued for negligence per se in state court after the defendant allegedly violated HIPAA by making an unauthorized disclosure of the plaintiff's prescription drug records.[2] The defendant removed the case to federal district court on the ground that the claims presented a significant federal question. The plaintiff moved to remand.[3] In granting the plaintiff's motion to remand, the U.S. District Court for the Middle District of Tennessee reasoned that "HIPAA's provisions do not completely preempt state law" and, in fact, "expressly preserve state laws that are not inconsistent with its terms."[4] The district court concluded that the plaintiff's claim for negligence per se fell "within that broad class of state law claims based on federal regulations in the state court."[5]

***Acosta v. Byrum*, 180 N.C.App. 562 (2006)**

The plaintiff in *Acosta* alleged that a physician acted negligently by allowing an employee to use the physician's access information to obtain copies of the plaintiff's psychiatric information and other PHI.[6] The plaintiff further alleged that the employee disclosed her PHI to third parties without her authorization.[7] The plaintiff did not cite a specific HIPAA regulatory provision to establish the physician's duty to maintain her privacy. She merely alleged that HIPAA (as well as applicable provider rules and standards) established the standard of care. Accordingly, the court held that the plaintiff "sufficiently pled the standard of care in her complaint."[8]

***K.V. v. Women's Healthcare Network, LLC*, No. 07-0228-CV-W-DW, 2007 WL 1655734 (W.D.Mo. June 6, 2007)**

In *K.V.,* the defendant removed the plaintiff's negligence lawsuit from state to federal court because the plaintiff alleged that the defendant violated HIPAA.[9] The U.S. District Court for the Western District of Missouri remanded the case, reasoning that "the privacy standards imposed by HIPAA are not uniquely federal and do not raise any issue of great federal interest." It held that a state-law claim for negligence per se can be based on a HIPAA violation.[10]

***Doe v. Southwest Community Health Center, No.* FSTCV085008345S, 2010 WL 3672342 (Conn. Super. Ct. Aug. 25, 2010) (unpublished)**

The plaintiff in *Doe* alleged, in part, that the defendants had a duty to maintain the confidentiality of the plaintiff's PHI under HIPAA and were negligent because they failed to adequately safeguard the confidentiality of that PHI. The defendants sought summary judgment on several grounds, including the fact that "the existence of a statutory remedy precludes a common law cause of action, and therefore, the plaintiff had to report the alleged HIPAA violations to the appropriate federal agency[.]"[11] The Superior Court denied the motion, reasoning that "the duty element of a negligence action can be established by the requirements of a statute" and "Connecticut courts have [historically] allowed a plaintiff to maintain a negligence claim for the violation of other privacy statutes."[12]

***I.S. v. Washington University*, No. 4:11CV235SNLJ, 2011 WL 2433585 (E.D. Mo. June 14, 2011)**

In *I.S.,* the plaintiff alleged that Washington University released "information regarding [his] HIV status, mental health issues, and insomnia treatments" to his employer without his authority. He further alleged that the disclosure violated HIPAA and caused him harm. The plaintiff pleaded a negligence claim and theorized that HIPAA established the defendant's standard of care.[13] The district court acknowledged that HIPAA does not create a private cause of action, but held that the negligence per se claim was viable nonetheless.[14]

***R.K. v. St. Mary's Medical Center, Inc.*, 229 W. Va. 712 (2012)**

The plaintiff in *R.K.* sued the defendant Medical Center, alleging state law tort claims arising from the Medical Center's alleged unauthorized disclosure of psychiatric information.[15] The plaintiff had received psychiatric care at the Medical Center during his divorce proceeding, and the Medical Center allegedly disclosed his psychiatric records to his estranged wife and her divorce lawyer. The Medical Center filed a motion to dismiss, arguing that the plaintiff's state law claims were preempted by HIPAA and were more appropriately governed by the West Virginia Medical Professional Liability Act ("MPLA").[16] The West Virginia Supreme Court of Appeals held that the patient's claims were not preempted by HIPAA and that a violation of HIPAA could serve as the basis for a state law negligence claim.[17]

The Byrne Case

The facts of *Byrne* are similar to those of preceding cases. Plaintiff Emily Byrne was a patient at the Avery Center for Obstetrics and Gynecology (Avery Center).[18] While a patient at the Avery Center, she asked her physician to refrain from providing her PHI to her estranged partner, Mendoza. Shortly thereafter, Mendoza filed a paternity suit against Byrne and served the Avery Center with a subpoena requesting Byrne's medical records.[19] The Avery Center produced the medical records in response to the subpoena without consulting with Ms. Byrne.[20] Byrne alleged that she suffered harassment and extortion threats from Mendoza as a result of the disclosure.[21]

Byrne filed an action against the Avery Center alleging common-law negligence, negligent misrepresentation and negligent infliction of emotional distress, among other claims.[22] The negligence claims were all premised on the Avery Center's alleged failure to comply with HIPAA.[23] The trial court dismissed the negligence claims, finding that HIPAA did not provide a private right of action and preempted Byrne's claims.[24]

On appeal, Byrne acknowledged that HIPAA does not establish a private right of action, but reiterated that she was not asserting a claim for relief premised on a HIPAA violation.[25] Instead, Byrne argued that HIPAA informs the standard of care in common-law negligence actions based on health privacy breaches.[26]

The Avery Center countered with a series of federal cases holding that HIPAA does not create a private right of action. It argued that, as a result, "a plaintiff cannot use a violation of HIPAA as the standard of care for underlying claims, such as negligence."[27]

The Supreme Court of Connecticut reviewed the regulatory history underlying HIPAA and determined that "HIPAA . . . does not preempt causes of action, when they exist as a matter of state common or statutory law, arising from health care providers' breaches of patient confidentiality in a variety of contexts." The Supreme Court noted that several courts have determined that "HIPAA may inform the relevant standard of care" for such breaches.[28] Specifically, the Supreme Court relied upon *Harmon*, *Acosta*, *I.S.*, and *Doe* in holding that HIPAA informs the standard of care in common law negligence actions in Connecticut.[29]

Practice Pointer

Federal and state courts across the country are increasingly allowing plaintiffs to prove negligence by showing noncompliance with HIPAA, despite the plain language in HIPAA precluding a private right of action. While Georgia has not yet considered the issue, the law is trending in favor of plaintiffs. Contrary to conventional wisdom, Georgia plaintiffs may now be able to seek redress for HIPAA violations through civil actions for common law negligence.

While evidence of an alleged HIPAA violation may establish the standard of care and breach thereof, defense counsel should remember that the plaintiff must still prove damages. Plaintiffs in other jurisdictions have had difficulty proving either monetary damages or cognizable non-monetary damages (*e.g.*, emotional distress or reputational harm).[30] The best defense against a pending privacy lawsuit may thus be lack of damages.

All organizations that handle PHI should remain cognizant of their potential exposure under the common law in light of the evolving standard of care. Ultimately, the best strategy for minimizing that exposure may be striving for HIPAA compliance. So dust off your privacy and security policies and procedures, and ensure that they align with the current HIPAA requirements!

1 *See*, *e.g.*, Tatiana Melnik, "An Interview with Neal Eggeson, Discussing His Privacy Breach Win Against Walgreen Company Hinchy Case Creates Precedent for the Future," 17 J. Health Care Compliance 5, 7 (2015) ("[W]e have a published appellate decision which is binding in Indiana and which may be used as persuasive authority in every other state. Now all the pieces are in place: privacy victims around the country have cases which allow them to use HIPAA to get their lawsuits off the ground[.]"); Ifeoma Ajunwa, "Genetic Testing Meets Big Data: Tort and Contract Law Issues," 75 Ohio St. L.J. 1225, 1262 (2014) ("Tort law represents an avenue for an individual, who has been harmed by the negligent disclosure of genetic information, to be made whole."); and Jack Brill, "Giving HIPAA Enforcement Room to Grow: Why There Should Not (Yet) Be A Private Cause of Action," 83 Notre Dame L. Rev. 2105, 2124 (2008) ("[I]f other state courts adopt the notion that HIPAA can provide guidance as to the standard of care in negligence claims, then courts may see a dramatic increase in HIPAA-related litigation.")
2 2005 WL 2133697, at *1.
3 *Id.*
4 *Id.* at *3.
5 *Id.* at *4.
6 180 N.C. App. at 565, 568.
7 *Id.* at 565.
8 *Id.* at 568.
9 2007 WL 1655734, at *1.
10 *Id.*
11 2010 WL 3672342, at *7-8.
12 *Id.* at *7 (*citing Skrzpiec v. Noonan*, 228 Conn. 1, 3-4, 633 A.2d 716 (1993)).
13 *Id.*
14 *Id.* at *1-2.
15 229 W. Va. at 720-21.
16 *Id.* at 714-15.
17 *Id.* at 723.
18 314 Conn. 433.
19 *Id.* at 435-37.
20 *Id.* at 438-40.
21 *Id.* at 437.
22 *Id.* at 463.
23 *Id.* at 438-41.
24 *Id*. at 435-36.
25 *Id*. at 444-45.
26 *Id*. at 445-46.
27 *Id*.
28 *Id*. at 454-55.
29 *Id*. at 455-57.
30 *See, e.g., Cooney v. Chicago Pub. Sch*., 407 Ill. App. 3d 358, 366 (2010) (*citing Rowe v. UniCare Life & Health Ins. Co.*, No. 09 C 2286, 2010 WL 86391 (N.D.Ill. Jan. 5, 2010)) (holding that cost of credit monitoring services was not an economic injury); *Aliano v. Texas Roadhouse Holdings LLC*, No. 07 C 4108, 2008 WL 5397510 (N.D.Ill. Dec. 23, 2008).

Health Information Technology: Compliance Bytes

by Jill M. Girardeau, (with research assistance provided by Yami Mackenzie)

Attorneys who serve the health care industry are familiar with the promises of health information technology (HIT): better coordination of care; reductions in duplicative testing, errors, and readmissions; and improved population health resulting from data-driven analytics. In addition, the Medicare and Medicaid Electronic Health Record Incentive Programs (also known as the Meaningful Use Programs) continue to provide financial incentives for the use of electronic health records (EHRs). For these reasons, many institutional providers are exploring ways to put EHRs and other HIT into the hands of individual providers.

Of course, when a hospital or laboratory wishes to give anything of value to other health care providers, especially referring physicians, the parties must consider the implications under the federal physician self-referral law (the Stark Law), the federal Anti-Kickback Statute (AKS), and similar state laws.[1] This article analyzes the Stark Law and AKS implications of common scenarios in which health care providers are offered HIT items and services.[2]

Stark Law and AKS Definitions of "Remuneration"

When analyzing the Stark Law and AKS implications of the provision of HIT to providers, a threshold question is whether the HIT is "remuneration" for purposes of those laws. The Stark Law's definition of remuneration is broad and includes "any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind."[3] That definition, however, contains certain exceptions, one of which is "the furnishing of items, devices, or supplies (not including surgical items, devices, or supplies) that are . . . used solely to order or communicate the results of tests or procedures for the entity."[4] For purposes of the AKS, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.[5]

Hospitals and other entities (like laboratories) have long relied on the Stark Law exception to the definition of remuneration to offer dedicated computers, printers, and other devices to referring physicians. In a 2008 Advisory Opinion, the Centers for Medicare & Medicaid Services (CMS) considered whether a custom software interface paid for by a hospital for a physician practice constituted remuneration. In that case, the custom interface was determined not to meet the definition of remuneration because the interface would be used only to order or communicate the results of tests and procedures furnished by the hospital and could not be used for any other purpose.[6] Similarly, the U.S. Department of Health and Human Services—Office of Inspector General (HHS-OIG) has repeatedly stated that computers or other devices with limited functionality may not have independent value and therefore may not constitute remuneration for purposes of the AKS.[7]

While the provision of dedicated computers, printers, and other devices is not as common as it was several years ago, it is still important to remember that an initial step in analyzing an arrangement involving HIT should be a review of the definitions of remuneration.

Access to EHR Systems

Hospitals using an EHR often grant non-employed providers (usually members of the medical staff) remote access to the EHR. Such access allows the non-employed providers to obtain information in hospital records for follow-up care and billing purposes. Those providers may also be able to take necessary actions, like "signing" orders. In many cases, the information available to non-employed providers through remote access is the same type of information that is already available to them through other means.

In addition to considering issues like privacy and security, hospitals must also consider whether remote access constitutes remuneration under the Stark Law or the AKS. In 2006, CMS offered the following guidance:

> *Typically, information about a particular patient's health status, medical condition, or treatment exchanged between or among the patient's health care providers and suppliers for the purpose of diagnosing or treating the patient would not constitute remuneration to the recipient of the information. In this regard, the electronic exchange of patient health information is comparable to the exchange of such information by mail, courier, or phone conversation. Thus, when related to the care of individual patients, information such as test results, diagnosis codes, descriptions of symptoms, medical history, and prescription information are part of the delivery of the health care services and would not have independent value to the recipient.*[8]

CMS went on to note that data related to research or marketing, or data otherwise available only through a subscription or paying of a fee could constitute remuneration for purposes of the Stark Law.[9] Given this guidance, many hospitals have concluded that providing remote access to their EHR for treatment and billing purposes does not constitute remuneration and therefore does not implicate the Stark Law or the AKS.

Provision of HIT Generally

EHRs are not the only type of HIT that can be useful to health care providers. Many providers are now using

their smartphones and tablets to exchange text messages and emails with patients and other providers. Because such communications present privacy and security concerns, hospitals may, by way of example, wish to offer a secure text messaging solution to both employed and non-employed physicians. Of course, the provision of such a solution to non-employed physicians raises questions under the Stark Law and the AKS.

In 2004, when discussing the Stark Law Phase II rules, CMS offered commentary that gives a bit more guidance than the exception to the definition of remuneration. CMS stated that a "hospital's provision of a computer or other technology that is wholly dedicated to use in connection with hospital services provided to the hospital's patients would be for the hospital's benefit and convenience and would not constitute remuneration to a physician."[10] In other words, technology that does more than order or communicate the results of tests or procedures may still not be remuneration depending on its use.

In this example, however, a hospital must carefully consider whether the secure text messaging solution is "wholly dedicated" to use in connection with hospital services provided to hospital patients. What types of messaging does the technology support and with whom? When a non-employed physician uses it to communicate about a patient that is not ultimately seen by a hospital-employed provider, can that patient be considered a "hospital patient"? In a small community with one hospital, one might argue that all patients could be considered the hospital's patients, even if the patient does not see a hospital-employed provider in one particular instance. On the other hand, in a larger community with multiple hospitals, that would not necessarily be true. If a fact-intensive assessment leads to the conclusion that certain technology is remuneration, any arrangement between the hospital and a referring physician must be structured to meet a Stark Law exception and should, if possible, be structured to meet an AKS safe harbor.

Specific Stark Law Exceptions and AKS Safe Harbors for HIT

In 2006, in a joint effort to promote the adoption of EHRs, CMS and HHS-OIG promulgated rules allowing entities to subsidize certain EHR software and technology for providers if specific conditions are met (the "EHR Rules").[11] The EHR Rules allow hospitals to help physicians and other providers obtain EHRs for use in private practice. The EHR Rules were originally set to expire on December 31, 2013, but CMS and HHS-OIG have extended the expiration date to December 31, 2021. They have also specifically excluded laboratories as entities that could make EHR donations under the EHR Rules.[12]

The EHR Rules provide that, if all of the listed conditions are met, nonmonetary remuneration (*i.e.*, software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive EHRs does not create a financial relationship for purposes of the Stark Law or constitute "remuneration" under the AKS. The types of items and services that may be donated are limited. Before receipt of the items and services, the recipient must pay 15% of the donor's cost for the items and services, and the donor (or any party related to the donor) cannot finance or cover the recipient's payment for the items and services. When ongoing costs and expenses are donated, this cost-sharing obligation must be carefully managed to ensure that no items or services are donated prior to the donor's receipt of the cost-sharing amount. Additionally, some states have specific laws or guidance prohibiting or discouraging EHR donations, though usually in the context of donations by laboratories.[13]

The Stark Law also contains an exception for community-wide health information systems.[14] The exception, finalized in 2004, permits the provision to physicians of certain information technology that allows access to and sharing of EHRs, general health information, and related information in order to enhance the community's overall health. The information technology must enable the physician to participate in a community-wide health information system and must be principally used by the physician as part of that system. In addition, the system must be available to all providers, practitioners, and residents of the community who desire to participate. There is little guidance on this exception, and there is no corresponding AKS safe harbor. Many hospitals have been reluctant to utilize this exception given the vague but seemingly onerous requirements.[15]

Another Stark Law exception that can prove useful in the context of HIT is the exception for nonmonetary compensation, assuming that the HIT is of relatively low value and the other conditions of the exception can be met.[16]

Finally, in 2011, CMS and HHS-OIG issued waivers of healthcare fraud and abuse laws related to Accountable Care Organizations ("ACOs"). Pre-Participation and Participation Waivers can protect a variety of financial arrangements between ACOs, ACO participants, and ACO providers or suppliers. Financial arrangements involving information technology—including EHR systems and electronic health information exchanges—may be protected if all requirements for the waiver are met.[17]

Conclusion

While CMS and HHS-OIG have provided some methods by which hospitals can help put HIT, especially EHRs, into the hands of health care providers, compliance with the Stark Law and the AKS remains complicated. A hospital looking to implement an HIT plan that involves non-employed providers must carefully factor in the cost of compliance and the risk of non-compliance.

1 While this article does not permit a discussion of relevant tax issues, a tax-exempt hospital must also consider whether the provision of technology to health care providers results in impermissible private benefit or inurement in violation of Section 501(c)(3) of the Internal Revenue Code.
2 Because the Stark Law is a strict liability statute (as opposed to the AKS, which is intent-based), this article does at times focus more on the Stark Law analysis than the AKS analysis.
3 42 C.F.R. § 411.351.
4 *Id*.
5 *See*, for example, OIG Advisory Opinion No. 15-04.
6 *See* CMS Advisory Opinion CMS-AO-2008-01.
7 *See* Publication of OIG Special Fraud Alerts at 65 Fed. Reg. 65372, 65377-78, December 19, 1994. See also the July 3, 1997 letter from Kevin G. McAnaney, Chief, Industry Guidance Branch, OIG, regarding free computers, facsimile machines, and other goods available at http://oig.hhs.gov/fraud/docs/safeharborregulations/freecomputers.htm.
8 71 Fed. Reg. 45140, 45143.
9 *Id*. at 45144.
10 69 Fed. Reg. 16054, 16113.
11 Given the differences in the Stark Law and the AKS, the Stark Law exception for the donation of EHRs focuses on the donation of EHRs to physicians, whereas the AKS safe harbor for the donation of EHRs focuses on the donation of EHRs to an individual or entity engaged in the delivery of health care. Also, in 2007, the Internal Revenue Service issued guidance describing a safe harbor under which the IRS will not treat the provision of EHR items or services by a tax-exempt hospital as impermissible private benefit or inurement in violation of Section 501(c)(3) of the Internal Revenue Code resulting in intermediate sanctions and/or a revocation of tax-exempt status.
12 42 C.F.R § 411.357(w); 42 C.F.R. §1001.952(y).
13 *See*, for example, the State of Tennessee Office of the Attorney General Opinion No. 13-16 available at http://pathologyblawg.com/wp-content/uploads/2013/03/TN-EMR-donation.pdf. Authorities in New York, West Virginia, New Jersey, Pennsylvania, Missouri, and Washington have also limited or prohibited EHR donations by laboratories. In all cases, relevant state self-referral, anti-kickback, and similar laws should be reviewed prior to making any EHR donation.
14 42 C.F.R. § 411.357(u).
15 The commentary on the community-wide health information system exception can be found at 69 Fed. Reg. 16054, 16113.
16 42 C.F.R. §411.357(k).
17 *See* 76 Fed. Reg. 67992, 68003.