HLB
Hooper, Lundy & Bookman, PC
HEALTH CARE LAWYERS & ADVISORS

Health Law PERSPECTIVES

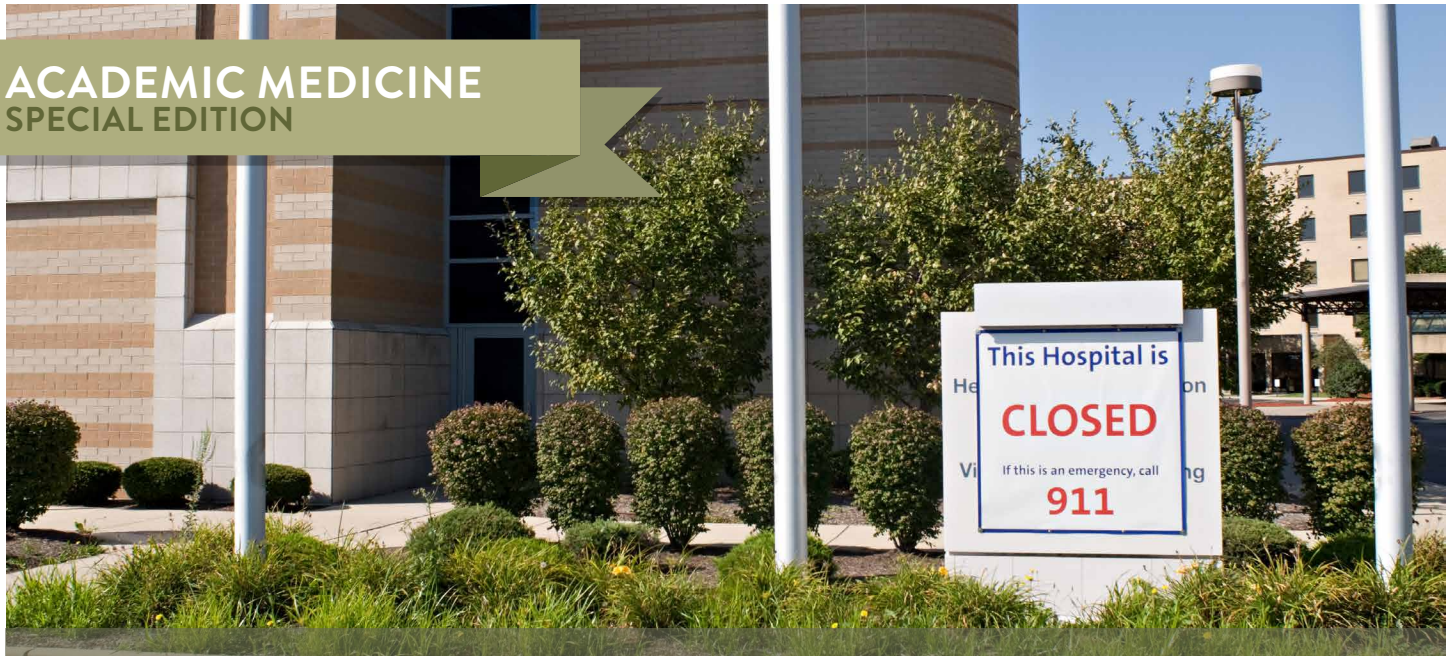
ACADEMIC MEDICINE SPECIAL EDITION

IN THIS ISSUE

In this **special edition** of **Health Law Perspectives**, members of **HLB's Academic Medical Centers** and **Teaching Hospitals** (AMC/TH) Working Group provide analyses of select key issues that impact academic medicine providers. The first four articles and the government relations and public policy outlook update are all components of the Academic Medicine Special Edition, and are identified by an Academic Medicine Special Edition banner. HLB's AMC/TH Working Group was started in 2018 to consolidate the firm's expertise in key issues arising from health care law and regulations applicable to academic medical centers and teaching hospitals, given their tripartite mission of patient care, medical education, and research. We hope you enjoy this Academic Medicine Special Edition.


HLB
Hooper, Lundy & Bookman, PC
HEALTH CARE LAWYERS & ADVISORS

ACADEMIC MEDICINE
SPECIAL EDITION



The Closure of Hahnemann University Hospital and the "Sale" of Residency Slots in Bankruptcy Proceedings

By: David J. Vernon[1]

On June 26, 2019, Hahnemann University Hospital ("Hahnemann") announced that it would abruptly close its doors. The hospital was an important safety-net provider for over 170 years in Philadelphia and was also a large teaching hospital with about 583 residents and fellows. The closure also took on national importance when the bankruptcy court took the unprecedented step of adopting bidding procedures for Hahnemann's "residency program assets"—i.e., its residency slots. Although the bankruptcy court approved the sale of the slots for $55 million, CMS has appealed based on its rules concerning assignment of the Medicare provider agreement and the redistribution of a closed hospital's graduate medical education ("GME") residency slots to other teaching hospitals under Section 5506 of the Affordable Care Act ("ACA").

The ongoing battle between hospitals looking to purchase Hahnemann's teaching slots, as if the slots are an asset, and CMS, has been an interesting one. This article outlines the typical rules governing residency programs and the closure of a teaching hospital, the Hahnemann bankruptcy proceedings, and the potential implications of the appeal.

GME REIMBURSEMENT BACKGROUND AND BALANCED BUDGET ACT OF 1997

In 1997, in an effort to limit the cost of the Medicare program, Congress passed the Balanced Budget Act of 1997 ("BBA '97"). Among other things, BBA '97 instituted a cap on the number of allopathic and osteopathic residents for which Medicare would provide reimbursement in the form of direct graduate medical education ("DGME") and indirect medical education ("IME") payments. The cap was limited to the number of full-time equivalent ("FTE") residents training at a hospital in 1996. Although there are limited exceptions permitting increases to the FTE cap, the cap is difficult to grow. The residency cap has significantly limited growth in aggregate DGME and IME reimbursement to teaching hospitals and academic medical centers in the United States. Nonetheless, in the years following BBA '97, teaching hospitals continued to grow residency programs and training opportunities to fill community needs. Due to the cap, the training of these additional residents would not be paid for by Medicare DGME and IME reimbursement. As a result, teaching hospitals attempted to capture

[1] Thanks to Erin Sclar, a current law student at U.C. Hastings and 2019 summer associate at Hooper, Lundy & Bookman, for her research assistance with this article.

additional residency slots that were not being used by another teaching hospital or that were "lost" due to another teaching hospital's closure.

AFFORDABLE CARE ACT CHANGES TO RESIDENCY SLOT REDISTRIBUTION

In 2010, Congress addressed the disposition of unused residency slots and those slots "lost" through hospital closures in ACA Sections 5503 and 5506. Under Section 5503 of the ACA, FTE resident caps are reduced for certain hospitals training fewer residents than their caps and those slots may be redistributed to other qualified hospitals.

> On June 26, 2019, Hahnemann University Hospital ("Hahnemann") announced that it would abruptly close its doors.

Section 5506 of the ACA instructs CMS to establish a process for redistributing residency slots after a teaching hospital closes. This allows for a permanent increase in the FTE resident caps for certain hospitals, so that the closed hospitals' resident slots would no longer be "lost." By statute, the process for distributing the residency slots prioritizes hospitals in certain geographic areas, and also provides that a preference be given within each priority category to hospitals that are members of the same affiliated group with the closed hospital. Slots are redistributed: first, to a hospital located in the same, or a contiguous, core-based statistical area ("CBSA") to the closed hospital; second, to a hospital located in the same state as the closed hospital; third, to a hospital located in the same region as the closed hospital; and fourth, if slots still have not been distributed under the first three categories, to qualifying hospitals in accordance with the criteria established for distributing unused slots under Section 5503 of the ACA.

In the Final Rule implementing Section 5506, CMS adopted eight Ranking Criteria to prioritize hospitals within each of the first three statutory priority categories (that is, same or contiguous CBSAs, same state, and same region). The first three Ranking Criteria prioritize: (1) assumption of and continued operation of an entire program from the closed hospital; (2) use of slots received as part of the most recent affiliation agreement with the closed hospital to continue to train at least those residents it was training; and (3) where the hospital took in displaced residents and will use those slots to continue training the displaced residents until they complete their training, as well as will maintain those slots to continue training others in the same programs as the displaced residents. For the remaining five criteria, the Ranking Criteria prioritize the planned use of the new slots for primary care or otherwise prioritized residency programs over nonprimary care programs: (4) in a geriatrics residency program; (5) if located in a Health Professional Shortage Area ("HPSA"), in a primary care or general surgery residency program; (6) if not located in a HPSA, in a primary care or general surgery residency program; (7) some in a primary care or general surgery program, but the program does not meet Ranking Criterion 5 or 6 because the hospital is also separately applying under Ranking Criterion 8 for slots to establish or expand a nonprimary care or non-general surgery program; and (8) the hospital will use the slots to establish or expand a nonprimary care or a nongeneral surgery program.

In addition to considering the ranking categories and criteria, Section 5506 requires CMS to only award slots to hospitals where the Secretary "determines the hospital has demonstrated a likelihood of filling the positions made available under [42 U.S.C. § 1395ww(h)(4)(H)(vi)] within 3 years."

ORPHANED RESIDENTS

When a teaching hospital closes, displaced residents may continue their training at any other hospital that is willing to take them. Generally, under 42 C.F.R. § 413.79(h), a hospital that accepts a resident from the closing hospital can receive a temporary adjustment to its FTE cap. This occurs so long as the acquiring hospital, no later than 60 days after the hospital begins to train the new residents: (1) submits a request to its Medicare Administrative Contractor ("MAC") for a temporary adjustment to its FTE cap; (2) documents that the hospital is eligible for this temporary adjustment by identifying the residents who have come from the closed hospital and have caused the hospital to exceed its cap; and (3) specifies the length of time the adjustment is needed.

HAHNEMANN'S RESIDENCY SLOTS

Hahnemann filed for Chapter 11 Bankruptcy protection on June 30, 2019. Subsequently, Hahnemann and Tower Health entered into an agreement to transfer Hahnemann's residency program to Tower Health for $7.5 million. The mechanism of this agreement was that Tower Health would acquire and accept assignment of Hahnemann's Medicare Provider Agreement such that it would not trigger ACA Section 5506 because there would not be a closure of the hospital. On July 19, the bankruptcy court approved bidding procedures for the "residency program assets." The procedures set an August 5 deadline for entities other than Tower Health to submit a bid, and scheduled a hearing on the sale of the assets for August 9. The procedures also permitted

entities to file objections to the bidding procedures or sale of the assets on or before August 5.

On August 5, the Centers for Medicare and Medicaid Services ("CMS") filed objections to the proposed sale of assets to Tower Health. Most notably, CMS opposed the Tower Health deal because, first, Hahnemann's Medicare Provider Agreement terminates with the closure of the hospital[2] and therefore cannot be transferred. Second, even if Hahnemann's Medicare Provider Agreement could be assigned to another entity, CMS argued that the proposed arrangement with Tower Health would violate federal law because Tower Health would not purchase all of the assets necessary to operate Hahnemann and would avoid successor liability. Third, CMS argued that "[t]he applicable statute (42 USC § 1395ww(h)(4)(H)) and regulation (42 CFR § 413.79(h)) do not contemplate that a hospital chain can absorb one hospital's residency slots and distribute those slots amongst its affiliated hospitals."

On August 8, despite CMS's objections to the sale of the residency slots, six Philadelphia-based hospitals, led by Thomas Jefferson University ("Thomas Jefferson"), won the bidding for Hahnemann's residency slots at $55 million. Thomas Jefferson and the debtors negotiated concerning the asset purchase agreement for a number of weeks. The debtors moved to have the bankruptcy court approve the sale of the residency programs to Thomas Jefferson, and on September 4, 2019, CMS objected with many of the same arguments.

In objecting, CMS argued that residency slots are not property of the Debtors' estate and that private parties do not have the authority to contract for the sale of permanent Medicare-funded residency slots from a closed hospital when Congress has given such power to redistribute slots from closed teaching hospitals, exclusively to the HHS Secretary (i.e., ACA Section 5506). CMS also argued that residency slots are in the exclusive control of the Secretary and exist only in the context of Medicare participation.

Six Philadelphia-based hospitals, led by Thomas Jefferson University ("Thomas Jefferson"), won the bidding for Hahnemann's residency slots at $55 million.

When a teaching hospital closes, displaced residents may continue their training at any other hospital that is willing to take them.

In addition to the arguments that Section 5506 cannot be circumvented, CMS argued that Hahnemann had closed and that, as a result, its Medicare Provider Agreement was terminated and could not be sold in or out of bankruptcy. CMS argued that the Medicare Provider Agreement, even if still active, cannot be transferred unless there is a change in ownership ("CHOW") under 42 C.F.R. 489.18 and there was no such CHOW, as sale of the residency slots alone, cannot be a CHOW.

At the September 5, 2019 hearing, Bankruptcy Judge Kevin Gross ruled orally that he would approve the sale of the residency programs to Thomas Jefferson. Judge Gross's rationale was that there had not been a cessation of business of Hahnemann at any time prior to the closing of the asset purchase agreement and that therefore the Medicare Provider Agreement was still in full force and effect[3]. CMS moved then orally for a stay pending its appeal of the to-be-entered order.

On September 10, 2019, the Bankruptcy Court approved the asset purchase agreement with Thomas Jefferson authorizing the sale of the residency programs. On September 12, 2019, CMS appealed the decision to U.S. District Court for the District of Delaware, reiterating many of the same arguments it raised on September 4, 2019.

On September 16, 2019, U.S. District Court Judge Maryellen Noreika temporarily stayed the sale of the residency slots to Thomas Jefferson. In reaching that conclusion, Judge Noreika stated that it was not clear that Hahnemann was still in business, such that the Medicare Provider Agreement could be assumed by the buyer, along with the residency slots. The appeal is still pending at this time.

While the residency slots appeal was pending in the District Court of Delaware, Hahnemann's owners

---

[2] Hahnemann's last patient left the inpatient hospital unit on July 25, 2019 and the emergency department was closed on August 16, 2019. According to CMS, Hahnemann permanently closed on September 6, 2019.

[3] Judge Gross also allowed for the resident slots that temporarily followed the residents to other programs to revert to the purchaser once the residents are done with their programs. This is a peculiar result, as the orphaned resident rules are not triggered unless a hospital closes.

and debtors filed an emergency motion to block the revocation of Hahnemann's hospital license. Judge Richard Andrews denied the motion, determining that the Pennsylvania Department of Health is entitled to revoke Hahnemann's hospital license because Hahnemann is no longer operating and that doing so "would not be a preventable harm, but merely a state enforcing the law because the hospital does not meet the state's requirements." Revocation of the hospital's license further imperils the $55 million sale of the residency training program because without a hospital license, it is more difficult for the debtors and Thomas Jefferson to argue that the hospital is not closed and that therefore, ACA Section 5506 should not apply.[4]

A "DANGEROUS PRECEDENT?"

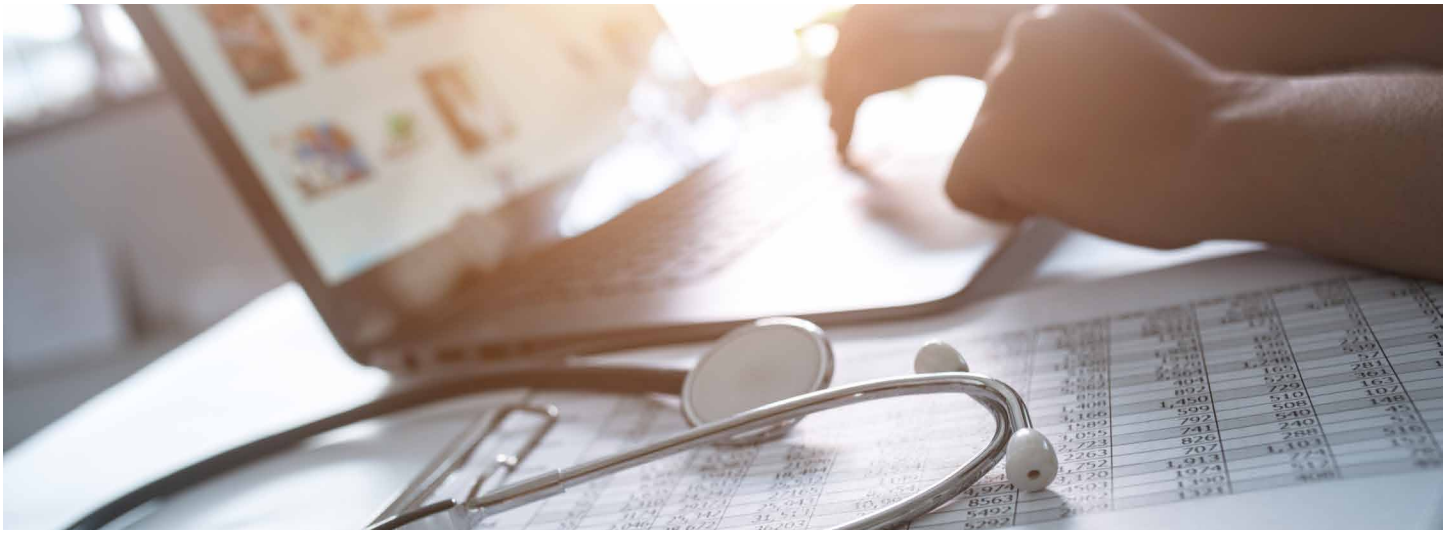
After the Bankruptcy court authorized the sale of the residency slots, House Energy and Commerce Chairman Frank Pallone, Jr. (D-NJ) and Ways and Means Chairman Richard Neal (D-MA) issued a joint statement that the "sale sets a dangerous precedent and sends a signal to Wall Street that there is money to be made off the downfall of community hospitals." Echoing the same sentiment, an attorney representing the Pennsylvania Association of Staff Nurses and Allied Professionals, the union that represented about 800 nurses at Hahnemann, stated that "this sets a dangerous precedent allowing hospitals to be sold for [their] parts, when the parts are maybe more valuable than the whole."

If Thomas Jefferson is ultimately able to acquire the residency slots as if they are an asset owned by Hahnemann, without also acquiring and operating the rest of the hospital, this could open the door to hospital systems trying to bundle and sell off residency programs as a commodity. This might significantly impact rural teaching hospitals that are struggling financially, incentivizing them to sell resident slots to wealthier areas, further increasing rural physician shortages and decreasing access to care. Moreover, given the financial condition of many teaching hospitals, private equity and other hospital purchasers might now view residency programs at financially distressed hospitals as valuable assets available for purchase.

If Thomas Jefferson is ultimately able to acquire the residency slots as if they are an asset owned by Hahnemann [...] this could open the door to hospital systems trying to bundle and sell off residency programs as a commodity.

It is still too early to tell how this case will be resolved or what will be its impact on GME reimbursement and teaching hospital well-being. While it seems unlikely at this stage that Thomas Jefferson (or any other potential buyer) might be able to permanently acquire the Hahnemann residency slots in a manner which appears to circumvent ACA Section 5506, there is certainly still a possibility that the relevant courts will create new law which would significantly impact CMS's ability to control the residency slot redistribution process. The potential ramifications are far-reaching and HLB will provide relevant updates as the case develops.

For more information, please contact David J. Vernon in Washington D.C. or your regular Hooper, Lundy & Bookman contact.



[4] As of publication, the hospital license has not been revoked.

ACADEMIC MEDICINE
SPECIAL EDITION

Noteworthy Stark Law Case Eases Burden on Qui Tam Relators

3RD CIRCUIT OVERTURNS DISMISSAL OF UNIVERSITY OF PITTSBURGH MEDICAL CENTER WHISTLEBLOWER SUIT

by Amy Joseph, Ben Durie, and Charles Oppenheim

In a September 17th opinion, the 3rd U.S. Circuit Court of Appeals overturned a District Court decision dismissing whistleblower claims against the University of Pittsburgh Medical Center ("UPMC") alleging violations of the Stark Law and the False Claims Act ("FCA").[1] The claims stem from allegations of improper compensation paid by UPMC to a number of employed neurosurgeons. At the heart of this case is the compensation structure described in employment agreements between the neurosurgeons and UPMC-affiliated entities, which is a compensation structure that is common at many hospitals, including academic medical centers. The physicians' compensation was made up of a base salary and a bonus based on the amount of work each physician actually performed throughout the year. The more work the physicians performed, the larger their productivity bonus. If the physicians failed to meet their production targets, their base salary would be reduced the following year. The Court held that the plaintiffs in the case, a neurosurgeon and other former UPMC employees, had provided enough evidence to plausibly allege violations of the Stark Law and the FCA, meaning that the case can move forward to the discovery phase of the litigation.

This case is significant for a number of reasons. First, the Court's interpretation of the Stark Law sets the bar to discovery very low, which will arguably make it easier for relators to bring Stark-related FCA actions involving compensation arrangements in the future. Second, the Court's application of the intent requirement in the FCA claim effectively shifted the burden of proof from the plaintiffs to the defendant. Third, the underlying allegations made by the whistleblowers involve a productivity-based compensation structure that is extremely common in hospital-physician arrangements. These three key takeaways from the Court's opinion are examined further below.

The Court's opinion in this case is aggressive (arguably flawed), and may have been influenced by allegations of claims submitted for services not performed and other similar alleged fraud. As written, the holdings could arguably be applied to any hospital-physician relationship which falls under the Stark Law – a common occurrence – and has additional language which increases risk with respect to any hospital-physician relationship where a physician is paid based on productivity and/or compensation is on the high end of fair market value.

In the current post-*Tuomey* Stark

[1] *United States. ex rel. Bookwalter v. UPMC* (Sept. 17, 2019, No. 18-1693) __ F.3d ____ (3d Cir. 2019).

Law enforcement environment, this decision further demonstrates that it is more critical than ever for hospitals and affiliated entities that employ or contract with physicians to very closely evaluate the compensation paid to physicians, paying particular attention to compensation with incentive or bonus components and compensation that falls on the high end of a fair market value range.[2] In addition, hospitals would be well advised to complete files for each arrangement with physicians that document compliance with an applicable Stark Law exception, including documentation regarding fair market value and the business rationale for the arrangement, and consider implementing additional safeguards such as auditing of records where productivity appears to be an outlier, to ensure the services are being performed as billed and at the standard of care expected of the physician.

This decision may be of particular interest for academic medical centers, where the business model is often one of closely aligned legal entities, including the school, health system, and faculty practice group, often where the health system and faculty practice group are affiliates with the same parent and with significant overlap at the leadership level. Such overlap was a factor that the court focused on in its opinion. The court also identified circumstances where physician compensation exceeds collections as another area of focus, which is also not an uncommon occurrence in the academic medical center setting (for legitimate reasons, as detailed further below).

On a positive note, CMS's recently issued proposed rule, which would revise the Stark Law as part of the Regulatory Sprint to Coordinated Care (see pg. 19 of the newsletter), could be helpful to curb *qui tam* actions such as this action in the future. In particular, the proposed rule, if finalized, would significantly limit what financial relationships are considered indirect compensation arrangements. The current definition requires that the compensation link closest to the physician "varies with or takes into account the volume or value of referrals or other business generated;" the proposed definition would remove the "varies with" language and significantly limit which compensation methodologies are considered to "take into account" referrals or other business generated. In related commentary, CMS expressly rejects language in the *Tuomey* decision which raised questions about what methodologies could be considered to take into account referrals or other business generated, confirming longstanding guidance that a productivity bonus does not meet this standard just because corresponding hospital services are performed each time a physician personally performs a service. CMS also clarifies in the proposed rule that arrangements can be commercially reasonable although not profitable.

LOW THRESHOLD FOR REACHING DISCOVERY PHASE IN AN FCA ACTION INVOLVING INDIRECT COMPENSATION ARRANGEMENTS

One troubling aspect of this case is the low threshold the Court requires for a FCA case predicated on Stark Law violations to survive a motion to dismiss and move to discovery. The Court defines a prima facie Stark Law violation as having three elements: (1) referrals for designated health services; (2) a compensation arrangement (or ownership or investment interest); and (3) a Medicare claim for the referred services. It goes on to state that this "combination of factors suggests potential abuse of Medicare. When they are all present, we let plaintiffs go to discovery." That statement, on its own, is so broadly worded that it implicates almost all direct or indirect physician relationships with hospitals, the vast majority of which are presumably compliant with law (although relators would still need to plead a FCA violation).

In this case, because the compensation arrangement was not directly between the hospital and the physicians, the relator alleged that there was an indirect compensation arrangement, which is defined under Stark to, among other things, include aggregate compensation that varies with or takes into account the volume or value of referrals. If there is no indirect compensation arrangement, the Stark Law would not apply. In analyzing whether an indirect compensation arrangement exists, the Court discusses at length that "varies with" means "correlation," and "takes into account" means "causation," meaning to show that an indirect compensation arrangement exists one need show only that compensation tends to rise and fall in "correlation" with the volume or value of referrals. In doing so, the Court notes that the Stark Law:

> *casts a wide net of initial suspicion, followed by narrower safe harbors. A correlation between pay and referrals suggests that hospitals are rewarding doctors for referrals. And healthcare providers get to use the Stark Act's exceptions [which, under these circumstances, would require that compensation "take into account" volume or value of referrals] to show that there is no problematic causal relationship. Only if they cannot should those cases go to discovery.*

The court noted that because these neurosurgeons were practicing at UPMC, every time they performed a procedure at a UPMC hospital they

[2] This opinion is one of several notable cases and enforcement actions in recent years involving compensation of employed physicians, including *U.S. ex rel. Drakeford v. Tuomey, U.S. v. Halifax Hosp. Medical Center*, and *U.S. ex rel. Reilly North Broward Hosp. Dist.*

made a referral of the associated hospital claims. According to the Court, if the compensation in fact varied with the value of the physician's Medicare referrals, which it did by definition, arguably that correlation could be used to establish violations of the Stark Law and the False Claims Act.

In its conclusion, the Court identifies the following key allegations of the relator as sufficient to survive a motion to dismiss in this case: a compensation relationship that varies based on referrals, submission of claims to Medicare for the corresponding facility fee, and the hospital's knowledge of the physicians' compensation, and states: "With all this smoke, a fire is plausible." While the Court may have been influenced by the particular factual allegations in this case, the Court's holding is more broadly stated. Although the Court acknowledges in passing the concurring opinion's "legitimate concerns about opening the floodgates of litigation," the Court quickly dismisses this concern by putting the burden on the Department of Justice to dismiss qui tam actions over a relator's objection to bar frivolous cases from reaching discovery.

What is troubling about this conclusion is that it implies the mere fact that a physician is compensated based on personal labor in a hospital setting, where by necessity there is a corresponding facility fee payable to the hospital, is enough to be suspect. As described by Judge Ambro in his concurring opinion, the decision suggests "that any hospital that pays its affiliated physicians according to some metric of the work they personally perform at the hospital falls under suspicion of violating the Stark Act."

BURDEN OF PROOF AND INTENT REQUIREMENTS

The Court also addressed the interplay between the Stark Law and the FCA, with respect to what a plaintiff must plead. The defendants raise a compelling, and in our view the better, argument that because the FCA includes falsity and knowledge elements, a plaintiff must also have to plead that no Stark Law exception applies, as opposed to putting the burden on the defendants to raise as an affirmative defense. The defendants argued that if a person thinks an exception applies, they would not know that a claim is false, which is a key element of a FCA action. While the Court acknowledges that such argument "has force," it is immediately rejected based on prior precedent. The Court holds that a defendant has the burden to plead the applicability of a Stark Law exception.

> This decision may be of particular interest for academic medical centers, where the business model is often one of closely aligned legal entities.

Under the Stark Law, where an entity's claim for designated health services is denied due to noncompliance with the Stark Law, if the entity appeals the payment denial the entity, not CMS, bears the burden of proof that a Stark Law exception applies.[3] This might make sense when the entity is contesting a payment denial. However, placing this same burden on a defendant in a FCA case does not make sense, since one of the key elements in a FCA case is for the plaintiff to allege that the false claim was submitted knowingly (meaning with actual knowledge, reckless disregard, or deliberate ignorance). Particularly because a vast majority of hospital-physician financial relationships likely fall within a Stark law exception in compliance with law, it seems that the plaintiff should have to allege that the defendant submitted claims with actual knowledge, reckless disregard, or deliberate ignorance that no Stark Law exception is available.

The Court goes on to note that even if a plaintiff would have the burden of pleading no Stark Law exception applies, the plaintiff did so here, since the affiliated entities had overlapping officers and board members, the hospital received data regarding compensation and productivity, there was a centralized billing department, the entities were familiar with the Stark Law and the fact that indirect compensation arrangements existed, and the entities "knew or recklessly disregarded" that the compensation varied with referrals and allegedly exceeded fair market value (addressed further below). As with the discussion regarding the compensation structure, what the Court fails to acknowledge is that based on this standard, these same circumstances could potentially be alleged at every hospital where a board receives financials and approves compensation packages, including hospitals that directly employ physicians as part of their workforce, where a physician's compensation is on the high end of fair market value.

COMPENSATION IN EXCESS OF FAIR MARKET VALUE AND "TAKING INTO ACCOUNT" REFERRALS

Although the "correlation" between compensation and referrals was sufficient to survive a motion to dismiss, the court focused on

[3] 42 C.F.R. § 411.353(c)(2).

additional factors in its opinion in taking the position that the plaintiff had also pled "causation," noting that where aggregate compensation exceeds fair market value that can also be evidence that the compensation takes into account the volume or value of referrals, and both concepts are incorporated in the applicable Stark Law exceptions.

The Court stated that the following allegations, when read together, make plausible claims that the physician compensation exceeded fair market value: (i) compensation exceeded collections, (ii) compensation exceeded the 90th percentile, (iii) productivity exceeded the 90th percentile, (iv) the bonus per "Work Unit" exceeded the Medicare rate, and lastly, (v) the relators alleged fraudulent practices including use of incorrect coding or submitting claims for services not performed.

Although in some circumstances the first four factors could indicate a potential compliance issue, in many cases there may be a legitimate underlying rationale (the fifth factor, if true, is clearly a problem). For example, with respect to the first factor, although the concept that compensation exceeding collections suggests a violation has gotten some traction in various court decisions, physicians are often compensated not just for providing professional services, but also for providing a range of other services including medical direction, on call coverage and other administrative services. In addition, there may be other compelling reasons that compensation exceeds collections, such as in areas where securing physician staffing is challenging and compensating at a certain level is required to meet community need.

In addition, CMS has long recognized that some subsidization may be necessary for certain physician arrangements in an academic medical center setting in order to support the teaching and research missions. In establishing a Stark law exception specific to academic medical centers, CMS effectively recognizes that some transfer of funds from the clinical component is necessary to support the other components of the academic medical center, since often there is not sufficient revenue for teaching or research for such functions to be self-sustaining. In prior commentary, CMS has also noted that in "the academic medical center (AMC) setting or similar settings . . . 'support payments' or other similar monetary transfers are common . . . ."[4]

With respect to the second factor, 10 percent of all physicians by definition are paid above the 90th percentile, and that does not mean those physicians are being paid above fair market value under the circumstances (there are many legitimate reasons to pay this amount, such as if the compensation reflects a significant community need, the physician is an outlier with respect to how much time they dedicate to work, and/or the physician stands out as a leader in the field). Note that sophisticated AMCs often draw top talent and with that likely comes compensation.

Similarly, with respect to the third factor, while physicians with productivity exceeding the 90th percentile are outliers, and this case did allege that some of the productivity numbers stretched the imagination of what is possible, most physicians who have that productivity level are just extremely busy and committed to a work schedule that most would not want.

It is also worth noting that payment based on productivity, which could lead to higher compensation that "correlates" with referred services to hospitals, is an extremely common compensation method. In many ways setting minimum wRVU threshold expectations, paying unit-based compensation in additional, set-in-advance increments for additional wRVUs personally performed, and potentially adjusting compensation if a physician does not meet a minimum threshold, can be viewed as a safeguard against fraud and abuse as it protects against overcompensating a physician who is not putting in sufficient work effort for the remuneration received, but may otherwise be generating referrals to a hospital. In our experience, independent valuation firms often look to historical and anticipated wRVUs in assessing fair market value compensation, and in some instances may recommend setting minimum wRVU thresholds to ensure the services provided warrant the level of compensation received. CMS itself, in commentary addressing the bona fide employee exception under the Stark Law, made clear that paying a productivity bonus in a hospital setting is permissible. In response to a commenter's inquiry regarding a hospital-employed physician assigning the right to bill to the hospital and receiving payment from the hospital for each patient seen at an outpatient clinic, meaning the physician services are "inevitably linked" to a facility fee billed by the hospital, CMS responded that "[t]he fact that corresponding hospital services are billed would not invalidate an employed physician's personally performed work, for which the physician may be paid a productivity bonus (subject to the fair market value requirement)."[5]

For more information, please contact Amy Joseph or David Schumacher in Boston, Ben Durie or Paul Smith in San Francisco, Charles Oppenheim or David Henninger in Los Angeles, or your regular Hooper, Lundy & Bookman contact.

---

[4] 72 Fed. Reg. 64161 (Nov. 15, 2007). Similarly, in prior advisory opinions regarding academic medical centers analyzing applicability of the federal anti-kickback statute, the OIG has noted that substantial donations by hospitals to major referral sources could be problematic, but ultimately approved multiple scenarios for such "mission support" payments in the academic medical center setting given the shared mission. See, e.g., OIG Advisory Opinion No. 02-11 (Aug. 19, 2002).

[5] 69 Fed. Reg. 16089 (March 26, 2004).

ACADEMIC MEDICINE
SPECIAL EDITION

Navigating Privacy Laws and the Impact on Disclosures at University Student Health Centers

By: Alicia Macklin, Amy Joseph, and Paul Smith

Navigating the various state and federal patient privacy laws to ensure compliance can be challenging, and one setting where confusion often arises is when universities provide health care services, including at student health centers. This article provides an overview of some of the key privacy laws and considerations when determining whether a contemplated disclosure of patient information is permitted or required.

In an integrated academic medical center setting, a single legal entity may operate a university as well as provide a wide variety of healthcare services, including operating hospitals, operating clinics staffed by an affiliated faculty practice group, operating a student health center that sees students, student dependents, and employees, offering an employee health plan, and conducting clinical research. Such legal entities can designate themselves as hybrid entities under the Health Insurance Portability and Accountability Act (HIPAA), defined as a single legal entity whose business activities include both covered and non-covered functions, and identify the health care components (the functions performed which make the entity a health plan, health care provider, or health care clearinghouse) under HIPAA.[1] This designation is important – without it, HIPAA may extend to health information in every corner of the enterprise.

Although a university student health center would typically be considered a health care component under HIPAA, in many cases FERPA (the Family Educational Rights and Privacy Act[2]) would apply, and not HIPAA. Making such a determination is critical because privacy laws vary in how they protect patient information, including with respect to what types of disclosures are permitted or required, what constitutes a valid patient consent, what notice must be provided to patients, the potential liability for non-compliance, and the scope of information they protect. If the correct suite of privacy laws have not been identified, information could be impermissibly disclosed.

When assessing whether a particular use or disclosure of patient information is permitted at a university student health center,[3] the entity should first determine whether HIPAA or FERPA applies. In many cases, FERPA will likely apply, not HIPAA. However, that may be only the first step in the inquiry. The entity should also consider whether other federal

[1] 45 C.F.R. §§ 164.103, 164.105.

[2] 20 U.S.C. § 1232g; 34 CFR Part 99. FERPA applies to all educational agencies and institutions that receive funds under any program administrated by the Secretary of Education.

[3] For purposes of this article, we have generally focused on postsecondary education, as opposed to elementary or secondary school.

or state privacy laws that provide more stringent protection to certain categories of information apply, such as 42 C.F.R. Part 2, the federal regulations addressing confidentiality of substance use disorder information, and various state privacy laws, such as laws protecting the confidentiality of mental health records. A summary of the key federal laws follows, along with some examples of how the applicable law could impact whether information can be disclosed without patient consent.

HIPAA OVERVIEW

Health care providers that engage in certain electronic payment-related transactions for which HIPAA has established standards are subject to HIPAA.[4] "Health care provider" is defined broadly, including, but not limited to, health care facilities such as hospitals or clinics, as well as physicians, dentists, and any other persons or organizations that furnish, bill, or are paid for health care in the normal course of business.[5] Health care providers subject to HIPAA must comply with standards for electronic payment-related transactions, such as submission of claims to health plans.[6] They must also comply with the HIPAA Privacy Rule and Security Rule. Under the Privacy Rule, a covered entity (or a business associate, on the covered entity's behalf) may not use or disclose protected health information without a valid authorization, except as permitted or required by the Privacy Rule. Under the Security Rule, the covered entity and any business associates must also implement reasonable and appropriate administrative, physical, and technical safeguards to protect health information.[7]

However, the HIPAA Privacy and Security Rules do not apply to "education records" under FERPA (discussed in more detail below), even if the records are held by an institution's student health center that may also be a covered entity under HIPAA. Such records are expressly carved out from the HIPAA definition of protected health information.[8]

The HIPAA Privacy and Security Rules do not apply to "education records" under FERPA

FERPA OVERVIEW

FERPA, unlike HIPAA, was not designed to deal specifically with health records or the particular issues that may arise with such records. Instead, FERPA generally protects the privacy rights of parents and students in a student's "education records." Under the law, a parent or eligible student (18 years or older or attends a postsecondary institution) must provide a signed and dated written consent before the agency or institution discloses personally identifiable information in most instances from student's education records.

Education vs. Treatment Records. As noted above, FERPA applies to "education records," which are those records that are directly related to a student and maintained by the educational agency or institution.[9] However, at postsecondary institutions, medical and psychological treatment records of eligible students are excluded from the definition of "education records" if they are made, maintained, and used only in connection with treatment of the student and disclosed only to individuals providing the treatment.[10] These records are commonly referred to as "treatment records."

Treatment records, unlike education records, may be disclosed for treatment purposes without consent, even to healthcare professionals outside of the institution. For disclosures other than the student's treatment, consent is needed, or the disclosure needs to fit into one of the permissive or mandatory FERPA exceptions. And, once a record is available or disclosed to[11] persons other than those providing such treatment, including the student, the record no longer falls under the treatment record exception, and becomes an "education record," subject to all of FERPA's privacy protections.

The biggest practical differences between education and treatment records are that (1) a student has the right to access his or her own education records, but not treatment records[12];

---

[4] 45 C.F.R. § 160.102.

[5] 45 C.F.R. § 160.103.

[6] 45 C.F.R. §§ 162.100 *et seq.*

[7] 45 C.F.R. Parts 160 and 164, Subparts A and E (HIPAA Privacy Rule); 45 C.F.R. Parts 160 and 164, Subparts A and C (HIPAA Security Rule).

[8] 45 C.F.R. § 160.103.

[9] Records created after a person is no longer a student (an "alumni record") are not covered under FERPA.

[10] 20 U.S.C. § 1232g(g)(a)(4)(B)(iv).

[11] *See* 34 C.F.R. § 99.3: *Disclosure* means to permit access to or the release, transfer, or other communication of personally identifiable information contained in education records by any means, including oral, written, or electronic means, to any party except the party identified as the party that provided or created the record.

[12] An educational institution *could* allow a student to inspect his or her treatment records, but, such records would no longer be excluded from the definition of "education records."

and (2) an educational agency or institution may share treatment records for treatment purposes without student consent, but cannot do the same with education records.

Disclosure of Education Records. Most of the exceptions under FERPA to the general prohibition on disclosure of education records without student consent are permissive, as opposed to mandatory. These permissive exceptions include disclosures –

- to educational agency or institution officials with a "legitimate educational interest" in the records;
- in event of a health or safety emergency;
- in response to judicial orders or subpoenas (with notice to student);
- in the event of litigation initiated by the student; and
- for accreditation and audit/evaluation of programs by certain federal agencies.

Given that the FERPA exceptions are generally permissive, there is latitude for entities to make policy decisions to disclose less information than may be legally permitted. And, as mentioned above, entities must also consider whether other federal or state privacy laws that provide more stringent protection to certain categories of information apply, and would prohibit disclosure even where there is a permissive FERPA exception.

OTHER POTENTIALLY APPLICABLE FEDERAL AND STATE LAWS

As with any analysis regarding a potential disclosure of patient information, reviewing the relevant provisions of HIPAA or FERPA is not the end of the inquiry. More stringent federal and state laws could prohibit or otherwise place additional requirements on disclosure of information.

42 C.F.R. Part 2: If a provider operates a federally assisted substance use disorder program, strict federal regulations apply. "Federally assisted" and "program" are broadly defined, and may capture more patient records than is intuitive to many providers. For example, if the legal entity operating a university and its student health centers is a nonprofit corporation with federal tax-exempt status, and there is a unit within the clinic that is held out as providing substance use disorder counseling and provides such counseling, these regulations would apply. Part 2 not only places significant restrictions on when information can be disclosed without consent (including disclosure to third party payors for payment purposes), it also places significant restrictions on what is required for a valid consent. Recently, the Substance Abuse and Mental Health Services Administration (SAMHSA), issued two notices of proposed rulemaking on Part 2 (see our summary **here**), proposing additional guidance and clarification for Part 2 programs and lawful holders regarding permitted disclosures, with and without patient authorization.

More stringent State laws. Other restrictive State laws may apply. For example, in California, one or more of the following may need to be considered:

- *Health & Safety Code § 11845.5.* California's equivalent state law to Part 2 applies to treatment conducted, regulated, or assisted by California's Department of Health Care Services and similarly prohibits the disclosure of substance use disorder records, without consent, in most situations.
- *Confidentiality of Medical Information Act (CMIA):*[13] The CMIA is California's general patient privacy law. It is in many ways is the state counterpart to HIPAA, and addresses when a health care provider is permitted or required to use or disclose medical information. However, it is by not identical to HIPAA, and may in certain instances take a more stringent approach to protection of patient information.
- *Lanterman-Petris-Short Act (LPS)*:[14] The LPS Act addresses confidentiality of patient information received by certain providers in the course of providing mental health services. Of note, if the LPS Act applies, the CMIA does not apply.
- *Other Laws Applicable to Certain Categories of Information:* A number of other state laws could potentially apply, including laws with respect to confidentiality of HIV test results and genetic testing results.[15]

The Federal Common Rule. In addition, if the institution is engaging in federally funded research involving human subjects research subject to the "Common Rule" (regulations issued by various federal agencies), requirements include review and approval by an institutional review board, which must, among other things, assess whether there are adequate protections to protect the privacy of individuals and maintain the confidentiality of the data.[16]

INTERPLAY BETWEEN PRIVACY LAWS – EXAMPLES OF IMPACT ON DISCLOSURES IN STUDENT HEALTH CENTERS

[13] Cal. Civ. Code §§ 56 et seq.

[14] Cal. Welf. & Inst. Code §§ 5328 et seq.

[15] *See, e.g.*, Cal. Health & Safety Code §§ 120975, 124975 et seq., and the Genetic Information Nondiscrimination Act of 2008 (GINA), 42 USC §§ 2000ff – 2000ff-11.

[16] 45 C.F.R. § 46.111.

Identifying the applicable laws is critical to determining whether a contemplated disclosure is permitted. In particular, FERPA and HIPAA may intersect when a school provides health care to students, such as through on on-campus student health center.

The student health center is a "health care provider," as defined by HIPAA and, if the center conducts any covered transactions electronically, it is a "covered entity" under HIPAA as well.[17] Even as a covered entity, however, the student health center will not be required to comply with either the HIPAA Privacy or Security Rules because education and treatment records are carved out of the definition of protected health information under HIPAA.[18] On the other hand, if the student health center is a covered entity and provides health care to non-students, such as staff or family members of students, the records related to those non-students are subject to HIPAA.

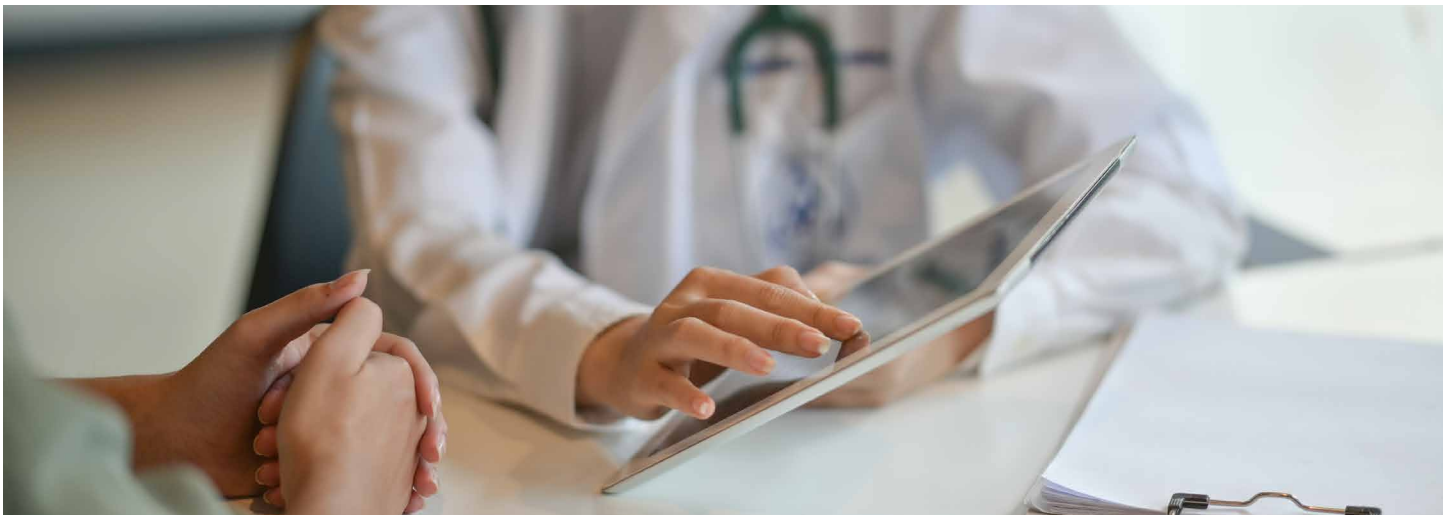
This distinction could lead to different disclosure rules for records at the same location. For example, before the health center discloses a student's education or treatment records for payment purposes, FERPA requires consent. Under HIPAA, a covered entity may disclose a patient's protected health information for payment purposes without consent. The following are other examples to help highlight some of the differences between potentially applicable federal laws:

With respect to *disclosure of information to campus administrators*, FERPA allows disclosure to school officials or agents that have legitimate educational interests. HIPAA does not as a rule permit disclosure for educational purposes. Part 2 likely would not permit disclosure for educational purposes either.

With respect to *deceased patients*, FERPA protections do not apply, HIPAA's protections apply for 50 years after death, and Part 2 applies without limit (although both HIPAA and Part 2 have special exceptions under certain circumstances).

Finally, with respect to *subpoenas and court orders* for patient records, FERPA permits disclosure to comply with a judicial order or lawfully issued subpoena. The educational entity generally must make a reasonable effort to notify the parent or eligible student so that he or she may object to the disclosure. Such notice is not required, however, if the subpoena is issued by law enforcement and the court or other issuing agency has ordered that the existence of the subpoena or information furnished in response not be disclosed. HIPAA similarly permits disclosure in response to a subpoena where the covered entity has received evidence that there have been reasonable efforts to (1) notify the person who is the subject of the information about the request, so the person has a chance to object to the disclosure, or (2) seek a qualified protective order for the information from the court. HIPAA also permits disclosure with a court order for specific information. Under Part 2, however, disclosure is only permitted when a court order that meets certain requirements is obtained. A subpoena alone will not suffice.

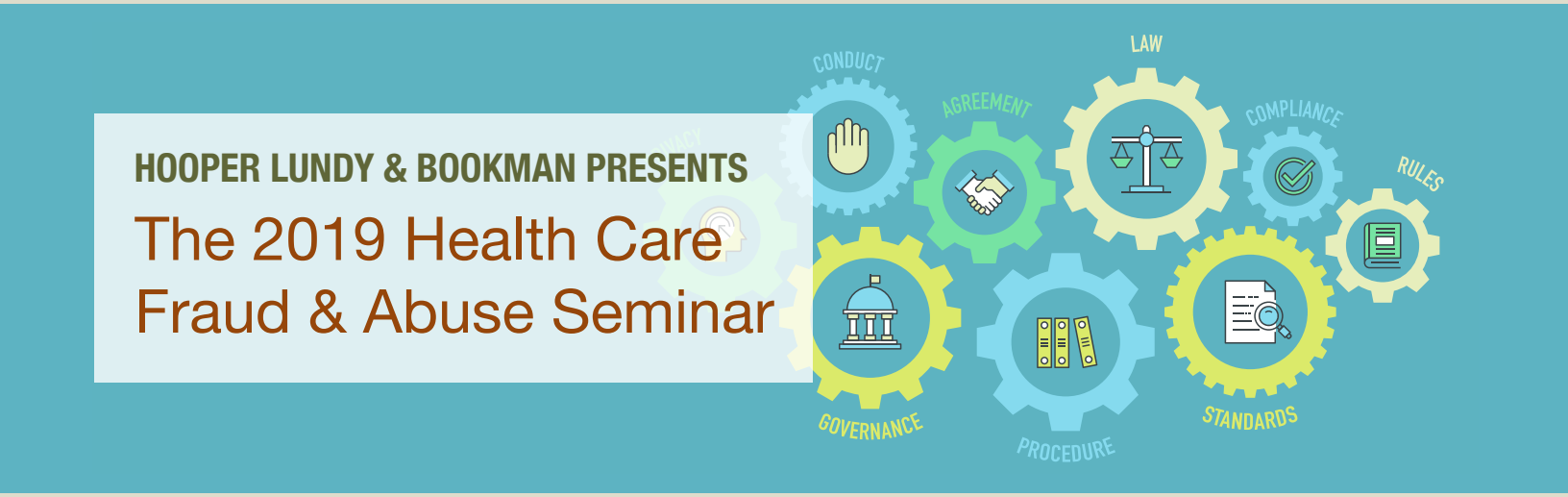
If you would like more information, please contact Amy Joseph in the Boston office, Alicia Macklin in the Los Angeles office, Paul Smith in the San Francisco office or your regular Hooper, Lundy & Bookman contact.



[17] The student health center will still have to comply with the HIPAA Administrative Simplification Rules for Transactions and Code Sets and Identifiers as a covered entity.

[18] If, instead, students receive treatment at a university hospital or academic medical center, the HIPAA Privacy Rule would apply to records generated and maintained from such treatment services. This is because university hospitals "generally do not provide health care services to students on behalf of the educational institution. Rather, these hospitals provide such services without regard to the person's status as a student and not on behalf of a university. Thus, assuming the hospital is a HIPAA covered entity, these records are subject to all of the HIPAA rules, including the HIPAA Privacy Rule." HHS and DOE, Joint Guidance on the Application of FERPA and HIPAA to Student Health Records (Nov. 2008).

UPCOMING EVENT



Tuesday, December 3, 2019
The LA Grand Hotel, 333 South Figueroa Street, Los Angeles, CA, 90071
8:00 AM to 4:00 PM
$95 per person
CLE: Approved

2019 HEALTH CARE FRAUD & ABUSE SEMINAR

Health care providers face a perilous enforcement environment. Federal and state regulators and private payors are more aggressive than ever, targeting providers with timetested and new, creative theories of enforcement. Now more than ever, providers need to be aware of recent enforcement developments to protect your organization and prepare, and guard against, an investigation. Please join us for a fastpaced discussion on cutting edge issues in health care fraud and abuse, including:

- False Claims Act recent developments
- Opioid Policy and Enforcement
- Managed Care and Patient Support
- Hot Topics in Investigations
- Stark and Antikickback Law
- And more

Breakfast and lunch will be provided, as well as CLE credit and written materials.

WHO SHOULD ATTEND

This seminar is appropriate for chief executive officers, chief financial officers, inhouse counsel, managed care directors and managers, compliance personnel, and patient financial services directors and managers.

Register Here

ACADEMIC MEDICINE
SPECIAL EDITION

Updating IRB Written Procedures to Reflect the Current Regulatory Landscape

By: Kelly Carroll, Andrea Frey, and Amy Joseph

Institutional Review Boards, or IRBs, play a critical role in human subjects research, by engaging in review of proposed and ongoing research studies to ensure appropriate steps are taken to protect the rights and welfare of human subjects. In doing so, IRBs may be subject to one or both of the Common Rule regulations and regulations issued by the U.S. Food & Drug Administration (FDA),[1] depending on the particular research study in question.

Both sets of regulations include similar requirements for IRB written procedures, including procedures that address: (1) conducting initial and continuing review of research and reporting related findings; (2) determining which projects to review more often than annually and which need verification from sources other than the investigators that no material changes have occurred since the prior review; (3) ensuring prompt reporting to the IRB of proposed changes in a research activity, and that investigators will conduct the research in accordance with the terms of the IRB approval; and (4) ensuring prompt reporting to the IRB, institutional officials, and the applicable federal agency of any unanticipated problems involving risks to subjects or others, any serious or continuing non-compliance, and any suspension or termination of IRB approval.[2] As with other policies and procedures (such as a covered entity's privacy and security policies), IRB written procedures are most effective when they are drafted and revisited periodically to ensure they provide a clear implementation roadmap for individuals, as opposed to merely reciting the law, and otherwise are aligned with an entity's operational needs.

In recent years, there has been significant regulatory activity impacting IRB operations, in the form of both revised regulations and new agency guidance, and this changing regulatory landscape requires changes to existing IRB written procedures. If an IRB has not revisited its written procedures in the past few years, given the recent regulatory activity it should consider doing so now. Certain key regulatory changes are addressed below.

REVISED COMMON RULE

In January 2017, the federal departments and agencies that follow the Federal Policy for the Protection of Human Subjects, better known as the "Common Rule," issued a Final Rule substantially revising the regulations governing clinical research involving human subjects, including multiple

[1] 21 C.F.R. § 56.101 et seq.; 45 C.F.R. § 46.101 et seq. Further harmonization of these regulations are expected, pursuant to the 21st Century Cures Act, Pub. L. No. 114-255 § 3023.

[2] 21 C.F.R. § 56.108; 45 C.F.R. § 46.103, or § 46.108 (revised Common Rule).

changes to IRB requirements. The Final Rule originally set the effective compliance date as January 19, 2018, though implementation was twice delayed. However, as of January 21, 2019, IRBs must ensure that all new research comply with the requirements of the revised Common Rule in their entirety, with the exception of the requirement for use of a single IRB for all U.S. sites engaged in cooperative research, which is required as of January 20, 2020. Research initiated prior will remain subject to the former Common Rule's requirements, though institutions may voluntarily elect to transition to compliance under the revised Common Rule.

Below are some of the key changes to the Common Rule that IRBs should consider and address when making any updates to their procedures. Another helpful starting point would be to review the **Written Procedures Guidance** issued in 2018 by the FDA and the Office for Human Research Protections (OHRP), and discussed in more detail below.

- *Changes to informed consent requirements.* The revised Common Rule articulates a number of new requirements for the organization and content of informed consent forms focused on ensuring that potential research participants are sufficiently informed of the scope of research and the risks and benefits of participation in a practical way. Under 45 C.F.R. §46.116, consent forms are now required to begin with a "concise and focused" explanation of the most important information that would allow a potential participant to understand the reasons to participate or decline. The regulations specify that all information in the informed consent needs to be constructed in a way that "facilitates" understanding and comprehension and must not "merely provide lists of isolated facts." Consent forms must also include statements about potential commercial profit from biospecimens, if applicable, whether research involving biospecimens will or may include whole genome sequencing, and whether clinically relevant research results will be provided to the subjects. IRBs will need to review consent forms for compliance with the revised requirements and update any reviewer checklists to ensure that they incorporate these requirements.
- *Added use of broad consent for certain secondary research.* The Final Rule establishes a framework for "broad consent," a new type of regulatory consent under the Common Rule for non-exempt storage, maintenance, and research use involving identifiable information and biospecimens.[3] Broad consent is intended to serve as an alternative to traditional informed consent for secondary research only, meaning the re-use of identifiable information and identifiable biospecimens that are collected for some other initial activity. Obtaining broad consent requires several additional elements under §46.116(d) as compared to traditional informed consent, none of which may be omitted or altered. IRBs will need to make revisions to their policies to address the use of broad consent and develop processes for tracking when broad consent is sought or refused.
- *Expedited and Limited Review.* Limited IRB review is a new concept established by the revised Common Rule that is available for research that will record, store, maintain, or make secondary use of identifiable private information. It is an alternative to the IRB approval criteria otherwise used for review of research and is acceptable where the following three criteria are met: first, the IRB must establish that broad consent for the "storage, maintenance, and secondary research use" of identifiable biospecimens was properly obtained; second, the IRB must then establish that the consent or waiver was appropriately documented; finally, the IRB must find that there are appropriate provisions in place to protect the privacy of the information if a change has been made in the way the data is stored or maintained. IRBs may also use an expedited review procedure to review either or both of the following: research that involves no more than minimal risk or minor changes to previously approved research.
- *Continuing Review Requirements.* Previously, IRBs were required to continuously review non-exempt research projects at least annually, consider proposed changes as they were submitted and review reports of unanticipated problems. The revised Common Rule removed this requirement for research eligible for expedited review, exempt research conditioned on limited IRB review, and research that has completed all interventions and will further include only analyzing data or accessing follow-up clinical data from care procedures. Importantly, investigators are not required to provide annual confirmation to an IRB that such research is ongoing and that no changes have been made that would require the IRB to conduct continuing review. However, investigators will still need to meet current obligations to report various developments (such as unanticipated problems or proposed changes to the study) to the IRB.
- *Single IRB Review*. Institutions engaged in cooperative research must obtain separate, local IRB

[3] Prior to the Final Rule's adoption of an express regulatory broad consent, there was a longstanding practice by many research institutions to obtain broad consent to future research uses of data and biospecimens. The Final Rule's adoption of broad consent should not necessarily be construed to invalidate broad consent forms signed prior to the promulgation of the Final Rule, however. As interpreted by the Secretary's Advisory Committee on Human Research Protections (SACHRP) in its **Guidance on Broad Consent under the Revised Common Rule**, "SACHRP believes that future research consent forms signed before and after the effective date of the Final Rule . . . will continue to be effective."

approval of the study, often resulting in a time-consuming, duplicative approach. To address this, the revised Common Rule implemented a new requirement, which takes effect January 20, 2020, that all multi-site cooperative research must use a single IRB (commercial, academic, or hospital-based) for research conducted in the U.S., unless more than one IRB is required by law, or a supporting federal agency determines that the use of a single IRB is not appropriate.

Practically speaking, with most of the Common Rule changes fully implemented, clients are encouraged to proceed with implementing and incorporating such changes into their procedures, to the extent not already done so. It is also important to recognize that there may be many different approaches as to how best to update policies and procedures to reflect the transition to the revised Common Rule's requirements, depending on the institution and how many studies are ongoing that remain subject to the requirements of the prior version of the regulations. If current studies that commenced prior to January 21, 2019 have already transitioned or are ending in the relatively near future, it may make more sense to have two sets of policies, one addressing the procedures under each respective version of the regulations, so that the institution will soon just have one policy in place devoid of extraneous information. However, if an institution will have many of both types of studies for years to come, one universal document addressing scenarios under both the prior regulations and the revised Common Rule (as well as FDA or other applicable requirements) may serve IRBs and investigators better.

OHRP/FDA COMBINED GUIDANCE FOR IRB WRITTEN PROCEDURES

On May 17, 2018, OHRP and the FDA announced the availability of guidance entitled "Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs" (Written Procedures Guidance). The agencies developed this **guidance document** as part of their joint efforts to harmonize the agencies' regulatory requirements and guidance for human subjects research, and they designed the document to assist staff at IRBs and institutions responsible for preparing and maintaining written procedures.[4] The guidance includes useful information on what steps to take during review at IRB meetings, review via expedited procedures, informed consent development, determining that IRB criteria for research approval are met, communicating findings to the investigator and institution, reporting of research changes to the IRB, and how to handle unanticipated problems and noncompliance.

While HHS and FDA regulations afford institutions and IRBs flexibility in the content and form of their written procedures, the regulations require that IRBs must follow written procedures in the context of performing the four functions described at the beginning of this article. The Written Procedures Guidance describes each of these regulatory requirements in more detail and provides suggestions about operational details to include in support of each regulatory requirement. Throughout the guidance document, the agencies include useful references to other underlying regulations that the agencies recommend institutions and IRBs consider when preparing their procedures (e.g., regulations governing research involving children, prisoners, and pregnant women). The Written Procedure Guidance also identifies additional topics the institution or IRB may consider in developing written procedures, including IRB membership, IRB functions and operations, IRB records, and the scope and authority of the IRB. OHRP and the FDA intend that the guidance will facilitate an improved understanding of the regulatory requirements for written procedures for the IRB, and will be a tool for developing meaningful content and operational details both to meet those requirements and help IRB members carry out their duties in a consistent and effective way.

OTHER RECENT GUIDANCE

In addition to the revised Common Rule and the Written Procedures Guidance referenced above, there have been a number of other guidance documents issued for IRBs in recent years which could impact an IRB's written procedures, including, without limitation, **Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations** (FDA, October 2018) and **IRB Waiver of Alteration of Informed Consent for Clinical Investigations Involving No More than Minimal Risk to Human Subjects** (FDA, July 2017). There are also changes to come, including the requirement for use of a single IRB for applicable federally-funded research under the revised Common Rule, effective in 2020, and further harmonization of the Common Rule and FDA regulations expected under the 21st Century Cures Act. HLB can assist IRBs with reviewing and revising written procedures to ensure compliance with the aforementioned applicable requirements and will continue to monitor upcoming changes to the regulatory landscape around clinical research.

For further information, please contact Kelly Carroll in the Washington, D.C. office, Andrea Frey in San Francisco office, Amy Joseph in the Boston office, or your regular Hooper, Lundy & Bookman contact.

[4] As noted in the document, the references to the Common Rule in the Written Procedures Guidance do not reflect the final revisions to the rule from January 2017 and January 2018, so some of the cross-references are no longer current.

Proposed Stark & Anti-Kickback Regulations Are A Big Deal

By: Charles Oppenheim, David Hatch, Sandi Krul, Robert Miller, Brett Moodie, Ben Durie, Stephanie Gross and Amy Joseph

Proposed anti-kickback statute and Stark law regulations issued on October 9, 2019 signal potentially significant easing of compliance concerns throughout the healthcare community. The highly-anticipated proposed regulations would create new anti-kickback safe harbors (for certain "value based" arrangements, and other activities) and ease compliance with existing ones, and would create similar new Stark law exceptions (there is also a new safe harbor under the civil monetary penalties law ("CMP")). Notably, the proposed Stark law regulations would also facilitate compliance with current regulations by adopting provider-friendly interpretations of terms such as "fair market value" and "commercially reasonable" that are used throughout the regulations, and have been a breeding ground of uncertainty.

VALUE BASED ARRANGEMENTS

In an effort to remove regulatory obstacles to value based payment arrangements, the Centers for Medicare and Medicaid Services ("CMS"), which has jurisdiction over the Stark law, proposes three new Stark law exceptions, and the Office of Inspector General of the Department of Health and Human Services ("OIG"), which has jurisdiction over the anti-kickback statute, proposes three corresponding new safe harbors to the anti-kickback statute.

The proposed regulations use a common set of terms to refer to a "value based arrangement", which is "an arrangement for the provision of at least one value based activity for a target population." The value based arrangement must involve a "value based enterprise." In the preamble to the Stark regulation, CMS explained, "We intend the definition of value based enterprise to include only organized groups of health care providers, suppliers, and other components of the health care system collaborating to achieve the goals of a value based health care system." A value based enterprise must be made up of two or more parties "collaborating to achieve at least one value based purpose," which can refer to coordinating and managing patient care; improving care; appropriately reducing costs; and transitioning from a payment system based on volume to one based on value. Under the proposed Stark regulations, the scope of permitted "participants" in a value based enterprise contains no exclusions; however, the anti-kickback statute regulations exclude pharmaceutical manufacturers; DMEPOS manufacturers, distributors and suppliers; and laboratories.

There are proposed Stark law exceptions and safe harbors for *full* financial risk arrangements, as well as for arrangements where the physician has *meaningful or substantial* downside financial risk. The two sets of regulations set forth different quantitative thresholds for taking

on "meaningful" and "substantial" downside risk, respectively, so parallel analyses are necessary to ensure that a particular value based arrangement satisfies both a Stark law exception and a safe harbor.

The burden of complying with each exception would depend on the level of risk, and arrangements involving greater risk are subject to fewer requirements. Again, however, the requirements do not line up across the proposed Stark law regulations and the proposed anti-kickback safe harbors, so two analyses are necessary to determine whether a particular value based arrangement satisfies an exception and a safe harbor.

The OIG has proposed a separate safe harbor for in-kind remuneration that is used for care coordination and care management activities. By way of example, the OIG suggested that the safe harbor could be used to allow a value based enterprise participant to share a care coordinator with another value based enterprise participant. In addition to satisfying other requirements, the arrangement must require the recipient to pay for at least 15% of the cost of the in-kind remuneration. The safe harbor does not require a party to take on financial risk.

Finally, the proposed Stark regulations contain an additional exception for a value based arrangement that involves neither full nor meaningful financial risk, and does not require the parties to take on downside risk at all. While there is no clear analog to this exception among the new safe harbors, CMS sought comment on whether to include additional requirements to align this exception with the safe harbor for in-kind remuneration used for care coordination and care management activities.

PATIENT ENGAGEMENT AND SUPPORT SAFE HARBOR

The OIG has proposed a new anti-kickback statute safe harbor for providing patient engagement tools and support to improve quality, health outcomes, and efficiency, but the proposed safe harbor would be available only to "value based enterprise" participants (as this term is used in the OIG's proposed new value based arrangement exceptions). The OIG indicates it seeks to promote "well-coordinated care" with a goal to help "patients to actively participate and engage in their preventive care, treatment, and general health," and notes the significant potential cost-savings to the Medicare and Medicaid programs from such care.

The safe harbor would protect the provision of in-kind preventive items or services such as health-related technology, health-related monitoring tools and services, or support services to identify and address social determinants of health, if they are recommended by the patient's licensed provider, have a direct connection to coordination or management of care, and advance certain healthcare goals, e.g., treatment plan compliance. The value of these items or services is generally capped at $500 per year, unless an exception is based on an individualized financial needs determination. The safe harbor would not permit providing cash or cash equivalents, or items or services used for marketing or resulting in medically unnecessary or inappropriate care.

> Proposed anti-kickback statute and Stark law regulations issued on October 9, 2019 signal potentially significant easing of compliance concerns

LOCAL TRANSPORTATION SAFE HARBOR

The proposed regulations would modify the local transportation safe harbor to (1) extend the distance residents of rural areas may be transported from 50 to 75 miles; and (2) remove the 25-mile limit on transportation of a patient upon discharge, to the patient's residence. The OIG is considering expanding the safe harbor to include transportation for health-related, non-medical purposes, e.g., to food stores or banks, social service facilities, exercise facilities, and chronic disease support groups. The OIG also clarifies that it is permissible to provide local transportation through ride-sharing services, so long as the requirements of the local transportation safe harbor are satisfied, and explains that the safe harbor protects not just the transportation, but also the support necessary to get patients safely to their destination, e.g., assisting the patient with a wheelchair, oxygen equipment, and ambulating in and out of the pickup and drop-off points.

CMS-SPONSORED MODEL ARRANGEMENTS AND PATIENT INCENTIVES

The OIG proposes a new safe harbor for delivery and payment arrangements, as well as beneficiary incentives, provided in connection with models under either the CMS Innovation Center or the Medicare Shared Savings Program. The proposed safe harbor would be an alternative to the current model-by-model fraud and abuse waiver process, and would provide greater efficiency and consistency across all eligible models. The safe harbor would be applicable to each CMS-sponsored model, if CMS notifies participants the safe harbor applies. CMS may also choose to impose additional conditions to using the safe harbor for particular models.

In addition to any CMS imposed

conditions, the proposed safe harbor includes several requirements, e.g., the arrangement or patient incentive (as applicable) must advance one or more goals of the CMS-sponsored model, and any patient incentives must have a direct connection to the patient's healthcare. CMS does not propose a corresponding Stark exception. However, the proposed value based arrangements exceptions to Stark, and the corresponding proposed anti-kickback statute safe-harbors, are not limited to CMS-sponsored models. So, depending on the nature of the arrangement, those exceptions and safe harbors might protect participants in CMS-sponsored (or other alternative payment models).

The OIG proposes significant modifications to the existing safe harbor for personal services and management contracts

PERSONAL SERVICES SAFE HARBOR

The OIG proposes significant modifications to the existing safe harbor for personal services and management contracts. For example, the requirement that the aggregate compensation be set in advance would be replaced with the requirement that the methodology for determining compensation be set in advance. This is an extremely advantageous change, as it is more in line with the corresponding Stark personal services exception, and would cover common wRVU-based compensation structures (and other formula-based arrangements where the exact dollar amount of compensation is not fixed in advance). Another proposed change would eliminate the requirement that periodic, sporadic or part-time arrangements must specify the exact schedule, precise length, and the exact charge for those intervals (again, more in line with the corresponding Stark personal services exception).

The OIG also proposes to exclude from the definition of "remuneration" certain outcome-based payments, in recognition of newer payment models intended to facilitate better care coordination, provider engagement across care settings, and that promote the shift to value. The OIG proposes defining outcome-based payments to mean payments for (1) improving (or maintaining improvement in) patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across care settings; or (2) achieving one or more outcome measures that appropriately reduce payor costs while improving, or maintaining the improved, quality of care for patients. This would potentially cover shared savings and shared losses, gainsharing, pay-for-performance, and episodic or bundled payments. The parties would be required to regularly monitor and assess performance on each outcome measure, and periodically "rebase" (reset) the benchmark or outcome measure for outcomes-based payments when feasible, to account for improvements achieved.

Payments made by a pharmaceutical manufacturer, a DMEPOS manufacturer, distributor, or supplier, or a laboratory, whether directly or indirectly, would be excluded, and the OIG is considering excluding pharmacies, PBMs, wholesalers and distributors, and also possibly limiting protection for outcomes-based payment arrangements to value based enterprise participants. Payments that relate solely to achieving internal cost savings for the principal would also be excluded. So, for example, the safe-harbor would not protect outcomes-based payment arrangements between a hospital and physician group where the parties share financial risk or gain only with respect to items or services reimbursed to the hospital under the Medicare prospective payment system for acute inpatient hospitals, but if it involved sharing financial risk or gain across care settings (e.g. inpatient stay plus the 60-day post-discharge period), then it could qualify as an outcome-based payment if the other safe harbor requirements are met.

CYBERSECURITY TECHNOLOGY AND RELATED SERVICES

The OIG and CMS have coordinated to propose a new anti-kickback statute safe harbor and a new exception to the Stark law to allow for donations of cybersecurity technology and related services (but excluding hardware and monetary support). The proposals are intended to help improve cybersecurity by "removing a real or perceived barrier that would allow parties to address the growing threat of cyberattacks that infiltrate data systems and corrupt or prevent access to health records and other information essential to the delivery of healthcare."

The proposals would permit non-monetary donations of cybersecurity technology and services if certain conditions are met, e.g., the technology and services must be "necessary and used predominantly" to implement, maintain or reestablish cybersecurity, and the donation of technology or services may not take into account the volume or value of referrals or other business generated between the parties. Likewise, the recipient of the technology or services may not condition doing business with the donor on such donation. The arrangement must be documented in writing, and meet other requirements.

ELECTRONIC HEALTH RECORDS

The OIG and CMS also collaborated to make recommended changes to the safe harbor and Stark law exception for the donation of interoperable electronic health records ("EHR") software or information technology and training services. Among other things, the proposals would eliminate

the current sunset provision included in each regulation, to make the safe harbor and exception permanent. The proposed modifications are primarily designed to incorporate definitions used in the 21st Century Cures Act and related regulations. Practically, the revised definitions are intended not to be substantially different from the existing definitions, but to reflect updated terminology and understandings, as well as to provided consistency between the separate regulations. The OIG and CMS have also invited comments on modifications to the existing requirement that a recipient of EHR technology contribute 15 percent of the donor's cost. While no specific text has been proposed, comments have been requested regarding whether the contribution requirement should be reduced or even eliminated for certain providers.

The OIG provides guidance on how it interprets the statutory exception in the CMP law for certain telehealth technologies

TELEHEALTH TECHNOLOGIES FOR IN-HOME DIALYSIS

The OIG provides guidance on how it interprets the statutory exception in the CMP law for certain telehealth technologies provided to end stage renal disease ("ESRD") patients. The OIG clarifies that it interprets the regulation as requiring the telehealth technologies be furnished to the patient by the provider of services or the renal dialysis facility that is currently providing the related care to the patient, to prevent arrangements in which telehealth technologies are provided to non-patients in an effort to convert them into patients. The OIG also proposes to exclude provision of technology that has "excessive" value, and defines "telehealth technologies" by building off the definition of "interactive telecommunications system" used for Medicare Part B, and would include any "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time, interactive communication between the patient and distant site physician or practitioner," e.g., smart phones.

WARRANTIES

The OIG proposes to update the safe harbor for warranties to (1) protect warranties for one or more items and related services upon certain conditions; (2) revise reporting requirements; and (3) define "warranty" directly, not by reference to another statute. In OIG's view the current safe harbor does not protect arrangements where a warranty applies to bundled items and services, such as wound care products and related support services (see Advisory Opinion No. 01-08). The proposed regulation would modify the safe harbor to permit these arrangements where certain conditions are met. The OIG's proposed changes to reporting requirements would accommodate outcomes-based warranty arrangements where the efficacy of an item might not be known in the current reporting period and exclude beneficiaries from reporting requirements applicable to buyers.

ACO BENEFICIARY INCENTIVE PROGRAM

By statute, accountable care organizations ("ACOs") participating in certain CMS-approved, two-sided risk models may provide incentive payments to beneficiaries who receive qualifying primary care services. The proposed new safe harbor codifies the existing statutory exception through wording very similar to the existing statute, although the proposed safe harbor clarifies that an ACO may provide incentive payments only to beneficiaries assigned to the ACO by CMS.

OTHER KEY PROPOSED STARK CHANGES

Although much of the focus and attention surrounding the new proposed Stark Law regulations has been the creation of new exceptions to help support the transition to value based reimbursement, CMS has also proposed significant changes to the existing exceptions – an exercise it describes as "recalibrating the scope and application" of the Stark regulations. Many of the proposed changes are a direct response to a series of False Claims Act ("FCA") whistleblower cases that have been decided over the last 10 years including the 2015 decision in *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, and provide helpful clarifications of the existing regulations. Below is a high-level summary of several of the most significant definitional and special regulation changes:

Isolated Financial Transactions: The Stark Law provides an exception for remuneration paid to physicians as part of an "isolated financial transaction" so long as certain requirements are satisfied, including that the transaction involves only a single payment, consistent with fair market value for the items or services provided. Because the exception does not require the arrangement to be in writing, it has long been used by healthcare providers to protect unwritten arrangements of various types, so long as the arrangement entails only a single payment.

In the proposed regulation, CMS describes at length its position that the isolated transactions exception is not intended to protect arrangements where a party makes a single payment for multiple services provided over an extended period of time. To clarify this position, CMS proposes modifying

the definition of "isolated financial transaction" to include an affirmative statement that an "isolated financial transaction" cannot include "a single payment for multiple or repeated services (such as a payment for services previously provided but not yet compensated)."

Although CMS asserts the new text is just a "clarification" of its long-standing policy, it represents a significant departure from an interpretation of the exception that (1) has been widely held within the industry (as CMS recognizes in its commentary), and (2) is well-supported by the plain wording of the regulations. The Stark regulations currently define a transaction as "an instance or process of two or more persons or entities doing business," meaning that the term "transaction" includes not only "instances" of business, but also ongoing business arrangements. Under the current regulations, the definition of a "transaction" is subsumed within the definition of an "isolated financial transaction," which "means one involving a single payment between two or more persons or entities...." Both the statute and regulation provide examples of "isolated transactions" that include the one-time sale of property or a practice, but these are offered as examples, without any indication or suggestion that they are intended to be exhaustive. Accordingly, by the plain wording of the regulations, it is far from clear that the exception, as currently written, would prohibit a single, fair market value payment for services performed over a period of time (assuming the other requirements of the exception are satisfied).

Although CMS asserts the new text is just a "clarification" of its long-standing policy, it represents a significant departure from an interpretation of the exception that has been widely held within the industry

Commercial Reasonableness: A key element of most Stark Law exceptions is that the arrangement be commercially reasonable. This requirement has been the subject of numerous FCA actions over the last several years and has been source of significant enforcement action. Despite the importance of this requirement, the Stark Law itself has never included a definition for the term.

In response to requests from stakeholders and confusion generated from prior FCA litigation, CMS has proposed to define "commercially reasonable" as meaning that "the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements." Importantly, the definition goes on to state that "[a]n arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties." This last clarification is very significant because the question of whether an arrangement can be commercially reasonable even if a hospital loses money has been the subject of significant controversy in multiple recent FCA actions. The government and private whistleblowers have repeatedly argued that if hospitals lose money on arrangements with physicians when considering the collections for physicians' services compared to the physicians' compensation, then it must mean the hospital is taking account of referrals or other business generated by the physicians (something that is prohibited under the Stark law).

Volume or Value Standard and the Other Business Generated Standard: The requirement that compensation to physicians cannot take into account the "volume or value" of referrals made by the physicians is a central concept within the Stark Law and has been the subject of controversy in recent FCA cases. As with the term "commercial reasonableness," despite being a key term within the Stark law, there has never been a definition of the "volume or value" standard within the regulations. Except in connection with the special rules on compensation for unit-based compensation (which contain exclusions from the standard).

CMS now proposes that compensation will be considered to take into account the volume or value of referrals *only* when the "mathematical formula used to calculate the amount of the compensation" includes a variable identifying the specific number of referrals or other business generated by the physician and "the amount of the compensation correlates with the number or value of the physicians referrals." Importantly, CMS also clarifies that (despite some questions raised by the holdings in *Tuomey* and other FCA cases) when a hospital is paying physicians productivity based compensation, it is not considered to take into account the value or volume of the physicians' referrals solely because corresponding hospital services are billed by the hospital each time the physician provides a service in the hospital or outpatient department/clinic.

Indirect Compensation Arrangements: The proposed regulation would significantly limit which financial relationships are considered indirect compensation arrangements, which then create a financial relationship for purposes of the Stark law. The current definition requires that the compensation link closest to the physician "varies with or takes into account the volume or value of referrals or other business generated;" and the proposed definition would remove the "varies with" phrase. This change, in addition to the significant limitation regarding which compensation methodologies are considered to "take into account" referrals or other business generated

(discussed above), may mean that many indirect financial relationships that would previously require scrutiny will no longer be subject to the Stark Law.

Designated Health Services: CMS proposes clarification of what constitutes a "designated health service" for hospital inpatients. The change could significantly reduce the number of hospital inpatient claims "tainted" by prohibited financial relationships. CMS proposes that any individual service provided by a hospital to an inpatient (such as an X-ray or diagnostic test) does not constitute a designated health service if the service does not affect the amount Medicare pays for the inpatient under the inpatient prospective payment system ("IPPS"). This would mean that if a physician who ordered a diagnostic test had a financial relationship with a hospital that failed to comply with a Stark exception, the hospital would not be prohibited from billing for the admission so long as the physician who ordered the inpatient admission did not have an impermissible financial relationship with the hospital, and the diagnostic test ordered did not affect the hospital's payment.

Period of Disallowance: Currently the Stark Law contains a process providers can use to calculate the "period of disallowance," i.e., the period when, as a result of a prohibited financial relationship, a physician cannot make referrals of designated health services and entities cannot bill Medicare for the referred designated health services. A general principle under the Stark Law is that a period of disallowance starts on the date a financial relationship fails to meet the requirements of an applicable exception and ends when the financial relationship ends or is brought into compliance, and the current regulations deem certain kinds of financial relationships to last a specific period of time for purposes of calculating the period of disallowance. By removing these provisions CMS is arguably creating more flexibility for providers to determine the appropriate period of disallowance on a case-by-case basis, but it may also introduce confusion by eliminating a provision that was intended to act as a bright line regulation.

Of note, in the commentary addressing the period of disallowance, CMS expressly acknowledges that "imperfect performance" does not necessarily create a Stark law violation, stating that "parties who detect and correct administrative or operational errors or discrepancies during the course of the arrangement are not necessarily 'turning back the clock'," and providing an example of payment errors that are corrected over the course of the arrangement. This firm has long taken the position that such imperfect performance is defensible.

CMS expressly acknowledges that "imperfect performance" does not necessarily create a Stark law violation

Fair Market Value and General Market Value: CMS proposes to update the regulatory definition of "fair market value" to more closely align with the statutory definition. The updated definition addresses two distinct concepts – fair market value and general market value (now more closely tied to the valuation definition of "market value"). Fair market value is the hypothetical value of an asset or service in an arms' length transaction, with like parties under like circumstances, consistent with general market value. The updated definition makes clear that general market value is the specific value to the actual parties of a transaction set to occur within a specific timeframe as a result of bona fide bargaining between the buyer and the seller.

Group Practices: Among other things, CMS proposes to "clarify" its interpretation of how "overall profits" from designated health services may be distributed to physicians in the group. The current regulations permit distribution of the group's overall profits, defined as the "entire profits derived from designated health services," and a common interpretation has been to permit distribution on a service-by-service basis (e.g., profits from laboratory services distributed one way and profits from diagnostic imaging services distributed another way). CMS proposes revising the regulatory language to prohibit distributing overall profits based on particular designated health services service lines.

Limited Remuneration to a Physician (Proposed New Exception): In addition to the proposed new Stark law exceptions corresponding to the proposed new safe harbors, as addressed above, CMS has proposed an additional exception for compensation up to $3,500 in a calendar year (adjusted for inflation annually), paid to a physician for items or services provided by the physician, and no writing is needed. Other requirements apply, e.g., compensation must be fair market value, and compensation for leasing space or equipment may not be based on percentage of revenue or per-unit formula. This proposed exception is intended to provide additional flexibility to protect short term arrangements (90 days or less), or payments otherwise made outside of a written agreement (e.g., where a physician receives an hourly rate of payment that is higher than the amount stated in the written agreement).

This would create another solution for arrangements that do not squarely fit within another exception. In addition, if CMS does not change course from its proposed changes to the isolated transactions exception, this limited remuneration exception, along with other new proposed modifications, will be critical to protect at least some

payments made to physicians for services without a written agreement.

Temporary Noncompliance with Writing and Signature Requirements: CMS has previously provided flexibility for obtaining signatures after an arrangement begins, and clarified that a collection of writings could be combined to satisfy the writing requirement in lieu of a formal executed agreement. The proposed regulations would go further, to allow compliance with both the signature and writing requirements up to 90 days after the arrangement begins. This change is helpful, as it recognizes that services might need to begin before an agreement can be memorialized. CMS, however, emphasizes that all other applicable requirements must be met, including that the compensation be set in advance. This raises the question of how parties would prove compensation was set in advance if the arrangement was not reduced to writing, particularly in more complex compensation arrangements, although documenting that the parties previously agreed to the compensation and other terms prior to commencement of the arrangement might be a reasonable approach. CMS also notes that records of a consistent rate of payment would support the inference that compensation is set in advance.

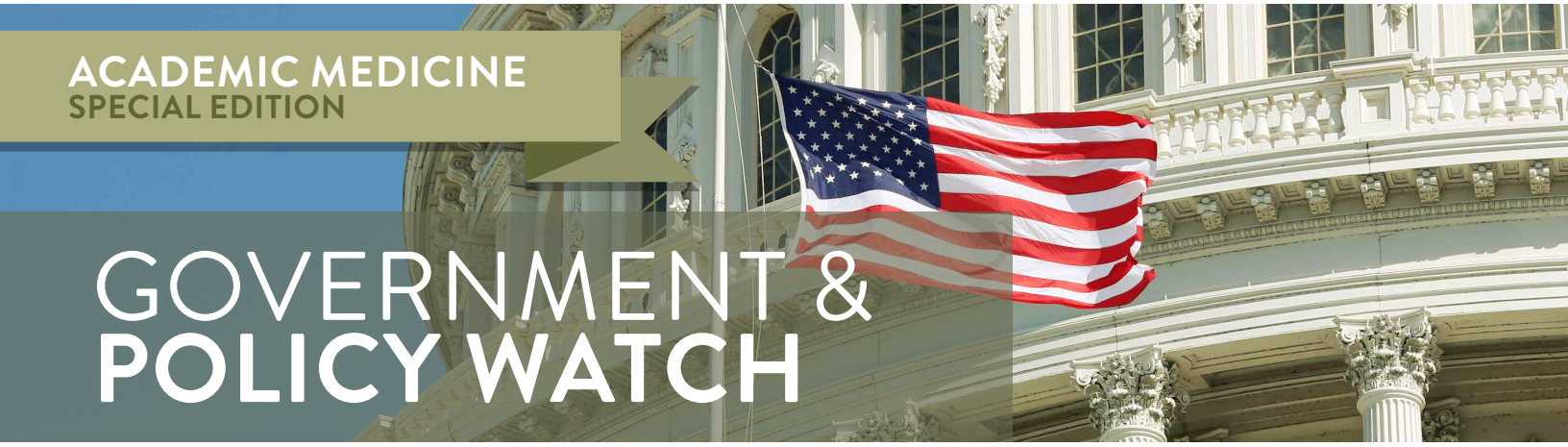
> Also, CMS proposes to revise the exception for remuneration unrelated to designated health services

Other Modifications of Note to Existing Exceptions: CMS proposes changes to a number of other existing exceptions, such as revisions to the exception for recruiting non-physician practitioners. These exceptions are not addressed in detail here but, along the same theme as many other changes, provide additional flexibility. For example, with respect to office and equipment leases, CMS proposes to revise the "exclusive use" requirement to clarify that multiple lessees may use the space or equipment to the exclusion of the lessor. CMS also proposes to allow the use of the fair market value compensation exception for space leases, providing more flexibility with respect to the term of a lease, and such exception would be revised to incorporate the restriction on compensation methodologies for rental payments currently included in other exceptions.

Also, CMS proposes to revise the exception for remuneration unrelated to designated health services to clarify that remuneration from a hospital to a physician does not relate to the provision of designated health services if it is for items or services that are not related to patient care services (e.g., serving on a governing body along with non-licensed individuals).

For more information, please contact Charles Oppenheim, David Hatch, Sandi Krul, Robert Miller or Brett Moodie in Los Angeles, Ben Durie or Stephanie Gross in San Francisco, Amy Joseph in Boston, or your regular Hooper, Lundy & Bookman contact.

ACADEMIC MEDICINE
SPECIAL EDITION



GOVERNMENT & POLICY WATCH

By: Monica Massaro

Congress has a busy fall work period both in and outside of health policy. In health policy, the focus remains on legislation addressing surprise medical bills and drug pricing. Below is a roundup of recent Congressional activity impacting the academic medical arena:

CONGRESS PASSES CONTINUING RESOLUTION FUNDING GOVERNMENT THROUGH NOVEMBER 21

Last month, Congress passed a continuing resolution (CR) to fund the government through November 21 in order to continue negotiations on appropriations for FY 2020. In addition to funding the government past September 30, several expiring health care extenders were added that were due to expire this month, but now are delayed until Nov 21, including funding for Community Health Centers, Medicaid in Puerto Rico and the U.S. territories, Demonstration Program for Certified Community Behavioral Health Clinics, the Special Diabetes Program, and a short-term delay of Medicaid DSH cuts, amongst others. The House Appropriations Committee passed their version of the FY 2020 Labor, Health & Human Services (LHHS) funding bill **earlier this year** while the Senate continues to work out an agreement on their version of health spending.

HOUSE COMMITTEE PASSES OPIOID WORKFORCE ACT

The Opioid Workforce Act (H.R. 3414),introduced earlier this year, would fund 1,000 new residency positions in hospitals that have, or are in the process of establishing accredited programs in addiction medicine, addiction psychiatry or pain management over the next five years. This bipartisan legislation was passed out of the Ways and Means Committee in June despite some concerns from Republican members that the legislation as written does not do enough to address the issue in rural areas. The legislation does not have a Senate companion but is supported by a number of physician and hospital organizations.

GME RESIDENT ROTATOR BILL INTRODUCED

In July, members of both the House and the Senate representing the state of New Jersey including Senators Cory Booker (D-NJ), Bob Menendez (D-NJ) and Representatives Josh Gottheimer (D-NJ) and Bill Pascrell (D-NJ), introduced the **Supporting Graduate Medical Education at Community Hospitals Act (H.R. 3752/S. 2116)**, legislation which would establish rules for payment for graduate medical education (GME) costs for hospitals that establish a new medical residency training program after hosting resident rotators for short durations.

If you would like more information, please contact Monica Massaro in the Washington D.C. office or your regular Hooper, Lundy & Bookman contact.

LAWYER Q+A

David J. Vernon

ABOUT DAVID

David is a member of HLB's regulatory department, where he assists health care providers, including hospitals, skilled nursing facilities, and physicians with a broad range of licensing and certification, reimbursement, fraud and abuse, and compliance issues. He focuses his practice on Medicare and Medicaid reimbursement, especially on Graduate Medical Education reimbursement, and on licensing and certification. David is a co-founder of the firm's Academic Medical Center/ Teaching Hospitals Working Group and a member of the firm's Fraud & Abuse Practice Group.

David received his B.A. degree in Neuroscience and Behavior from Vassar College in 2006, graduating with departmental and general honors. He received his J.D. degree from the University of California, Berkeley, School of Law in May 2012, where he was Co-President of the Boalt Healthcare and Biotech Law Society. In law school, David worked as a research assistant for the Warren Institute's Health, Economic & Family Security Program on legal issues impacting the creation of safety-net ACOs. He was also a two-time Prosser Prize winner and an Advocacy Award winner.

Prior to attending law school, David worked as the research analyst to the President/CEO of the Association of American Medical Colleges, where he published a number of articles in peer-reviewed biomedical journals.

Did you always know that you wanted to be an attorney?

No. I was a Neuroscience undergrad with plans to be a medical researcher and clinician. I'd worked at NIH in pediatric oncology one summer, and then my first job after graduating from Vassar was in a Circadian Rhythms laboratory at Columbia University and Barnard College. I wasn't passionate about the work in the lab and was looking for a change.

Fortunately, the then-President and CEO of the Association of American Medical Colleges (AAMC) was hiring for his first research analyst. When Dr. Kirch hired me, I was still thinking about going to medical school. But while at the AAMC, I learned so much about the legal and regulatory hurdles that academic medical centers, medical schools, and teaching physicians face. It was then that I knew that I wanted to become a healthcare attorney working on behalf of providers like academic medical centers and teaching hospitals.

How has your practice evolved in the last 5 years?

I've been at Hooper, Lundy & Bookman since I graduated from U.C. Berkeley School of Law. I started in our San Francisco office and developed extensive expertise in licensing, certification, and operations matters predominately impacting post-acute care providers.

Since moving to the Washington, D.C. office in 2014, while maintaining and strengthening my knowledge in licensing and certification, I've been able to grow my graduate medical education (GME) reimbursement practice, as well as my Medicare and Medicaid reimbursement

practice, more generally. Now my practice includes advising on GME reimbursement matters, as well as appealing numerous Medicare reimbursement issues (i.e., wage index, rural floor) to the Provider Reimbursement Review Board (PRRB) and federal court.

What do you like most about your job?

By far, it's working with healthcare providers to help them navigate complex legal and regulatory issues so that they can do what they are meant to do—help care for our nation's patients. I wanted to be a medical researcher and clinician to heal patients and to improve their lives. I didn't end up heading down that path, but being able to support healthcare providers in their efforts to heal and improve the lives of their patients is a joy.

Who inspires you?

My wife. She's a brilliant attorney and incredible mother and partner. With young kids and extraordinarily busy schedules these days, we know we can't have it all, at least not all at once. Still, I marvel at her ability to juggle so much as we parent our kids and service our respective clients.

FIRM NEWS

Things happening at Hooper, Lundy & Bookman

SUPER LAWYERS RECOGNIZES HLB BOSTON ATTORNEYS

Hooper, Lundy & Bookman congratulates Boston attorneys David Schumacher, Ryan Cuthbertson, Amy Joseph, and Jeremy Sherer for being selected to the 2019 *Super Lawyers* and *Rising Stars* lists.

Mr. Schumacher is a partner in the firm's Litigation Department and co-chair of the firm's Fraud and Abuse Work Group, Ms. Joseph is a partner in the firm's Business Department and co-chair of the firm's Academic Medical Center/Teaching Hospital Work Group, Jeremy Sherer is an associate in the firm's Regulatory Department and co-chair of the firm's Digital Health Task Force and Mr. Cuthbertson is an Associate in the firm's Business Department.

No more than 2.5 percent of attorneys in each state who are 40 years old or younger or have been practicing for less than ten years are recognized as Super Lawyer Rising Stars. Super Lawyers ranks those who have attained a high degree of peer recognition and professional achievement, and the selection process includes independent research, peer nominations, and peer evaluations.

David Schumacher

Ryan Cuthbertson

Amy Joseph

Jeremy Sherer

IRON-LAWYER

Partner Devin Senelick finished his THIRD Ironman on October 13 in Louisville, Kentucky. Congratulations!

HLB'S 2019 MANAGED CARE UPDATE SEMINAR IN LOS ANGELES AND BERKLEY WAS A GREAT SUCCESS. DON'T MISS IT NEXT YEAR!

Back from Right to Left: Stephanie Gross, Catherine Wicker, Devin Senelick, Bridget Gordon, Middle: Katrina Pagonis, Kiki Carson, Sansan Lin, Joseph LaMagna, Paul Garcia, Front: Eric Chan, Alicia Macklin, Jeffrey Lin, Kelly Delmore (not pictured)

CALENDAR

DATE	EVENT
October 8	**HLB-Wolters-Kluwer Webinar Series (Part 4)** Bob Roth, Kelly Carroll, Eric Chan, Monica Massaro and Alicia Macklin present **Looking Back and Looking Ahead — What's In Store for the Rest of 2019**
October 15	**Northeast Regional Telehealth Conference** Jeremy Sherer co-presented **Consumer Protection in Telehealth and Artificial Intelligence**
October 17	**Los Angeles County Bar Association 16th Annual Healthcare Compliance Symposium, Los Angeles, CA** Stephanie Gross presents **Understanding the New Knox-Keene Regulations** Charles Oppenheim presented **Anti-Kickback and Stark Law Primer** Jeremy Sherer presented **Navigating the Telehealth Compliance Minefield**
October 22-23	**HLB Managed Care Seminar, Los Angeles and Berkley, CA** Hooper, Lundy & Bookman hosted **Managed Care 2019 Update**
October 29	**HLB Webinar** Amy Joseph, Ben Durie and Charles Oppenheim discuss the **Key Takeaways from the Proposed Stark and Anti-Kickback Rules and What You Need to Know Today**
October 30	**Hospice & Palliative Care Federation of Massachusetts Annual Conference, Boston, MA** David Schumacher Mark Johnson present **Fraud and Abuse Update: What You Need to Know Now to Protect Your Organization**
November 5	**HCCA's 5th Annual Healthcare Enforcement Compliance Conference, Washington, DC** Charles Oppenheim presents, **Ask the Stark Law Professionals**
November 7	**5th Annual North Country Telehealth Conference: The Value of Virtual, Lake George, NY** Jeremy Sherer and Amy Joseph present **Regulatory Trends in Digital Health: Understanding Developments in Telehealth Reimbursement, Enforcement, and Interoperability**
November 8	**MHA Conference Center, Burlington, MA** David Schumacher moderates the State and Federal Enforcement Priorities and Trends Panel Amy Joseph and Charles Oppenheim present Stark & Kickback: "*Recent Developments and Practical Compliance Tips*"
November 10-13	**CAHF Annual Conference, Palm Springs, CA** Mark Johnson and Scott Kiepen present **Transfer/Discharge Law for Skilled Nursing Facilities**
December 3	**HLB Fraud and Abuse Seminar, Los Angeles, CA** Hooper, Lundy & Bookman hosts **Health Care Fraud and Abuse Update 2019**
December 9	**CHA's Behavioral Health Care Symposium, Riverside CA** Alicia Macklin presents **EMTALA in the Psychiatric Environment**

HLB

HOOPER, LUNDY & BOOKMAN, PC

HEALTH CARE LAWYERS & ADVISORS

HLB
HOOPER, LUNDY & BOOKMAN, PC
HEALTH CARE LAWYERS & ADVISORS

1875 Century Park East, Suite 1600
Los Angeles, California 900677-2799