THE ABA HEALTH LAW SECTION

THE HEALTH LAWYER

IN THIS ISSUE

AMERICAN BAR ASSOCIATION
Health Law Section

Volume 23, Number 3
February 2011

MEDICAL TECHNOLOGY COMPANIES PARTNERING WITH ACADEMIC MEDICAL CENTERS: PRACTICAL APPROACHES TO MANAGING REGULATORY RISKS WHILE PRESERVING INNOVATION

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Introduction

Innovative medical technologies are a hallmark of the U.S. healthcare system whose developments arise, in large part, from the partnership of industry and academic medical centers. Medical technologies are typically products characterized by having a physical effect on the body (like artificial heart valves) or assisting in the diagnosis of disease (like MRIs). The efficacy of medical technologies is usually dependent on the skill of the physician using the technology, whereas the efficacy of pharmaceutical therapies is dependent on a patient's metabolic response. As a result, medical technology development necessitates collaboration between industry and physicians throughout the product lifecycle, from design to end user education, to be safe and effective. Academic medical centers, given their advanced research and training focus, are ideal collaboration partners and are highly sought after by the medical technology industry.

This innovation process, while developing numerous new products, is marred by instances of medical technology companies inappropriately influencing their various partners through illegal financial incentives, as highlighted below. Recent healthcare reform and federal anti-kickback statute ("AKB Statute") prosecutions are a response, in part, to these inappropriate financial relationships masked under the pretext of innovation.[1] The Department of Justice's ("DOJ") highly publicized investigations of the practices of certain orthopedic companies are a revealing window into this potential for fraud and abuse.[2] The investigations revealed that orthopedic companies paid significant royalty payments to physicians for product development without regard to the physicians' actual contributions to product designs, or worse, to physicians who performed little or no work.[3] Additionally, orthopedic companies paid physicians for quarterly reports on topics such as market trends and product issues, which in practice were so superficial and duplicative as to be of little or no value.[4] Physicians were also paid to attend daylong consultant panels at resorts

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Chair's Corner

The President's New Executive Order

Since we work in an industry as heavily regulated as healthcare, it's not surprising that most of us spend a substantial part of our work day (and night) poring over government regulations: identifying those that are applicable and then trying to determine exactly which type of conduct is permitted and which is prohibited. For that reason, President Obama's new Executive Order on Improving Regulation and Regulatory Review, issued on Jan. 18, 2011 likely will catch your attention, at least initially. The call for flexible approaches, public participation in the regulatory process and retrospective review of existing regulations to modify or repeal those that are outmoded, excessively burdensome, ineffective or insufficient is very appealing. I suspect a substantial number of our members, if not a majority, could easily point out at least one set of health law regulations that should be subject to such scrutiny and subsequent improvement.

However, despite the political machinations with the GOP claiming credit and certain liberal groups criticizing President Obama for allowing the GOP to frame the debate, the Executive Order ("E.O.") itself points out that it is consistent with and supplements E.O. No. 12866, promulgated by President Clinton in 1993. For example, the new E.O. calls on agencies to "seek the views of those who are likely to be affected, including those who are likely to benefit from and those who are potentially subject to such rulemaking" ***before*** issuing a notice of proposed rulemaking. E.O. No. 12866 had similar language. Perhaps the more important question is whether the new E.O. actually will be implemented in a meaningful way and needed changes will be made.

The new E.O. indicates that the public generally has the opportunity to be part of this dialogue. However, as an entity, the ABA Health Law Section ("the Section"), likely can have an even greater impact on these issues by sharing the collective expertise of our members. For this reason, I am very pleased to report the significant strides the Section is already making in developing thoughtful position papers and approaching agency officials so we can be part of the process, as appropriate. I encourage those of you who are interested to join these ongoing efforts or to suggest new areas that we may want to consider exploring. Bill Horton, the Chair of the Section's Policy Review and Coordination Committee is doing a terrific job heading up this effort, which he described as a Guest Columnist in the last issue of eSource. If you'd like to learn more about and/or participate in these efforts, that column is a must read.

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The Health Lawyer (ISSN: 0736-3443) is published by the American Bar Association Health Law Section, 321 N. Clark Street, Chicago, IL 60654-7598. Address corrections should be sent to the American Bar Association, c/o Member Records.

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during which minimum work occurred and attendees relaxed on the orthopedic companies' expense accounts.[5] These orthopedic company investigations highlight the risk of collusive conduct occurring under the guise of product innovation, and the potential for industry to inappropriately influence medical decisions for financial gain.[6]

As a by-product of recent healthcare reform and increasing AKB Statute enforcement, medical technology companies legitimately engaged in innovation partnerships with academic medical centers face increased scrutiny. Specifically, medical technology companies face a heightened risk that aspects of their innovation partnerships with academic medical centers could be mischaracterized as unlawful. In response, this article seeks to highlight recent regulatory changes and trends that, in large part, are the source of this increased risk, with a focus on the AKB Statute. This article then seeks to offer practical compliance suggestions that may reduce that risk for medical technology companies in such innovation partnerships. In a worse case scenario, these suggested measures may offer a defense for medical technology companies against allegations of an AKB Statute violation. Hopefully, these suggestions will assist lawyers counseling medical technology companies on how to reduce their clients' regulatory risks and enhance their compliance efforts. In this heightened enforcement environment, lawyers are critical to structuring compliant innovation partnerships for medical technology companies that collaborate with academic medical centers.

For purposes of this article, medical technology companies are defined broadly to include manufacturers and developers of devices, software and other products used in patient care, treatment and diagnosis ("Company" or "Companies"). The concept of an innovation partnership is meant to include a wide variety of arrangements between Companies and academic medical centers focused on technological advancements that improve patient care and treatment or aid in diagnosis, from product development to user education activities.

Regulatory Scheme in Flux

Federal Anti-Kickback Statute Developments

Innovation partnerships between Companies and academic medical centers fall under the ambit of the AKB Statute because such arrangements involve the provision of services that have value. The AKB Statute is a broadly conceived prohibition against giving anything of value with the intent to induce referrals or the purchase of goods or services for which payment may be made under a federal healthcare program (generally referred to as a 'kickback').[7] For a Company, the concept of a kickback is generally understood to mean any inappropriate inducement to use a particular kind of service or device or to use it to the exclusion of others. Further, the AKB Statute is violated when any aspect of an arrangement effectuates a kickback, regardless if other valid, legal purposes justify the arrangement.[8] AKB Statute violations are punishable by up to five years in prison and/or a $25,000 fine per violation, and the federal government also maintains broad discretion to exclude a Company from participating in federal healthcare programs.[9]

To address ambiguity within the AKB Statute, the Department of Health and Human Services ("HHS") issued voluntary safe harbors that are intended to ensure compliance with the AKB Statute.[10] However, the practical reality is that many of these safe harbors contain subjective standards that effectively obviate any certainty of compliance. For example, the Personal Services and Management Services Contract Safe Harbor ("Personal Services Safe Harbor") requires that an arrangement must not "involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law."[11] This *de facto* 'savings clause' allows the federal government, at its discretion, to review on a *de novo* basis any arrangement that otherwise fully complies with an applicable safe harbor. The bottom line is that any arrangement that meets the requirements of a safe harbor is, for all practical purposes, still vulnerable to challenge. Importantly, the Patient Protection and Affordable Care Act ("PPACA") clarifies and lowers the scienter requirement of the AKB Statute, as proof is no longer required that a defendant has actual knowledge of the AKB Statute to prove the intent requirement.[12]

In the context of the AKB Statute, the key concern for a Company partnering with an academic medical center is the purposely-broad concept of remuneration. The AKB Statute defines "remuneration" for purposes of a kickback to mean conveying anything of value.[13] This definition of remuneration is expressly drafted to include indirect arrangements that effectuate a kickback.[14] Certainly, remuneration includes financial relationships and arrangements designed as a subterfuge for buying referrals or conferring inappropriate benefits. The real difficulty faced by Companies is defining the limits of what constitutes remuneration, as the term is broadly construed to include anything of value. Companies face the risk that enforcement agencies and relators have wide latitude to argue that almost any benefit arising from an innovation partnership could constitute illegal remuneration. As a result, Companies entering into legitimate

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partnerships that thoroughly address compliance considerations still confront the risk that the partnerships may be characterized as conveying unlawful remuneration.

Recently, defendants in the controversial case U.S. *ex rel.* Dr. Harry F. Fry v. The Health Alliance of Greater Cincinnati, *et al.* ("*Fry*") settled alleged AKB Statute and False Claims Act ("FCA") violations with the federal government for $108 million.[15] The crux of the *Fry* controversy was defining what constituted remuneration for purposes of an AKB Statute violation. The defendants in *Fry* contentiously disputed the allegations made by the DOJ and the relator. Essentially, the relator alleged that time was allotted to the hospital's outpatient cardiovascular station based on the overall volume of services performed by cardiologists in the health system. As a reward for their productivity, the busiest cardiologists were assigned greater time at the cardiovascular station and allegedly gained additional patients for their practices.[16]

The hospital's plausible explanation to the relator's allegation was that no tangible value was provided by the hospital giving certain of the cardiologists a greater time allotment.[17] The relator's claim essentially rested on the theory that the opportunity to treat patients who had not selected or been assigned a cardiologist was remuneration.[18] This theory was subsequently adopted by the DOJ and accepted by the U.S. District Court.[19] However, this theory is possibly disconnected from hospital management's practical need to assure reliable physician coverage at the outpatient cardiovascular station. Further, this theory potentially discounts that the most active cardiologists in the health system are likely to be selected by new patients or assigned to those physicians in any case, regardless if they performed services at the outpatient station. Finally, the relator's theory is arguably detached from practical physician economics – necessary work is not necessarily profitable work and thus not a *de facto* economic 'opportunity' in each instance.

However, the DOJ and the U.S. District Court discounted the explanation that the outpatient station assignments were not an economic opportunity. Given the arguably novel theory of 'opportunity' equaling "remuneration", and despite the defendants' credible explanations, DOJ went so far as to describe this arrangement in a press release announcing the settlement as "unlawful remuneration to doctors in exchange for referring cardiac patients to The Christ Hospital in a *pay-to-play scheme*" (emphasis added).[20]

As applied to Companies, the DOJ's broad interpretation of "remuneration" arguably lowers the threshold as to what constitutes illegal remuneration and potentially could turn aspects of formerly compliant innovation partnerships into AKB Statute violations. For academic medical centers, the DOJ's interpretation increases the risk of being drawn into AKB Statute investigations as a byproduct of collaborating with Companies, irrespective of their culpability.

False Claims Act Developments: Exponential Liability

PPACA clarified that claims arising from an AKB Statute violation are false claims for purposes of the FCA, resulting in restitution and penalties up to three times damages.[21] Prior to PPACA, the federal government and relators relied on the legal theory that claims arising from arrangements that violated the AKB Statute were false claims because defendants certified compliance with the AKB Statute as a prerequisite for payment.[22] This legal theory – that a false certification arising from submitted claims creates a FCA violation – was contentious and heavily litigated. Under PPACA, AKB Statue violations are false claims for purposes of FCA and thereby expose defendants to dramatically increased civil fines and penalties.[23] Companies facing allegations of an AKB Statute violation must now consider FCA liability as well. Academic medical centers also face increased liability as a result of PPACA's clarification that AKB Statute violations are false claims for purposes of the FCA, as noted by the Association of American Medical Colleges ("AAMC").[24] In a January 14, 2010 letter to congressional leaders, AAMC noted the proposed FCA liability changes under PPACA "… subject virtually all violations of the antikickback provisions to penalties under FCA. [AAMC] believe[s] the change will involve teaching hospitals in unnecessary and unintended litigation."[25]

Overall, this potential for compounding liability under FCA dramatically increases the risk/magnitude calculus for lawyers counseling potential defendants. The net effect is that enforcement agencies and relators have significantly more leverage when alleging an AKB Statute violation because of the almost certain concurrent FCA liability. Now, the leadership of a Company or an academic medical center opting to pursue its available defenses in lieu of settlement could quite literally be risking the respective organization's financial viability.

Comprehensive Disclosure and Surveillance

Senator Charles E. Grassley (R-Iowa) is a longstanding advocate for greater transparency in the business of healthcare, and as part of healthcare reform, his Physician Payment Sunshine Act was enacted ("Sunshine Act").[26] In lobbying for the bill's passage, Senator Grassley stressed, "Transparency fosters accountability, and the public has a right to know about financial

relationships. Patients rely on their doctors' advice. … [T]he doctors conducting … research have a big influence on the practice of medicine."[27] Senator Grassley's critics are hard pressed to disagree with his concerns.

The Sunshine Act requires Companies to disclose to HHS financial payments to physicians and academic medical centers on an annual basis commencing in 2013.[28] The Sunshine Act specifically applies to manufacturers of drugs, devices, biologics, and medical suppliers that provide payments or otherwise transfer something of value to a physician or an academic medical center.[29] The Sunshine Act applies to payments greater than $10 or $100 in the annual aggregate and loans of equipment for longer than ninety days, among other payments.[30] The Sunshine Act requires annual disclosure of such payments commencing on March 31, 2013 for all payments from January 1, 2012 to December 31, 2012.[31] Also, it is important to note that numerous states have equivalent Sunshine Act disclosure and reporting requirements applicable to Companies.[32]

HHS will review the submitted information as part of its program integrity responsibilities and will seek the assistance of other agencies to indentify fraud and abuse.[33] Specifically, HHS' Office of Inspector General and the DOJ will have access to the information as part of their enforcement activities.[34] Consistent with Senator Grassley's intent, the Sunshine Act will facilitate, in part, efforts to discern inappropriate arrangements between Companies and academic medical centers. As a result of the annual disclosure requirement, Companies partnered with academic medical centers will confront ongoing surveillance by enforcement agencies (and, by extension, academic medical centers will face indirect surveillance), regardless if such arrangements are structured to comply with applicable laws.

The Sunshine Act causes particular concern for Companies and academic medical centers partnered together because the reported "transfers" could be substantial. It is a reasonable assumption that reporting a large "transfer" could draw scrutiny by the mere fact that the reported value is significant, a concern for Companies and academic medical centers alike. This could be the case even though a Company adequately and clearly describes the arrangement to HHS in the required report. Companies and academic medical centers also face a situation where there are no articulated, standardized criteria for what will trigger scrutiny. Finally, these investigation decisions could be made under a standard established after *Fry* that interprets remuneration much more broadly under the AKB Statute. Despite the benefits of the Sunshine Act and state law equivalents, Companies now face the increased risk that their legitimate innovation partnerships could be challenged as conveying unlawful remuneration to academic medical centers. As a further unintended consequence, academic medical centers risk being drawn into these costly and protracted investigations (possibly criminal in nature).

Sum of the Risks

Companies engaged in legitimate innovation partnerships with academic medical centers now face a regulatory regime aggressively postured to isolate and prosecute AKB Statute violations. Companies must now comply with the Sunshine Act's comprehensive disclosure regime (and state law equivalents). These disclosures will be scrutinized by a variety of enforcement agencies for violations of law by an undisclosed formula. If targeted because of a Sunshine Act report, a Company could be investigated for violations of the AKB Statute or other applicable law, with the partnering academic medical center drawn into the investigation.

However targeted, the enforcement agency may very well utilize an aggressive *Fry*-like standard under which intangible, opportunity-like benefits are construed as unlawful remuneration. It is well within the realm of reason that a *Fry*–like rationale could be applied to a whole host of otherwise legitimate and lawful innovation partnerships with academic medical centers. For example, post-*Fry*, it is not unreasonable to believe that an enforcement agency could argue that an arrangement that makes available medical technology for development purposes is unlawful remuneration in that it creates the opportunity to treat patients who may not have otherwise been treated. If nothing else, the *Fry* rationale creates a great deal of doubt, and at worst, could criminalize previously lawful innovation partnerships. It is important to note, however, the *Fry* rationale is novel and it remains to be seen whether or not the DOJ will apply it in future prosecutions.

In isolation, the *Fry* decision does not necessarily stifle innovation partnerships between Companies and academic medical centers, although it does create uncertainty. However, considered more broadly, the DOJ's legal position articulated in *Fry* regarding what constitutes unlawful "remuneration" could inhibit such legitimate arrangements in the future. The DOJ's argument that the "opportunity to bill" constitutes unlawful remuneration arguably increases the scope of the AKB Statute and potentially turns otherwise compliant arrangements, in the DOJ's own words, into "pay-to-play" schemes. Compounding matters further, AKB Statute violations can now be FCA violations that significantly magnify the financial penalties for alleged violations (and separately results in increased *qui tam* activity by relators' counsel). Taken as a whole, these regulatory developments create uncertainty that Companies can enter into innovation partnerships with academic medical centers without the risk

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of allegations of an AKB Statute violation. Further, in partial response to these enforcement trends, academic medical centers are actively self-regulating innovation partnerships with Companies, and many academic medical centers place institution-specific restrictions on such partnerships.[35]

Compliance Measures

In this aggressive enforcement environment, Companies considering innovation partnerships with academic medical centers must focus on compliance measures with renewed vigor. The following steps outline a potential compliance roadmap for Companies that can manage and potentially reduce the risk of regulatory scrutiny. First, the roadmap suggests general compliance measures for Companies that create a framework to effectively structure such partnerships. Second, specific compliance measures are suggested that seek to reduce the inherent regulatory risks for Companies engaged in such partnerships. Hopefully, these compliance steps may reduce the risk of scrutiny and improve the likelihood that, if challenged, such partnerships will be deemed to comply with the AKB Statute.

The Form of Agreement: Safe-Harbor Compliance

The Personal Services Safe Harbor is typically the applicable AKB Statute safe-harbor for innovation partnerships between Companies and academic medical centers.[36] As such, the Personal Services Safe Harbor should serve as the basic structure for such arrangements, even though compliance cannot guarantee AKB Statute compliance as a practical matter, as discussed above. On the other hand, if the arrangement does not comply with the Personal Services Safe Harbor, enforcement agencies have even greater discretion to scrutinize the arrangement on an individual basis considering, among other aspects, the totality of circumstances for the potential for fraud and abuse.[37] The Personal Services Safe Harbor is relatively straightforward and requires that:

1. The arrangement must be set out in writing, signed by the parties and for a term greater than one year.
2. The written agreement must cover all services and specify the services to be rendered, and specify when and how such services are to be provided.
3. All compensation paid over the term of the arrangement must be specified in the written agreement.
4. All compensation must be set in advance, consistent with fair market value in an arms-length transaction.
5. Compensation must not take into consideration the volume or value of any referrals or business otherwise generated between the parties.
6. The services performed under the arrangement must not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.
7. The aggregate services under the arrangement must not exceed that which are reasonably necessary to accomplish the commercially reasonable business purpose.[38]

The innovation partnership should be negotiated consistent with these requirements, and these requirements should be integrated into the written agreement. In effect, the Personal Services Safe Harbor should serve as the basic 'form of agreement,' thereby creating the initial defense that the arrangement meets the requirements of the safe harbor.

A Day-to-Day Compliance Program: The AdvaMed Code

In a productive innovation partnership, Companies will frequently interact with academic medical centers, and these exchanges present a broad range of compliance concerns. While the Personal Services Safe Harbor should serve as the basic contractual structure, the safe harbor provides no compliance guidance for these day-to-day exchanges. As a result, Companies must have a comprehensive compliance program to manage such interactions.

The Advanced Medical Technology Association's ("AdvaMed") Code of Ethics on Interactions with Health Care Professionals ("Code"), recently amended on July 1, 2009, is the best available comprehensive compliance program for Companies, addressing issues from intellectual property royalties to meals.[39] AdvaMed is the leading trade group representing medical technology companies and developed the Code in the early 1990s.[40] The Code's purpose is to assure patients' interests are protected during interactions between industry and healthcare providers.[41] The Code is practical and offers an extensive list of questions and answers applying its principals.[42] Arguably, the Code is the 'best practices' compliance standard for Companies, and if nothing else, addresses common issues and provides real world guidance.[43] In innovation partnerships, the Code should serve as the general framework that governs the parties' interactions. The written agreement should specifically state that the parties agree to comply with the terms and conditions of the Code. The Code, if successfully implemented, may eliminate or reduce the risk of conduct occurring in an innovation partnership that may be construed as unlawful.

Innovation Partnerships: Tailored Compliance Measures

Innovation partnerships complying with the Personal Services Safe

Harbor and the Code governing all interactions should reduce and better manage regulatory risks. However, Companies' partnerships with academic medical centers have unique aspects that neither the Personal Services Safe Harbor nor the Code adequately address. In considering such innovation partnerships, the following compliance measures will further reduce and manage regulatory risks for Companies:

1. Companies should seek to limit their innovation partnerships with academic medical centers to the absolute minimum necessary. Companies should avoid numerous arrangements that could be characterized as seeking 'mindshare' or 'presence' at leading institutions, regardless if such arrangements can be justified as legitimate. When it comes to partnering, a Company's philosophy should be 'less is more' and Companies should focus on only those critical relationships that will drive innovation. If an arrangement is challenged, Companies operating under this 'less is more' philosophy may have better success defending against allegations of an AKB Statute violation. Additionally, Companies operating under this philosophy may be perceived by academic medical centers as better partnership candidates from a regulatory risk analysis perspective.

2. Companies must forgo 'business as usual' once an innovation partnership is established, and no other major transactions should occur during its negotiation and for at least six months after its commencement.[44] It is critical not to create a situation in which the partnership could be viewed as a subterfuge for buying referrals or conferring inappropriate benefits in concurrent or subsequent transactions. Further, Companies should expressly prohibit any personnel from considering or discussing any aspect of the arrangement in other business transactions.[45] To effectuate this goal, the Companies' sales force personnel should be screened from any involvement with the partnership arrangement and its terms and conditions.

3. When possible, Companies should structure their innovation partnerships directly with academic medical centers (the institution as party to the agreement) and avoid concurrent arrangements with affiliated or employed physicians. The practical reality is that academic medical centers have compliance officers, legal departments and institutional protocols that mitigate the risk of AKB Statute violations. Direct concurrent arrangements with physicians at the institution risk weakening these institutional safeguards.

4. Companies should not use the academic medical center, intentionally or unintentionally, as a sales center for the technology that is the subject of the innovation partnership. It is appropriate that Companies highlight advancements in techniques or treatment protocols, and this may include organizing demonstrations of such technical advancements.[46] However, this is an area that is fraught with regulatory risks. Companies inclined to organize an educational visit, at minimum, should comply with all applicable institutional policies and procedures and comply with the Code's specific requirements for organizing and conducting such professional exchanges.[47]

5. The innovation partnership should not directly or indirectly pressure, financially or otherwise, the academic medical center to make any specific set of recommendations regarding the technology.[48] The academic medical center should not benefit or suffer based on the nature or content of its recommendations, conclusions, or findings. The agreement must expressly create a relationship where the academic medical center is free to provide unbiased and scientifically derived results without financial consequences or inducements. This suggestion will bolster the institution's medical and academic independence and help prevent any inappropriate influencing of the medical decision-making process.

6. The innovation partnership should call for mandatory ongoing disclosure of any financial arrangements between the Company and the academic medical center and its employed or affiliated physicians. This suggestion will increase transparency and keep the parties informed, on a real-time basis, about all financial relationships between the parties throughout the term of the agreement.

7. Counsel should 'deep dive' internally to document the technical and commercial need for any innovation partnership with an academic medical center. Counsel should work closely with engineering personnel to better understand the technology in question, thereby allowing counsel to better document those technical needs. As to the commercial justifications, counsel should delve into the rationale for the arrangement with business personnel. This 'deep dive' approach will allow counsel to better tailor the partnership to meet the actual technical and business requirements and counsel against any aspects that may be construed as inappropriate, all the while documenting the legitimate basis for the arrangement.

8. The innovation partnership should not impose any utilization levels for the technology, exclusivity requirements, or any purchase obligations. If the institution desires to purchase any used technology upon termination of the arrangement, an independent third-party healthcare appraisal firm should determine the fair market value purchase price. The price should not be influenced by the institution's findings.

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Conclusion

The greatness of the U.S. healthcare system is its focus on technological innovations that advance patient care and treatment. This innovation is a direct result of partnerships between Companies and academic medical centers. Recent regulatory developments are placing tremendous scrutiny on these partnerships. The leadership of Companies, as well as academic medical centers, if well informed about the present regulatory environment, may potentially decide not to engage in such partnerships. These decisions may very well be rational business choices in the best interest of their organizations. As a result, the risk is that the very patients this regulatory regime seeks to protect may, as an unintended consequence, be indirectly harmed over time by a reduced number of innovative medical technologies.[49] To help preserve and encourage innovation, this article seeks to offer suggestions that may permit Companies to reduce the risk of scrutiny in such partnerships and better defend against any alleged AKB Statute violations. But, like modern medical care itself, there can be no guarantees in the present regulatory environment.

Mr. Brewster would like to thank James B. Riley, Jr., Chairman of the Healthcare Department of McGuireWoods LLP, for his close reading of this article and his support throughout the years. Also, Mr. Brewster would like to thank Carrie Hogan, Partner at Jones Day, for her thoughtful editorial comments.

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Endnotes

1 *See* The Department of Health and Human Services and the Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2009 (May 2010) *available at http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2009.pdf*.

2 Press Release, United States Department of Justice, U. S. Attorney's Office, District of New Jersey, Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring (September 27, 2007) *available at http://www.justice.gov/usao/nj/press/files/pdffiles/hips0927.rel.pdf*.

3 Testimony of Gregory E. Demske, Assistant Inspector General for Legal Affairs, Office of Inspector General, Department of Health and Human Services, Senate Special Committee on Aging Hearing (February 27, 2008) at 4-6.

4 *Id.*

5 *Id.*

6 *Id.*

7 42 U.S.C. §1320a-7b(b).

8 *United States v. Greber*, 760 F.2d 68 at 71-72 (3rd Cir. 1985), cert. denied 474 U.S. 988 ("If the payments were intended to induce the physician to use … services, the [AKB Statute] was violated, even if the payments were also intended to compensate for professional services").

9 42 U.S.C. §1320a-7b(b).

10 42 C.F.R. § 1001.952 *et seq*.

11 42 C.F.R. § 1001.952(d)(6).

12 H.R. 3590 § 6402 (f)(2) ("a person need not have actual knowledge of this section or specific intent to commit a violation of this section").

13 *See Greber*, 760 F.2d 68 at 71-72.

14 *Id.*

15 Press Release, United States Department of Justice, The Health Alliance of Greater Cincinnati and the Christ Hospital to Pay $108 Million for Violating Anti-Kickback Statute and Defrauding Medicare and Medicaid (May 21, 2010) *available at http://www.justice.gov/opa/pr/2010/May/10-civ-602.html*.

16 *See U.S. ex rel. Dr. Harry F. Fry v. The Health Alliance of Greater Cincinnati, et al.*, 1:03-cv-00167 at 2-3 (S.D. Ohio December 18, 2008).

17 *Id.* at 11-18.

18 *Id.* at 1-5.

19 *Id.* at 12-18.

20 Press Release, United States Department of Justice, The Health Alliance of Greater Cincinnati and the Christ Hospital to Pay $108 Million for Violating Anti-Kickback Statute and Defrauding Medicare and Medicaid (May 21, 2010).

21 H.R. 3590 § 6402(f)(1).

22 *U.S. ex rel. Barrett v. Columbia/HCA Health Care Corp.*, 251 F. Supp.2d 28, 33 (D.D.C. 2003) (holding material because "compliance with the [AKB Statute] and Stark laws would affect the government's decision to pay").

23 H.R. 3590 § 6402(f)(1).

24 *See* Association of American Medical Colleges Letter to Congressional Leadership Opposing Inclusion of False Claims Act Provisions in Health Reform Legislation (January 14, 2010) at 2 *available at http://www.aamc.org/advocacy/library/research/corres/2010/011410.pdf*.

25 *Id.*

26 H.R. 3590 § 6002.

27 Press Release, Office of Senator Charles E. Grassley, Grassley Works to Disclose Financial Ties between Drug Companies and Doctors (January 22, 2009) *available at http://grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=18901*.

28 *See* H.R. 3590 § 6002.

29 *Id.*

30 *Id.*

31 *Id.*

32 For example, California, the District of Columbia, Maine, Massachusetts, Minnesota, Nevada, Vermont and West Virginia have varying state laws governing Companies' marketing practices and disclosure requirements, and other state legislative bodies are considering similar laws, all of which increase the risk of regulatory scrutiny.

33 H.R. 3590 § 6402.

34 *Id.*

35 For an introduction to the self-regulating efforts of academic medical centers, *see generally* In The Interest of Patients: Recommendations for Physician Financial Relationships and Clinical Decision Making, Report of the Task Force on Financial Conflicts of Interests in Clinical Care, Association of American Medical Colleges (June 2010) *available at https://services.aamc.org/publications/showfile.cfm?file=version163.pdf&prd_id=303&prv_id=375&pdf_id=163*.

36 *See* 42 C.F.R. § 1001.952(d).

37 *See* 56 Fed. Reg. 35952 (July 29, 1991).

38 42 C.F.R. § 1001.952(d).

39 *See* The Advanced Medical Technology Association's Code of Ethics on Interactions with Health Care Professionals ("Code") *available at http://www.advamed.org/NR/rdonlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf*. The

suggestion to implement the Code is primarily directed toward smaller to medium-sized Medical Technology Companies (large Medical Technology Companies have, for the most part, adopted the Code).

40 For more information about the Advanced Medical Technology Association, *see generally* www.advamed.org.

41 Code at 1-2.

42 *Id*. at 13-23.

43 *Id*.

44 The suggested six-month waiting period is not specifically required by any legislative enactments or administrative regulations relating to the AKB Statute. The author selected a six-month period by analogizing the situation to the "Isolated Transactions" exception within the Stark law. *See* 42 C.F.R. § 411.357(f). By way of background, the Stark law is an anti-self referral law governing certain designated health service referrals to entities in which a physician may have a financial interest. *See generally* 42 U.S.C. § 1395nn; 42 C.F.R. § 411.351 *et seq*. As such, the Stark law is designed to prevent conflicts of interest in certain physician referrals. Regulations promulgated under the Stark law specifically recognize an exception for isolated transactions, but require a six-month 'cooling off' period during which no other similar transaction may occur after the original transaction is completed. *See* 42 C.F.R. § 411.357(f). The concept of a 'cooling off' period is sound advice after an innovation partnership agreement is signed because it reduces the actual or perceived risk that the concurrent or subsequent transaction may be viewed as a subterfuge for buying referrals or conferring inappropriate benefits.

45 *See* Code at 3-6.

46 *Id*.

47 Code at 3-12.

48 Beyond violating the AKB Statute or FCA, there are numerous federal laws that broadly cover fraud or like conduct involving healthcare, including conspiracy to defraud the government (18 U.S.C. § 286), false statements relating to healthcare matters (18 U.S.C. § 1035), and mail and wire fraud (18 U.S.C. § 1341 and § 1343).

49 Economist Paul M. Romer has suggested that knowledge is a critical factor in the advancement of social development. *See* "Increasing Returns and Long-Run Growth," The Journal of Political Economy, Volume 94, Issue 5 (October 1986), 1002-1037. Sebastian Mallaby's "The Politically Incorrect Guide to Ending Poverty" discusses Mr. Romer's economic theories regarding the importance of ideas and innovation as background in his article. *See* The Atlantic Monthly (July/August 2010) *available at http://www.theatlantic.com/magazine/archive/2010/07/the-politically-incorrect-guide-to-ending-poverty/8134/2/*.

Chair's Corner

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The HLS Emerging Issues Conference – Something for Everyone

Exceptional Substantive Programs

By now, you should have received a copy of the brochure for our Emerging Issues Conference to be held in New Orleans on Feb. 23-26. As always, the program is broad reaching and innovative with a terrific group of expert speakers. Many thanks to Hilary Young, Joyce Hall and the EMI Planning Committee for their outstanding efforts. There truly is something at EMI for everyone. For more information about EMI, including a copy of the conference brochure, please visit *www.abanet.org/health*.

Attend a Few IG Meetings

In addition to the substantive programs, all of our Interest Groups ("IG"s) and Task Forces will be holding educational sessions/lunches at EMI. This is your chance to meet your colleagues and see how you can get involved in the many IG activities. You can attend any IG meeting(s); you don't have to be a member. (It's a great way to check out some of the other IGs to see if you'd like to join them, as well.) In addition, on **Wed. Feb. 23 at 9:00am**, those of you who are interested will have the opportunity to participate in the CLE sponsored by the Breast Cancer Task Force which will prepare you to counsel breast cancer patients on the legal issues they face as a result of their condition and treatment. This is one of the Section's major pro bono initiatives, and an incredibly worthwhile project.

Get the Inside Scoop: Attend Section Business Meetings

There are several innovations this year at EMI. First, as indicated in the brochure, a number of Section business meetings, including the Council meeting on Saturday Feb. 26 at 9am, will be held at EMI, and all Section members are invited to attend. This is your chance to learn some of the "secrets" of Section operations and see how you want to get involved going forward.

Enjoy the Weekend in New Orleans

The EMI Planning Committee also has planned a number of fun activities for those of you who can stay over to enjoy the weekend in New Orleans. On the afternoon of Feb. 26 (Saturday), you can sign up and join other Section members in taking a New Orleans cooking class, touring the World War II Museum or playing in the Section's Annual Margarita Cup at TPC Golf Course. The sign up details are in the EMI brochure. There also may be some opportunities to see an early Mardi Gras parade over the weekend. Finally, there's always a great party Saturday night in the Chair's Suite and if you're a Section member, you and your family are invited!

Get the Most Out of Your Section Membership

I can't emphasize enough how much more you can benefit by getting actively involved in Section activities; whether you're seeking professional development or recognition, a chance to network with colleagues or just have fun. We have been trying to highlight the wide variety of potential activities; please note that the next issue of *eSource*, available either via email or on the Section's website, will have more information about opportunities to participate in ABA commissions and committees. These can be very competitive positions but we can't nominate you unless we know you're interested, so please let us know.

See you in N'Orleans!

MEANINGFUL USE – WHAT DOES IT MEAN TO YOU?

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In February 2009, Congress passed and President Obama signed the American Recovery and Reinvestment Act of 2009.[1] Portions of this Act relating to health information technology, referred to as the Health Information Technology for Economic and Clinical Health Act ("HITECH Act"), establish incentive payments to eligible professionals ("EPs") and eligible hospitals participating in the Medicare and Medicaid programs that adopt and meaningfully use certified electronic health record ("EHR") technology.[2] On January 13, 2010, the Centers for Medicare and Medicaid Services ("CMS") published a proposed rule addressing the requirements under which EPs and eligible hospitals may establish eligibility for incentive payments through meaningful use of EHR technology.[3] On July 28, 2010, CMS published the long-awaited final rule setting forth meaningful use regulations and other EHR incentive program requirements.[4] The final rule was effective 60 days after its publication date, or September 26, 2010 – just in time for implementation, which began October 1, 2010.[5]

Evolution of the Rule from Proposed to Final

CMS received numerous comments to the proposed rule.[6] For example, the American Hospital Association ("AHA") filed comprehensive comments that covered many of the subjects of concern.[7] First, the AHA explained that the proposed definition of "hospital-based professional" would have severely limited the number of physicians eligible for the meaningful use incentive.[8] The AHA also commented on how hospitals are identified for eligibility and participation in the meaningful use incentive program.[9] Most importantly, the AHA noted concern, which was shared by many, about CMS's proposed "all-or-nothing" approach to demonstrating meaningful use.[10] The proposed rule would have required EPs to meet 25 objectives and eligible hospitals to meet 23 objectives in order to demonstrate meaningful use of EHR and qualify for incentives.[11] Many considered it impossible for most providers to meet all of these objectives at the levels required by CMS. CMS addressed many of these concerns in the final rule.

Addressing this concern about the EHR incentive program as proposed, CMS gave providers more flexibility in the final rule to demonstrate meaningful use. CMS stated in the preamble to the final rule,

> requiring that EPs, eligible hospitals and [critical access hospitals] satisfy all of the objectives and their associated measures in order to be considered a meaningful EHR user would impose too great a burden and would result in an unacceptably low number of EPs, eligible hospitals and [critical access hospitals] being able to qualify as meaningful EHR users in the first two years of the program.[12]

Who Is Eligible For The Incentive?

A Medicare EP is, basically, a physician. Physician assistants, nurse practitioners and other non-physician practitioners are not eligible for the Medicare EHR incentive program.[13] Notably, a physician who chooses to be a Medicare EP cannot also choose to take part in the Medicaid EHR incentive program.[14]. A physician does have the opportunity to switch programs one time before 2015.[15]

A Medicare eligible hospital is a hospital paid under the prospective payment system.[16] Unlike physicians who must choose either the Medicare or Medicaid EHR incentive program, an eligible hospital may participate in either the Medicare fee-for-service EHR incentive or the Medicare Advantage EHR incentive program *and* the Medicaid EHR incentive program, assuming the hospital meets all of the requirements of the programs it chooses.[17]

Medicaid EPs include additional categories of provider types: physicians, nurse practitioners, certified nurse midwives, and dentists. Medicaid EPs may also include physician assistants practicing in a Federally Qualified Health Center or Rural Health Clinic that is led by a physician assistant.[18]

Demonstrating Meaningful Use

The HITECH Act sets out three requirements for the demonstration of meaningful use.[19] The first prong is circular and does not give providers much guidance – meaningful use requires the use of EHRs in a meaningful manner.[20] The second requirement is the use of certified EHR technology for the electronic exchange of health information.[21] Third, certified EHR technology must be used to submit clinical quality data, which are described more fully below.[22]

Pursuant to the legislative mandate of the HITECH Act, CMS will fully define meaningful use in three stages over the course of five years.[23] The current rule deals only with "Stage One." CMS will engage in future rulemaking to define Stage Two by the end of 2011 and Stage Three by the end of 2013.[24]

CMS has developed Stage One objectives required to demonstrate

meaningful use.[25] As noted above, the proposed rule would have required EPs to meet 25 objectives and eligible hospitals to meet 23 objectives in order to demonstrate meaningful use of EHR and qualify for incentives.[26] The final rule gives providers some flexibility in demonstrating meaningful use and divides the objectives into a "core" group of required objectives and a "menu set" from which providers may choose five to meet the definition of a meaningful user of certified EHR technology in Stage One of the program.[27] There are fourteen core objectives for eligible hospitals.[28] Eligible physicians are subject to fifteen core objectives.[29] Both groups must choose five "menu set" objectives from a total of ten options.[30] The result is that providers are required to meet fewer objectives than would have been required under the proposed rule. Nevertheless, this final rule is only "Stage One." It is reasonable to assume that optional menu set objectives will become mandatory in subsequent Stages.

Eligible Hospital Incentive Payment Requirements

Another change from the proposed rule is that CMS lowered many of the thresholds for demonstration of meaningful use. Following is a list of the core objectives for eligible hospitals and eligible critical access hospitals ("CAHs").[31] The objectives themselves are fairly self explanatory. Notably, as described below, the compliance thresholds for many of these objectives were lowered in the final rule.[32]

1. Record patient demographics: More than 50 percent of inpatients' (and emergency room ("ER") admissions) demographic data, such as gender, race, ethnicity, date of birth and preferred language, must be recorded as structured data.[33] [34]
2. Record vital signs and chart changes in height, weight, blood pressure, and body mass index: More than 50 percent of inpatients (and ER admissions) two years of age and older must have these values recorded as structured data.[35]
3. Maintain an up-to-date problem list of current and active diagnoses: More than 80 percent of inpatients (and ER admissions) must have at least one entry recorded as structured data.[36]
4. Maintain an active medication list: More than 80 percent of inpatients (and ER admissions) must have at least one active medication entry recorded as structured data.[37]
5. Maintain an active medication allergy list: More than 80 percent of inpatients (and ER admissions) must have at least one medication allergy entry recorded as structured data.[38]
6. Record smoking status for patients thirteen years of age or older: More than 50 percent of inpatients (and ER admissions) thirteen years of age and older must have smoking status recorded as structured data.[39]
7. Provide an electronic copy of hospital discharge instructions at discharge, on request: More than 50 percent of all patients who are discharged from the inpatient or ER of a hospital, and who request electronic discharge instructions, must be provided with it. The purpose of this objective is to provide the option to patients to receive their discharge instructions electronically. Discharge instructions would not necessarily be included in a copy of health information and it is unlikely that a patient would request a copy of their health information at every discharge. Note that this requirement was 80 percent in the proposed rule.[40]
8. On request, provide patients with an electronic copy of their health information, including e.g., diagnostic test results, problem list, medication list and medication allergies: More than 50 percent of requesting patients must receive their electronic copy within three business days. Note that this requirement was 80 percent within 48 hours in the proposed rule.[41]
9. Use computerized provider order entry ("CPOE") for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines: More than 30 percent of patients with at least one medication in their medication list must have at least one medication entered through CPOE. Note that this requirement was 10 percent of any type of order in the proposed rule.[42]
10. Implement drug-drug and drug-allergy interaction checks. Functionality must be enabled for these checks for the entire reporting period.[43]
11. Implement capability to electronically exchange key clinical information, such as the problem list, medication list or diagnostic test results, among providers and patient-authorized entities. Perform at least one test of the EHR's capacity to electronically exchange information.[44]
12. Implement one clinical decision support rule related to a high priority hospital condition and ability to track compliance with the rule.[45] Note that the proposed rule would have required implementation of five clinical decision support rules.[46]
13. Implement systems to protect privacy and security of patient data in the EHR. Providers should conduct or review a security risk analysis, implement security updates as necessary, and correct indentified security deficiencies.[47]
14. Report clinical quality measures to CMS or the State Medicaid agencies.[48] Clinical quality measures are discussed in more detail below.

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Number 9 – the use of computerized provider order entry – is defined as entailing the providers' use of computer assistance to directly enter medical orders such as medications, lab services, and consultations with other providers from a computer or mobile device.[49] For Stage One, there is no requirement that the order then be transmitted electronically.[50] Interestingly, while CMS has lowered the compliance threshold for many of the other objectives as compared to the proposed rule, CMS has actually raised the threshold for CPOE from 10 percent to 30 percent and added emergency department ("ED") orders. The final rule has, however limited the use of CPOE to medication orders for patients with at least one medication on their medication list.[51] So, while the threshold is higher, it applies to a smaller set of transactions.

Number 12 also merits special mention. Although the meaningful use rule requires that eligible hospitals and CAHs implement EHR security measures, it does not specify what those measures should be, except that they must be in accordance with the HIPAA administrative safeguards regulations, where the security standards are defined.[52] Number 14 is also important, and ties directly into one of the specific requirements of the HITECH Act – that certified EHR technology be used to submit clinical quality data.[53] For 2011, hospitals will not need to actually submit quality measures electronically.[54] They will need to track quality measures and submit aggregate numerator and denominator values through attestation.[55] Submission of data is required for all of the quality measures, even if the values are zero.[56] Electronic submission will be required beginning in 2012.[57]

CMS has developed a list of 15 required quality measures that eligible hospitals must report on to demonstrate meaningful use.[58] This is 20 fewer quality measures than would have been required under the proposed rule. The full set of hospital quality measures is set out in Table 10 of the final rule.[59] The measures fall into three categories: ED, stroke, and venous thromboembolism prevention treatment.[60]

1. ED Throughput – median time from ED arrival to ED departure for patients admitted to the facility from the ED.
2. ED Throughput – admission decision time to ED departure time for admitted patients.
3. Ischemic Stroke – Discharge on antithrombotics.
4. Ischemic Stroke – Anticoagulation for A-fib/flutter.
5. Ischemic Stroke – Thrombolytic therapy for patients arriving within two hours of symptom onset.
6. Ischemic or Hemorrhagic Stroke – Antithrombotic therapy by day two.
7. Ischemic Stroke – Discharge on Statins.
8. Ischemic or Hemorrhagic Stroke – Stroke education.
9. Ischemic or Hemorrhagic Stroke – Rehabilitation assessment.
10. Venous Thromboembolism ("VTE") prophylaxis within 24 hours of arrival.
11. Intensive Care Unit VTE prophylaxis.
12. Anticoagulation overlap therapy.
13. Platelet monitoring on unfractionated heparin.
14. VTE discharge instructions.
15. Incidence of potentially preventable VTE.

The final rule also sets forth the "menu set" objectives for hospitals. Some of these objectives are new when compared to the proposed rule, such as number four listed below. Some of these objectives have lower compliance thresholds than their proposed rule counterparts.[61] What's important to remember is that the hospital needs to choose only five of these ten options, which may help hospitals demonstrate meaningful use based on their own level of technological readiness. Menu set objectives include the following:

1. Implement drug formulary checks.
2. Incorporate clinical laboratory test results into EHRs as structured data.
3. Generate lists of patients by specific condition to use for quality improvement, reduction of disparities, research or outreach.
4. Use EHR technology to identify patient-specific education resources and provide those to the patient as appropriate.
5. Perform medication reconciliation between care settings.
6. Provide summary of care record for patients referred or transitioned to another provider or setting.
7. Submit electronic immunization data to immunization registries or immunization information systems.
8. Submit electronic syndromic surveillance data to public health agencies.
9. Record as structured data whether a patient 65 years or older has an advanced directive.
10. Submit electronic data on reportable laboratory results to public health agencies.

Now that CMS has provided eligible hospitals and CAHs with meaningful use objectives, the question becomes: how does a hospital demonstrate meaningful use? For fiscal year 2011, which runs from October 1, 2010 to September 30, 2011, a hospital must meet the meaningful use objectives for only 90 consecutive

days.[62] This means that a hospital can implement its meaningful use program and demonstrate meaningful use as late as July 1, 2011 and still meet the requirements for 2011. In fiscal year 2012, in addition to attesting to compliance with meaningful use objectives, hospitals will need to submit quality measures electronically.[63]

The Hospital Incentive

Medicare fee-for-service incentive payments for hospitals will be calculated by adding together a base amount of two million dollars per eligible hospital plus a per-discharge amount and multiplying that number by what is called the Medicare share as well as an applicable transition factor.[64] The per-discharge amount is zero for the first through the 1,149th discharge.[65] For the 1,150th discharge through the 23,000th discharge, the per-discharge amount is $200.[66] For any discharge after 23,000, the per-discharge amount is again, zero, creating a de facto cap on the amount of incentive available to a hospital.[67]

The Medicare share is calculated as follows: The numerator is the estimated Medicare Part A and Medicare Advantage inpatient-bed-days.[68] The denominator is the total number of inpatient-bed days multiplied by a charity care ratio.[69] The effect of this factor would be to decrease the denominator as the proportion of charity care provided by a hospital increases, ultimately increasing the Medicare share factor, providing higher incentive payments to a hospital that provides a greater proportion of charity care.[70] Finally, the transition factor is utilized to decrease the incentive payment in each consecutive year of participation. The applicable transition factor equals one in the first year, three-quarters in the second year, one-half in the third year and one-quarter in the fourth year of participation.[71]

Beginning in fiscal year 2015, the HITECH Act provides for an adjustment to the market basket update to the inpatient prospective payment system payment rate for those eligible hospitals that are not meaningful EHR users.[72] This reduction will apply to three-quarters of the percentage increase otherwise applicable.[73] The reduction will be phased in over three years.[74] In other words, in 2015 the reduction will be one quarter of the percentage increase, in 2016 the reduction will be one-half, and in 2017 the full three-quarters reduction will be taken.

CAHs are paid incentive payments differently from PPS hospitals. In general, a qualifying CAH receives an incentive payment for its reasonable costs incurred for the purchase of certified EHR technology.[75] The final rule sets out a payment reduction for CAHs beginning in fiscal year 2015 if a CAH is not a meaningful user of EHR technology for a payment year.[76]

Eligible Professional Incentive Payment Requirements

The core objectives for EPs largely resemble those established under the eligible hospital incentive program. EPs, however, must satisfy fifteen, not fourteen, core objectives.[77] A core objective unique to the EP is the requirement that EPs provide a clinical summary to the patient within three days of a visit for at least 50 percent of patient visits.[78] Another notable variation from the eligible hospital incentive requirements includes a requirement that EPs submit 40 percent of "permissible prescriptions" electronically.[79]

Permissible prescriptions exclude those for Schedule II controlled substances, despite the fact that a Drug Enforcement Agency interim final rule published in March, 2010 indicates that electronic prescribing of Schedule II drugs is now permissible.[80] That rule notwithstanding, Schedule II drugs are excluded from pharmaceutical volumes prescribed per physician for the purposes of calculating Medicare incentive payments to EPs and are not included in either the numerator or denominator of pharmaceuticals prescribed in calculating the rate of permissible prescriptions ordered electronically.[81] In the final rule, CMS cited the narrow turnaround time between the publication of the Department of Justice electronic prescribing final rules and the implementation of the meaningful use Stage One incentive criteria in explaining that it would not immediately coordinate the policies between the two agencies:

> We note that the Department of Justice recently released a notice of proposed rulemaking that would allow the electronic prescribing of these substances; however, given the already tight timeframe for Stage 1 of meaningful use we are unable to incorporate any final changes that may result from that proposed rule. Therefore, the determination of whether a prescription is a 'permissible prescription' for purposes of the eRx meaningful use objective should be made based on the guidelines for prescribing Schedule II controlled substances in effect when the notice of proposed rulemaking was published on January 13, 2010.[82]

It is likely, however, given this explanation, that CMS will have an eye on incorporating the Department of Justice's policy regarding the electronic prescribing of Schedule II drugs, perhaps as soon as the implementation of Stage Two eRx meaningful use criteria.

Further, the final rule reduced the EP threshold for satisfaction of CPOE criteria from a proposal that EPs submit 80 percent of *all orders* through CPOE; rather, the rule merely requires that EPs submit 30 percent of *medications ordered* through CPOE.[83] The notable aspect of this change from the

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proposed rule is that this represents one of the few areas in which the compliance standard for eligible hospitals was *increased* in the final rule.[84] The CPOE requirement for eligible hospitals increased from 10 percent to 30 percent in the final rule, as noted above.[85] As is the case with respect to most other standards changed from the proposed rule, the final rule for EPs was drafted to provide greater flexibility in complying with meaningful use requirements under this criterion.

With respect to the menu set objectives, like an eligible hospital, the EP must select and satisfy five out of ten possible criteria in order to be considered a meaningful user of EHR and eligible for Medicare incentive payments.[86] Menu items unique to EPs, as compared to eligible hospitals, include requirements that physicians distribute patient reminders electronically to more than 20 percent of patients in the appropriate population sets.[87] Further, EPs must provide 10 percent of all patients with information, such as lab test results and patient education materials.[88]

In order to be eligible to receive Medicare meaningful use incentive payments, EPs must see at least 50 percent of all patients in a facility with EHR capabilities.[89] To the extent that the EP sees certain patients in a facility or facilities without EHR capabilities, such services are excluded from both the numerator and the denominator in determining any rate-specific EHR use requirements for calculations of EP incentive payment eligibility.[90]

Much like the requirement for eligible hospitals, EPs must merely submit an attestation claiming compliance with Stage One Medicare incentive payment criteria in 2011.[91] Likewise, EPs must submit certain requested clinical quality data by attestation in 2011. For years 2012 and thereafter, EPs must be prepared to electronically report clinical quality information.[92]

The clinical quality data sets upon which EPs must report are both general – every EP must report on a core group of quality measures – and specialty specific.[93] While the EP must submit such data in order to be eligible for incentive payments, successful quality reporting does not include a requirement that the EP achieve certain threshold levels of compliance with the reported measures.[94]

EPs must report on at least six quality measures, including three core measures and three specialty-specific measures.[95] In the event that the three initial core measures set forth under the regulations do not apply to a particular EP's practice, the EP must then report on an alternate three core measures.[96] The Medicare meaningful use incentive program requires that each EP report on his or her level of screening and treatment for the following core measures:

- hypertension,
- tobacco use assessment and cessation, and
- adult weight screening.[97]

To the extent that a particular EP does not treat or screen any patients for the above three conditions, such EP must then report on an alternate three core quality measures. These three measures include:

- adolescent weight assessment,
- adult influenza immunization, and
- childhood immunization.[98]

In addition to reporting on the measures indicated above, each EP must select specialty-specific measures on which to report.[99] There are 38 measures in total; each EP must select three.[100] For example, an EP may select to report on:

- diabetic blood pressure management
- diabetic eye exam, and
- diabetic foot exam.[101]

Or, an EP may report on:

- breast cancer screening
- cervical cancer screening, and
- Chlamydia screening for women.[102]

These 38 measures were intended to permit the EP the flexibility to report on the services that he or she provides in practice. However, the clinical quality reporting aspect of the meaningful use incentive program is not geared towards the EP's achievement of any particular clinical outcome with respect to the reported patient population. CMS notes that the "incentive program is voluntary. Similar to other Medicare quality measure reporting programs, EPs are not required to satisfy minimum clinical quality performance levels in order to qualify for the EHR payment incentive, but rather merely report on their ambulatory quality measure results."[103]

Eligible Professional Incentive Payments

EPs satisfying the Stage One EHR use and quality reporting requirements are eligible to receive payments under the Medicare meaningful use incentive program.[104] The total incentive payment for which an EP may be eligible is equal to three-quarters of the EP's allowed annual Medicare charges.[105] However, such figure is capped on the high end; for calendar year 2011, that upper threshold is $18,000.[106] This cap is similar to that imposed on eligible hospitals, except that the EP cap is expressed as a definitive monetary sum; the eligible hospital incentive is limited to reflect treatment of only its

first 23,000 patients per year.[107] Much the same as the eligible hospital program, the EP Medicare meaningful use incentive program provides diminishing rewards over the five years during which EPs may receive payments. In the second year of eligibility, EPs may receive payments up to $12,000.[108] Meaningful use incentive payments for EPs first successfully adopting EHR technology in 2011 and having demonstrated program compliance in each subsequent year would total $8,000 in calendar year 2013, $4,000 in calendar year 2014 and $2,000 in calendar year 2015.[109] In total, an EP first demonstrating meaningful use of EHR technology in 2012 and continuing to do so would be eligible for $44,000 in incentive payments under the Medicare program.[110]

EPs first adopting EHR technology in a meaningful way in 2012 would be eligible for the $18,000 initial payment, much the same as the 2011 adopter.[111] Similarly, the EP first demonstrating meaningful use of EHR technology in 2012 and successfully demonstrating such use in consecutive subsequent years would be eligible for the same $44,000 in incentive payments, broken down in the same increments as the 2011 adopter – $12,000 in 2013, $8,000 in 2014, $4,000 in 2015 and $2,000 in 2016.[112]

EPs first demonstrating meaningful use of EHR technology after 2012 will experience comparatively reduced eligibility for incentive payments.[113] EPs first adopting EHR technology in 2013 will be initially eligible for up to $15,000 in incentive payments at that time, followed by payments of $12,000 in 2014, $8,000 in 2015 and $4,000 in 2016, provided that the EP continues to demonstrate meaningful use of EHR technology.[114] In total, the 2013 adopter will be eligible for incentive payments totaling $39,000.[115] EPs first demonstrating meaningful use of EHR technology in 2014 will be eligible for further-reduced payments. Such incentives could be paid up to $12,000 in 2014, $8,000 in 2015 and $4,000 in 2016, for a total potential payment of $24,000.[116] EPs adopting EHR technology for the first time in 2015 will not be eligible for incentive payments.[117]

Further, EPs not adopting EHR thereafter will be subjected to certain penalties. Similar to the payment adjustments for hospitals not qualifying as eligible hospitals under the incentive program as discussed above, beginning in 2015, EPs not considered to be meaningful users in 2015 will receive reduced Medicare physician fee schedule payments.[118] Reimbursement for non-compliant physicians would be reduced by one percent at that time.[119] However, an EP deemed not to be successful electronic prescriber in 2014 as well will experience a two percent reduction to fee schedule reimbursement in 2015.[120] Further, in 2016, all EPs not considered to be meaningful users will experience a two percent reimbursement reduction.[121] In 2017 and in each subsequent year, EPs not considered to be meaningful users will experience a three percent reimbursement reduction.[122] CMS may reduce physician payments by up to five percent in 2018 and beyond if it determines that the total percentage of EPs who are meaningful users is below 75 percent.[123]

Hospital-Based Eligible Professionals

Hospital-based EPs are not eligible to receive meaningful use incentive payments; whether certain physicians may be considered to be hospital-based was the subject of considerable debate prior to the publication of the final rule.[124] Hospital-based EPs are not considered to be eligible due to the predominance of their practice in a hospital setting; this group of professionals is thought to rely on technology purchased and maintained by the hospital rather than by a private physician practice. CMS believed that to make incentive payments to this group would be essentially duplicative of the eligible hospital incentive payment program.

CMS indicates that a determination as to whether an EP may be considered to be hospital-based revolves around that professional's site of service. Initially, the HITECH Act identified all physicians providing substantially all services in the hospital, either in the inpatient or outpatient setting, as hospital-based, ineligible for EP meaningful use incentive payments.[125] However, this definition was ultimately revised due to public comment and subsequent legislative action.[126]

Public comments to the meaningful use incentive program proposed rule indicated a common belief that EPs in certain hospital-based ambulatory settings would be more appropriate for incentive under the EP program as compared to the eligible hospital program.[127] Subsequently, the April, 2010 adoption of the Continuing Extension Act of 2010 contained a provision revising the HITECH Act to exclude EPs practicing in hospital-based outpatient settings from the definition of hospital-based eligible professionals going forward.[128] This change is reflected in the meaningful use final rule; the definition of "hospital setting" now excludes provider-based departments.[129] Providing further clarity on the matter, "substantially all" was calculated under the final rule to be 90 percent of all professional services.[130] The end result of the changes made in the Continuing Extension Act of 2010 and reflected in the meaningful use final rule is that only professionals providing substantially all services in the inpatient setting or in the emergency department are now excluded from eligibility under the EP meaningful use incentive program.

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Incentive Payments to Multi-Campus Hospitals

Another issue receiving considerable public comment in response to the proposed rule is CMS's treatment of multi-campus hospitals for purposes of calculating eligible hospital incentive payments.[131] By definition, the HITECH Act provides incentive payments to subsection (d) hospitals.[132] CMS proposed "that, for purposes of this provision, we would provide incentive payments to hospitals as they are distinguished by provider number in hospital cost reports. We proposed that incentive payments for eligible hospitals would be calculated based on the provider number used for cost reporting purposes, which is the CMS Certification Number (CCN) of the main provider."[133] The problem with this interpretation, as expressed by certain commenters to the proposed rule, is that it provides single-facility hospitals and multi-campus hospital systems sharing a single Medicare provider number with the same reimbursement.[134] Commenters noted that CMS's policy in this regard would provide disparately low incentive payments to the multi-campus hospital system, especially in light of the disproportionately larger expense such systems would incur not only in outfitting each individual hospital, but in providing connectivity among system facilities.[135]

As discussed in greater detail above, payments to eligible hospitals are factored by the share of Medicare beneficiaries treated, as a function of the total inpatient population, and factored by the number of discharges per hospital.[136] Incentive payments are capped after recognition of the first 23,000 inpatients.[137] Logically, the multi-campus hospital system is more likely to meet and exceed the 23,000-patient cap, whereas a single facility hospital might not. This would lead the multi-campus hospital system to treat a disproportionately larger share of its patient population for which it does not receive incentive payments. Expressed differently, both the multi-campus hospital system and the single facility hospital will receive the same incentive payment, to the extent that each meets the patient cap. For the former, though, that payment is intended to incentivize the costs of EHR implementation for multiple facilities that would be otherwise eligible for their own incentive payments, were not they grouped under the same Medicare provider number. Public comments received in response to the proposed rule noted the arbitrary nature of basing the eligible hospital meaningful use incentive payment by provider number, as opposed to facility or uncapped discharge.[138]

Despite comments to the contrary, CMS maintained its approach in providing only one incentive payment for what it considers a subsection (d) hospital.[139] In the preamble to the final rule, CMS indicated that it based its decision on a desire to maintain consistency in the interpretation of the term "subsection (d) hospital," noting that altering its interpretive approach for the purposes of making meaningful use incentive payments would potentially open CMS to other reimbursement issues for those same hospitals.[140]

Despite CMS's response in the final rule, the issue continues to be a topic of discussion, including among legislators. The Electronic Health Records Incentives for Multi-Campus Hospitals Act of 2010, intended to correct this claimed inequity, was introduced in the United States House of Representatives shortly after CMS's publication of the meaningful use final rule.[141] That legislation would set forth alternative payment mechanisms, under which a multi-campus hospital system may elect to receive incentive payments.[142] Those alternatives include an option under which a multi-campus hospital system may elect to receive a separate base payment for each facility under the multi-campus hospital umbrella.[143] Another alternative in the bill would provide more flexibility in compensating multi-campus hospitals beyond the 23,000-patient cap currently in use.[144]

The Electronic Health Records Incentives for Multi-Campus Hospitals Act of 2010 was most recently referred to the House Committee on Ways and Means and Committee on Energy and Commerce for further consideration. Related legislation is under consideration by the United States Senate Committee on Finance.[145] However, given the results of the most recent election, it is unclear whether this legislation, or another approach directed at the same result, will come to pass. As it stands, the multi-campus hospital system will continue to be paid meaningful use incentives by Medicare provider number.[146] All facilities grouped under the same number will be considered to be one subsection (d) hospital for the purposes of making eligible hospital meaningful use incentive payments.[147]

Timing Issues Associated with Incentive Payments for Both Eligible Hospitals and EPs

CMS began the registration process under the meaningful use incentive program in January, 2011.[148] Both prospective eligible hospitals and EPs must register with CMS in order to receive incentive payments later in the year. Prospective eligible hospitals and EPs will be able to register through CMS's registration and attestation system, part of the EHR Incentive Program website.[149] As noted above, determinations of meaningful use in 2011 will be based on an eligible hospital's or EP's successful

submission of an attestation that it is compliant with the relevant requirements demonstrating meaningful use of EHRs.[150] Attestations may also be completed via CMS's registration and attestation system on the EHR Incentive Program website. Those attestations may be first submitted in April, 2011.[151] Finally, CMS anticipates that it will begin making incentive payments in May, 2011.[152]

Conclusion

In issuing the incentive payment program final rule, CMS recognized the anxieties that hospitals and physicians were voicing over the likelihood of being compliant with meaningful use requirements. By permitting eligible hospitals and EPs to submit attestations, rather than to report meaningful use criteria directly, CMS has acknowledged that the first and foremost priority for the meaningful use program is to get providers involved and on the EHR learning curve. The attestation requirement should not be considered an opportunity to receive meaningful use payments without having to legitimately undergo the EHR implementation process. CMS anticipates that, by nature of the attestation process, some providers will attempt to receive incentive payments without actually demonstrating meaningful use.[153] Accordingly, CMS has indicated that it will implement an audit strategy by which it will determine that all meaningful use incentive payments made were warranted.[154]

By providing greater flexibility in permitting eligible hospitals and EPs to choose meaningful use requirements relevant to their specific clinical practices, CMS is structuring the meaningful use program to foster early success. The meaningful use program recognizes that, ultimately, implementation of EHR technology will cost more than many eligible hospitals or EPs will receive under the incentive program. However, CMS has indicated that the long-term goal of the program for providers should be the recognition of cost savings and care improvement through the use of EHRs. In that regard, EHR implementation is ultimately intended to be its own reward. CMS also recognizes that, the greater the connectivity between providers, the greater the potential for cost savings and care improvement. Rather than seek to alienate potentially eligible hospitals and EPs by looking for a bigger bang for the buck on the front end, CMS is encouraging as many providers as possible to implement EHR technology as soon as possible.

As demonstrated in the final rule implementing the meaningful use incentive program, CMS is interested in having providers succeed at implementing EHR technology in a way that will be meaningful for the improvement of healthcare. Accordingly, potentially eligible hospitals and EPs should act now to begin the EHR implementation process.

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Endnotes

1 American Recovery and Reinvestment Act of 2009 ("ARRA"), Pub. L. 111-5.

2 ARRA, Title IV, Subtitles A and B. The HITECH Act directs the Office of the National Coordinator for Health Information Technology to support and promote meaningful use of certified EHR technology through the adoption of standards, implementation specifications, and certification criteria as well as the establishment of certification programs. Certification of EHR technology will provide assurance to purchasers and other users of health information technology that an EHR system offers the necessary technological capability, functionality, and security to meet meaningful use criteria through the adoption of standards, implementation specifications, and certification criteria as well as the establishment of certification programs.

3 75 Fed. Reg. 1844 (Jan. 13, 2010).

4 75 Fed. Reg. 44314 (Jul. 28, 2010).

5 *Id.*

6 *See* discussion of public comments beginning at 75 Fed. Reg. 44314, 44317.

7 Letter from Rick Pollack, Executive Vice President, American Hospital Association to Charlene Frizzera, Acting Administrator, Centers for Medicare & Medicaid Services, dated March 8, 2010; Public comments are available at www.regulations.gov. The AHA comments are discussed specifically in this article as representative of many of the public comments sent to CMS regarding the proposed rule, particularly with respect to the concerns shared by the hospital industry, which the AHA represents.

8 AHA Letter at 3.

9 *Id.* at 3.

10 *Id.* at 2.

11 *See* 75 Fed. Reg. 1844, 1993-95.

12 75 Fed. Reg. 44314, 44326.

13 *Id.* at 44572.

14 *Id.*

15 *Id.* An analysis of the physician's patient-mix should provide the physician with appropriate guidance for making the choice between the Medicare and Medicaid incentive program.

16 *Id.*

17 *Id.* at 44580.

18 *Id.* at 44578. A Federally Qualified Health Center ("FQHC") is a community-based organization funded under Section 330 of the Public Health Service Act that provides comprehensive primary care and preventative care to persons of all ages, regardless of their ability to pay. A Rural Health Clinic ("RHC") is a clinic located in a rural, medically underserved area that has a separate reimbursement structure under Medicare and Medicaid.

19 *See* ARRA, Title IV, Subtitle A, Sec. 4101.

20 *Id.* The final rule provides CMS's interpretation of this circular mandate.

21 *Id.*

22 *Id.*

23 *See* 75 Fed. Reg. 44314, 44321.

24 *Id.*

25 *Id.* at 44566.

26 *See* 75 Fed. Reg. 1844, 1993-95.

27 *See* 75 Fed. Reg. 44314, 44566.

28 *See Id.* at 44568-69.

29 *See Id.* at 44566-68.

30 *Id.* at 44566.

31 A CAH is a hospital that is certified to receive cost-based reimbursement from Medicare.

32 *Compare* 75 Fed. Reg. 44314, 44568-69 and 75 Fed. Reg. 1844, 1993-95.

33 Structured data is data that resides in fixed fields within a record or file, such as relational databases or spreadsheets.

34 75 Fed. Reg. 44314, 44569.

35 *Id.*

36 *Id.*

37 *Id.*

38 *Id.*

39 *Id.*

40 *Id.*

41 *Id.*

42 75 Fed. Reg. 44314, 44568-69. CMS specifically disagreed with commenters who suggested that anyone should be allowed to enter orders using CPOE, and indicated that allowing any licensed healthcare professional to enter orders using CPOE balances the potential workflow implications of requiring the ordering provider to enter every order directly with missing opportunities for clinical decision support and adverse interaction identification.

43 75 Fed. Reg. 44314, 44569.

44 *Id.*

45 75 Fed. Reg. 44314, 44350. CMS purposefully describes clinical decision support rules broadly, defining clinical decision support as health information technology functionality that builds upon the foundation of an EHR to provider persons involved in care processes with general and person specific information, intelligently filtered and organized, at appropriate times to enhance health and healthcare. In the proposed rule CMS asked providers to relate the selected decision rules to clinical priorities and diagnostic test ordering.

46 *Id.*

47 *Id.* CMS indicated that the final rule was phrased to ensure that meaningful use of the certified EHR technology supports compliance with the HIPAA Privacy and Security rules, but does not believe meaningful use of certified EHR technology is the appropriate regulatory tool to ensure HIPAA compliance. HIPAA compliance is required of all covered entities regardless of whether they participate in the EHR incentive program.

48 *Id.*

49 *Id.* at 44332.

50 *Id.* at 44334.

51 *Id.*

52 *Id.* at 44369.

53 *Id.* at 44380.

54 *Id.* at 44348.

55 *Id.*

56 *Id.*

57 *Id.*

58 *Id.* at 44412.

59 *Id.* at 44418-20.

60 *Id.* at 44412.

61 *Compare* 75 Fed. Reg. 44314, 44569-70 and 75 Red. Reg. 1844 1993-95.

62 75 Fed. Reg. 44314, 44566.

63 *Id.* at 44348.

64 *Id.* at 44573.

65 *Id.*

66 *Id.*

67 *Id.*

68 *Id.*

69 *Id.*

70 *Id.*

71 *Id.*

72 *See* ARRA, Title IV, Subtitle A, Sec. 4102(b).

73 *Id.*

74 *Id.*

75 75 Fed. Reg. 44314, 44573-74.

76 *Id.* at 44574.

77 *See* 75 Fed. Reg. 44314, 44566-69.

78 *Id.* at 44567-68.

79 *Id.* at 44567.

80 *See* 75 Fed. Reg. 44314, 44337. *See also* 75 Fed. Reg. 16236 (March 31, 2010).

81 *Id.*

82 75 Fed. Reg. at 44337.

83 See 75 Fed. Reg. 1844, 1993-95; 75 Fed. Reg. 44314, 44567-69.

84 75 Fed. Reg. at 44567-69.

85 *Id.*

86 75 Fed. Reg. 44314, 44566, 44568.

87 *Id.* at 44568.

88 *Id.*

89 75 Fed. Reg. 44314, 44329.

90 *Id.*

91 75 Fed. Reg. 44314, 44570.

92 *Id.* at 44570-71.

93 75 Fed. Reg. 44314, 44409-11.

94 *Id.*

95 75 Fed. Reg. 44314, 44409.

96 *Id.*

97 75 Fed. Reg. 44314, 44410.

98 *Id.*

99 *Id.* at 44409.

100 *See Id.* at 44398-408.

101 *Id.*

102 *Id.*

103 *Id.* at 44396.

104 75 Fed. Reg. 44314, 44442.

105 *Id.* at 44572.

106 *Id.*

107 *Id.* at 44573.

108 *Id.* at 44572.

109 75 Fed. Reg. 44314, 44572.

110 *Id.*

111 75 Fed. Reg. 44314, 44572.

112 *Id.*

113 75 Fed. Reg. 44314, 44572.

114 *Id.*

115 *Id.*

116 75 Fed. Reg. 44314, 44572.

117 *Id.*

118 *Id.* at 44447.

119 *Id.*

120 *Id.*

121 *Id.*

122 *Id.*

123 *Id.* at 44447-48.

124 75 Fed. Reg. 44314, 44439.

125 75 Fed. Reg. 44314, 44439-40.

126 *Id.*

127 75 Fed. Reg. 44314, 44439-42.

128 *Id.* at 44440. *See also* Continuing Extension Act of 2010, Pub. L. No. 111-157 (Apr. 15, 2010). The Continuing Extension Act of 2010, in addition to clarifying the definition of hospital-based physicians for the purpose of the EHR incentive program, extended certain federal unemployment and healthcare benefits. For example, the Continuing Extension Act of 2010 amended the Supplemental Appropriations Act of 2008, the Assistance for Unemployed Workers and Struggling Families Act and the Unemployment Compensation Extension Act of 2008 to extend unemployment insurance benefits. The Continuing Extension Act of 2010 also amended the Consolidated Omnibus Budget Reconciliation Act of 1985 to extend certain health insurance continuation benefits and amended the Social Security Act to extend reimbursement levels for physicians paid under the Medicare physician fee schedule.

129 75 Fed. Reg. at 44440.

130 *Id.*

131 75 Fed. Reg. 44314, 44448-50.

132 *See* 42 U.S.C. § 1395ww(n)(6)(B). Subsection (d) hospitals are generally, acute care hospitals. The term is defined under 42 U.S.C. § 1395ww(d)(1)(B) and includes hospitals other than psychiatric hospitals, rehabilitation hospitals, children's hospitals, long-term care hospitals, and certain cancer centers.

133 75 Fed. Reg. at 44448.

134 *Id.*

135 *Id.*

136 75 Fed. Reg. 44314, 44448-50, 44573.

137 *Id.* at 44573.

138 75 Fed. Reg. 44314, 44448-50.

139 75 Fed. Reg. 44314, 44450.

140 *Id.* at 44449.

141 *See* H.R. 6072, 111th Cong. (2010).

142 *Id.* § 2.

143 *Id.*

144 *Id.*

145 *See* S. 3078, 111th Cong. (2010).

146 75 Fed. Reg. 44314, 44450.

147 *Id.*

148 75 Fed. Reg. 44314, 44571.

149 *See* http://www.cms.gov/EHRIncentivePrograms/50_Registration.asp#TopOfPage.

150 75 Fed. Reg. at 44570.

151 *Id.* at 44464-65.

152 *Id.*

153 75 Fed. Reg. 44314, 44468.

154 *Id.*

EMERGING TRENDS IN CRIMINAL HEALTHCARE LAW ENFORCEMENT: THE PATIENT PROTECTION AND AFFORDABLE CARE ACT OF 2010 REDUCES THE CRIMINAL MENS REA REQUIREMENT FOR HEALTHCARE FRAUD AND INCREASES PENALTIES UNDER THE FEDERAL SENTENCING GUIDELINES

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Introduction

There has been a significant uptick in the number of criminal statutes enacted by Congress that diminish or eliminate the *mens rea*[1] or "guilty mind" requirement. The Patient Protection and Affordable Care Act of 2010 ("PPACA")[2] is the most recent and significant example of legislative relaxation of the standard of criminal culpability in federal courts, and for healthcare fraud cases in particular. Moreover, PPACA created a corresponding increase in the severity of the Federal Sentencing Guidelines for healthcare fraud offenses.

The exponential increase in the proliferation of perceived healthcare fraud contributed significantly to passage of criminal provisions in PPACA that reduce the government's burden of proof at trial and enhances sentences upon conviction under the Anti-Kickback Statute (AKS), 42 U.S.C. §1320a-7b(h)(2010), and the crime of healthcare fraud, 18 U.S.C. §1347(b)(2010). Responding to the rising prevalence of healthcare fraud offenses to the current Administration, the Departments of Justice and Health and Human Services reported increased enforcement actions between 2006 and 2009 reflecting a higher incidence of detected violations.[3] Though law enforcement actions to reduce healthcare fraud have been formidable,[4] PPACA's relaxation of the burden of proof and the imposition of enhanced sentences are intangible resources recently added to the government's arsenal.

Trend Toward Diminished Mens Rea Requirement in Healthcare Fraud

Prior to passage of PPACA, the American Recovery and Reinvestment Act of 2009[5] imposed criminal liability for certain HIPAA violations that are the product of "willful neglect,"[6] a term undefined by statute. However, under the Health Information Technology for Economic and Clinical Health Act ("HITECH"), federal regulations define the *scienter* requirement: "Willful neglect means conscious, intentional failure or reckless indifference to the obligation to comply with the administrative simplification provision violated."[7] It can be argued that this *scienter* requirement permits criminal liability to attach based on a theory of negligence with only a modicum of actual awareness of the wrongfulness of his or her conduct necessary to sustain a conviction.

The reduction of *mens rea* appears to mark a significant departure from prior law enforcement initiatives to enhance deterrence against fraud, waste, and abuse by employing lower evidentiary burdens at trial.

According to a benchmark study issued jointly by the National Association of Criminal Defense Lawyers and The Heritage Foundation in May 2010, the 109th Congress (2005-2006) proposed 446 *non-violent* offenses with diminished *mens rea* requirements, of which 36 were enacted into law.[8] The empirically-based study noted at the outset:

> For centuries, "guilty mind," or *mens rea*, requirements restricted criminal punishment to those who were truly blameworthy and gave individuals fair notice of the law. No person should be convicted of a crime without the government having proved that he acted with a guilty mind – that is, that he intended to violate a law or knew that his conduct was unlawful or sufficiently wrongful so as to put him on notice of possible criminal liability. In a sharp break with this tradition, the recent proliferation of federal criminal laws has produced scores of criminal offenses that lack adequate *mens rea* requirements and are vague in defining the conduct that they criminalize.[9]

PPACA focuses debate on the relative degree of *scienter* which society demands for prosecuting healthcare fraud offenses. Few tenets of criminal law more fundamentally alter the administration of criminal justice than modulating the "knowing" or "willful"[10] requirement of a criminal statute to ensure that only culpable conduct is criminalized, especially in complex healthcare cases. It lowers the government's burden for proving a defendant's state of mind. Diminution of the level of *mens rea* may lead to more prosecutions that disadvantage defendants due to the government's less formidable evidentiary burden under PPACA.

PPACA clarifies that healthcare fraud is a crime based on general intent. Before the Act, courts were divided as to whether general intent to violate the subject statutes satisfied the

mens rea requirement notwithstanding the "knowing" and willful" language of the Healthcare Fraud Statute and the specific intent contemplated by the Anti-Kickback Statute.

"Specific intent" is usually distinguished from "general intent." *United States v. Bailey*, 444 U.S. 394, 403, 100 S.Ct. 624, 62 L.Ed.2d 575 (1980). As most commonly understood, a general-intent crime is one that requires "proof of knowledge with respect to the *actus reus* of the crime," *Carter v. United States*, 530 U.S. 255, 269, 120 S.Ct. 2159, 147 L.Ed.2d 203 (2000), while a specific-intent crime, in contrast, is "one whose definition requires a special *mens rea* above and beyond that which is required for the *actus reus* of the crime."[11]

Although PPACA clarifies that healthcare fraud is a general intent crime, whether this represents an erosion of criminal *scienter* requirements will be determined by judicial construction of the new legislation.

Mens Rea Requirement for Criminal Healthcare Fraud Prior to Enactment of PPACA

"The general criminal "Healthcare Fraud Statute" is codified in 18 U.S.C. §1347. Enacted as part of the Health Insurance Portability and Accountability Act of 1996, until 2010[12] it contained elements of the offense underscoring that a specific intent to knowingly or willfully violate the criminal healthcare fraud statute was required:

> To support a conviction for health care fraud under 18 U.S.C. § 1347, the government must prove that the defendant: (1) knowingly and willfully executed, or attempted to execute, a scheme or artifice; to (2) defraud a health care benefit program or to obtain by false or fraudulent pretenses any money or property under the custody or control of a health care benefit program; (3) in connection with the delivery of or payment for health care benefits, items, or services.[13]

The common law of criminal healthcare fraud recognized the centrality to due process of the *scienter* requirement, including the right to constitutionally adequate notice of the proscribed conduct:

> To prove Defendant violated 18 U.S.C. § 1347, the government had to show she "knowingly and willfully" executed or attempted to execute a scheme to defraud a health care benefit program or a scheme to gain control of a health care benefit program's money or property through false pretenses, representations, or promises. *See* 18 U.S.C. § 1347. To establish knowledge and willfulness, " 'the Government must prove that the defendant acted with knowledge that [her] conduct was unlawful.' " *Bryan v. United States*, 524 U.S. 184, 191-92, 118 S.Ct. 1939, 141 L.Ed.2d 197 (1998) (quoting *Ratzlaf v. United States*, 510 U.S. 135, 137, 114 S.Ct. 655, 126 L.Ed.2d 615 (1994)).[14]

Critics of lowering the intent requirement in healthcare fraud cases cry foul notwithstanding the policy issues presented, including the loss of more than $100 billion per year to healthcare fraud, waste, and abuse.[15] Many see healthcare fraud as the scourge of the nation and seek stricter enforcement and enhanced punishment to stem its tide.[16]

Members of the healthcare bar and their criminal defense colleagues may find relaxation of the *mens rea* requirement to be disturbing. However the government is fully within its discretion to charge "the most serious offense that is consistent with the nature of the defendant's conduct, and that it is likely to result in a sustainable conviction."[17] Thus, PPACA facilitates criminal convictions and renders a case more easily provable.

Relaxed Scienter Requirement Under PPACA

PPACA amended 18 U.S.C. § 1347 by inserting subsection (b), which states: "With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section." The same language was added to the AKS (codified at 42 U.S.C. 1320a-7b(h)).[18] Though a certificate of compliance with federal healthcare law is a prerequisite to provider eligibility under the Medicare program,[19] fundamental notions of due process require that criminal statutes be drafted with clarity, attentive to defining the elements of the offense and providing adequate notice of the proscribed conduct. Irrespective of whether healthcare fraud is now a general rather than specific intent crime, the PPACA amendments in this regard appear to retreat from an optimal constitutional construction.

Defining the elements of a criminal offense is purely a legislative prerogative. Thus, the split among the Circuits regarding the appropriate level of *scienter* was unified by PPACA's new general intent standard of *mens rea*. The net effect of the diminished *mens rea* requirement of PPACA's enforcement paradigm suggests potential legislative overruling of decades of judicial precedent. For example, the Second Circuit held that "[i]n order to sustain its burden of proof against the hospital executive for the crime of violating the Anti-Kickback Statute, the government must prove beyond a reasonable doubt that the defendant. . . offered or paid remuneration with the specific intent to 'induce' referrals."[20] Similarly, the Tenth Circuit has observed that the Healthcare Fraud Statute requires a specific intent to defraud or misrepresent and, therefore, the argument that

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a defendant could be punished for an offense for which he was unaware is insufficient to sustain a conviction.[21]

Even before PPACA, courts did not agree about the perplexing distinctions between specific and general intent in healthcare cases. The *scienter* requirement had its analytical healthcare origins in the seminal case, *Hanlester Network v. Shalala*,[22] in which the Ninth Circuit construed the "knowingly and willfully" requirement of the AKS as requiring the government to allege and prove that a defendant: "(1) knew at time of the challenged conduct that the anti-kickback statute 'prohibits paying or offering to pay remuneration to induce referrals;' and (2) engaged in prohibited conduct 'with the specific intent to disobey the law.'"[23]

The Sixth and Eleventh Circuits also recognized the specific intent requirement of Sections 1347 and 1320a-7b. As discussed in *United States v. Puffenberger*,[24] circumstantial evidence from which to infer a defendant's specific intent is proper:

> To support a conviction for substantive health care fraud under 18 U.S.C. § 1347, the government must prove that the defendant (1) knowingly and willfully executed, or attempted to execute, a scheme or artifice to (2) defraud a health care program or to obtain by false or fraudulent pretenses any money or property under the custody or control of a health care benefit program, (3) in connection with the delivery of or payment for health care benefits, items, or services. 18 U.S.C. § 1347. Intent may be established through circumstantial evidence, so long as there is enough evidence from which a jury could reasonably infer that the defendant acted with the specific intent to defraud.

Yet intent was often proved on the basis of circumstantial evidence and the reasonable inferences drawn by the jury before the effective date of PPACA. In *United States v. Davis*,[25] the Sixth Circuit inferred guilt from surrounding circumstances "'[b]ecause it is difficult to prove intent to defraud from direct evidence, [thus] a jury may consider circumstantial evidence of fraudulent intent and draw reasonable inferences therefrom.' Intent can be inferred from efforts to conceal the unlawful activity, from misrepresentations, from proof of knowledge, and from profits."[26]

Although it's too early to assess the impact of the PPACA amendments on the criminal healthcare fraud statutes, it appears that a defendant no longer need believe that his or her conduct expressly violates Section 1347 or the AKS itself, and it is therefore unnecessary for the government to have to prove such knowledge to obtain a conviction. The belief that one's conduct is in some way illegal is still sufficient to violate the amended statutes.

On balance, PPACA harmonizes the *scienter* requirements of 18 U.S.C. §1347 and 42 U.S.C. 1320a-7b and offers clarification to divided federal courts of appeal. It is manifestly evident that Congressional frustration with fraud, waste, and abuse[27] in the healthcare system fueled its desire to facilitate federal healthcare fraud prosecutions by relaxing the standard of *mens rea* to deter criminality in this sector.

PPACA Mandates Increased Sentences for Healthcare Fraud

PPACA contains Congressional mandates directing the United States Sentencing Commission, an independent agency in the judicial branch[28] charged with responsibility for determining punishment ranges for categories of offenses and offenders,[29] to promulgate Sentencing Guidelines with more severe penalties for healthcare fraud.[30] Congress has made increased use of legislative mandates[31] directing the Sentencing Commission how to exercise its institutional expertise despite its grant of power to the Commission to serve as an expert agency.[32] This practice undermines the *Chevron*[33] deference owed to the Commission's independent rulemaking authority, although the legislative model always vested authority in Congress to proscribe specified conduct and establish minimum and maximum sentences.

Sentencing Commission Implements the Congressional Mandate

Responding to the PPACA imperative, the Sentencing Commission published notice of request for public comment[34] to implement "the directive in section 10606(a)(2)(A) of the Patient Protection and Affordable Care Act, Pub. L. 111–148, regarding health care fraud offenses."[35] The Commission is now considering such comments in anticipation of incorporating the legislative mandate into the next Sentencing Guideline amendment cycle effective November 1, 2011. However, the Sentencing Commission lacks authority to act in any way other than to enhance the guidelines for healthcare fraud as directed by Congress.

A significant drawback of legislatively mandated Sentencing Guidelines is Congressional failure to define "loss" and "relevant conduct," which are outcome-determinative terms of art under the Guidelines. These terms materially impact the sentencing provision of PPACA, which directs that:

> … the aggregate dollar amount of fraudulent bills submitted to the Government health care program

> [which] shall constitute prima facie evidence of the amount of the intended loss by the defendant.[36]

The notion that fluid and case-specific theories of loss and relevant conduct – particularly in complex healthcare fraud cases – could be summarily amended without debate, public comment, or a meaningful opportunity to be heard undermines the process and substance of guideline sentencing and is plainly inconsistent with the proper application principles. It ignores significant judicial appreciation of the proper methodologies and factual circumstances under which loss and relevant conduct must be determined.[37] Even under *Booker v. United States*,[38] "[t]he Guidelines do not present a single universal method for loss calculation under § 2B1.1 – nor could they – given the fact intensive and individualized nature of the inquiry."[39]

An Unintended Result of the PPACA Amendments Appears to Undermine the Common Law of Sentencing Based on the New Statute's Summary Treatment of "Relevant Conduct" and "Loss"

In addition to requiring a change in the Sentencing Guidelines, PPACA fundamentally alters the common law of sentencing, particularly with respect to the "cornerstone"[40] of the Federal Sentencing Guidelines, "relevant conduct."[41] This provision, read in conjunction with the Guideline section on "loss,"[42] largely pre-determines the seriousness of the offense and sentence length in healthcare fraud cases. While loss is often viewed as a proxy for culpability,[43] courts disagree in significant ways with respect to the appropriate methodology for determining, for example, the impact of extrinsic market conditions on healthcare fraud cases, whether a Special Rule applies, use of the net value theory of loss, etc.[44] Under the Federal Sentencing Guidelines, "relevant conduct" demands an element of causation[45] and examination of many layers of rules and exceptions which the PPACA amendments have failed to consider. Instead, PPACA takes a simplistic approach to loss determination. It appears that Congress underestimated the extent to which this will upset frequently litigated appellate sentencing issues.[46] PPACA raises the healthcare fraud guidelines significantly despite the lack of empirical data to support that doing so furthers the statutory purposes of sentencing under 18 U.S.C. §3553(a).[47] "Loss" is an elusive sentencing concept that is not subject to a single universal assumption of its definition:

> Were less emphasis placed on the overly-rigid loss table, the identification of different types of fraud or theft offenses of greater or lesser moral culpability or danger to society would perhaps assume greater significance in assessing the seriousness of different frauds.[48]

> [T]he common law of sentencing has recently reexamined punishment for white collar crimes and health care fraud in particular. The upshot is that the rules concerning the amorphous, outcome-determinative factor of "loss" must now be grounded in "economic reality." District courts must take a "realistic, economic approach to determine what losses the defendant caused or intended to cause.[49]

The more sensible practice is to recognize—certainly in Medicare and Medicaid fraud cases—that the programs pay only 80 percent of the "intended loss"[50] and that the Sentencing Guideline for fraud provides myriad credits, offsets, and exclusions from the loss calculus.[51] Once effective, the new guidelines will engender significant unwarranted sentencing disparities and considerable litigation.

PPACA is Driven by Congressional Directives for Increased Enforcement of Healthcare Fraud Statutes

Statutory sentencing purposes under PPACA are driven by a Congressional policy that promotes "increased penalties for persons convicted of healthcare fraud offenses in appropriate circumstances."[52] Moreover, PPACA is designed to "reflect the serious harms associated with healthcare fraud and the need for aggressive enforcement action to prevent such fraud.[53] The Guidelines will be amended in November 2011 to provide:

- a two-level increase in the offense level for any defendant convicted of a Federal healthcare offense relating to a Government healthcare program which involves a loss of not less than $1 Million and less than $7 Million;
- a three-level increase in the offense level for any defendant convicted of a Federal healthcare offense relating to a Government healthcare program which involves a loss of not less than $7 Million and less than $20 Million;
- a four-level increase in the offense level for any defendant convicted of a Federal healthcare offense relating to a Government healthcare program which involves a loss of not less than $20 Million; and
- if appropriate, otherwise amend the Federal Sentencing Guidelines and policy statements applicable to persons convicted of Federal healthcare offenses involving Government healthcare programs.[54]

Although the Bureau of Justice Statistics[55] does not distinguish – for offense classification purposes – between "fraud" and "healthcare fraud," it's a misconception to presume that healthcare fraud convictions are treated less severely than other white-collar offenses.

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The politics of sentencing[56] have manifested by folding criminal justice statutes into the healthcare reform law designed to sustain and improve the beleaguered medical infrastructure. Stronger law enforcement is said to justify such legislation as a whole in spite of the considerable number of stakeholders, including federal criminal defense lawyers and white-collar practitioners, whom would disagree. On the other hand, defense attorneys will likely argue against PPACA sentencing policies as a basis for a below-the-guideline sentence in appropriate cases.

Conclusion

PPACA represents the latest in a series of dozens of statutes[57] in which Congress diminished the *scienter* requirement of criminal law. The result of such legislation in the healthcare field is to create conflict between competing values of allocating criminal blameworthiness for culpable criminal conduct and reconciling social imperatives reflected by Congressional intent to deter burgeoning healthcare fraud.

Longer sentences notwithstanding, white collar offenders tend to have a lower incidence of recidivism;[58] therefore, PPACA's predominantly retributive orientation[59] undermines a balancing of sentencing purposes and may engender unwarranted disparities among similarly situated defendants, many of whom are healthcare practitioners or executives. Nevertheless, consideration of clearly defined legislative sentiment implicates a utilitarian analysis in which the allocation of scarce fiscal resources for stricter law enforcement under PPACA yields a social/cost benefit.

The legal issues that emerge from amendment of 18 U.S.C. §1347(b) and 42 U.S.C. §1320a-7b(h) will be the subject of significant litigation concerning both the guilt/innocence and penalty phases of federal healthcare fraud prosecutions.

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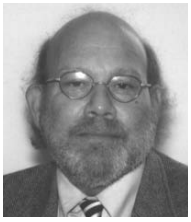

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Endnotes

1 *Mens rea*, like *scienter*, describes a culpable state of mind without which there can be no crime. It denotes a sense of moral blameworthiness if the actor intended the consequences of his or her actions. *See generally Morissette v. United States*, 342 U.S. 246 (1952); *Ratzlaf v. United States*, 510 U.S. 135, 141, 114 S.Ct. 655, 659, 126 L.Ed.2d 615 (1994).

2 Pub. L. No. 111-148, Title VI, §§ 10606, 6402, 124 Stat. 1008 (Mar. 23, 2010).

3 *See* HHS, DOJ, Health Care Fraud Abuse Control Program[s] Anuual Report[s] (FY 2006, FY 2009). www.hhs.gov/ (accessed Sept. 19. 2010).

4 *See e.g.*, Testimony of Daniel R. Levinson, Inspector General (HHS) before the Subcommittee on Health of the House Committee on Energy (Sept. 22, 2010).

5 Pub. L. No. 111-5, 123 Stat. 115 (Feb. 17, 2009).

6 42 U.S.C. §1320d-5.

7 45 C.F.R. §160.401.

8 Bryan W. Walsh and Tiffany M. Joslyn, *Without Intent: How Congress Is Eroding the Criminal Intent Requirement in Criminal Law*, www.nacdl.org/withoutintent (March 2010).

Interestingly, the National Association of Criminal Defense Lawyers advocating for criminal defense lawyers and their constituents, and The Heritage Foundation, a conservative think tank, typically find themselves at polar opposites of the socio-political spectrum. However, on this point, the two organizations are resolute in their uniform position concerning fundamental legal rights to impose criminal liability only when it is purposeful and provides fair notice of the proscribed conduct.

9 *See* Note 8, *supra* at Executive Summary.

10 "As a general matter, when used in the criminal context, a 'willful' act is one undertaken with a 'bad purpose.' In other words, in order to establish a 'willful' violation of a statute, 'the Government must prove that the defendant acted with knowledge that his conduct was unlawful.'" *Bryan v. United States*, 524 U.S. 184, 191-92, 118 S.Ct. 1939, 141 L.Ed.2d 197 (1998) (footnote omitted) (quoting *Ratzlaf v. United States*, 510 U.S. 135, 137, 114 S.Ct. 655, 126 L.Ed.2d 615 (1994)).

11 *United States v. Starnes*, 583 F.3d 196, 209 (3rd Cir. 2009).

12 Pub. L. No. 104-191, 110 STAT. 1396 (AUG. 21, 1996).

13 *United States v. Abdallah*, 629 F.Supp.2d 699, 720 (S.D.Tx. 2009).

14 *United States v. Franklin-El*, 554 F.3d 903, 910 (10th Cir. 2009).

15 Benson Weintraub, WHITE COLLAR CRIME: HEALTH CARE FRAUD (WEST) (2009-2010 ed.) at §1:3.

16 News Release, Attorney General Holder and HHS Secretary Sebelius Host Second Regional Health Care Fraud Prevention Summit in Los Angeles (Aug. 26, 2010). http://www.hhs.gov/news/press/2010pres/08/20100826a.html.

("In communities across the region, our health care system is under siege – exploited by criminals intent on lining their own

pockets at the expense of American taxpayers, patients and private insurers," said Attorney General Eric Holder. "But through the Health Care Fraud Prevention and Enforcement Action Team, we are fighting back in bold, innovative and coordinated ways. In addition, the *Affordable Care Act* provides new resources and includes tough penalties to help stop and prevent health care fraud. We will continue to work vigorously with our law enforcement and private sector partners to punish those who steal from taxpayers, patients, seniors and other vulnerable Americans.").

17 *See* Memorandum to All Federal Prosecutors from U.S. Attorney General Eric Holder (May 19, 2010)(citing USAM 9-27.300).

18 Pub. L. No. 111-148, Title VI, §6402(f), 124 Stat. 1008 (Mar. 23, 2010).

19 42 CFR §413.24(f)(4)(iv). *United States ex. rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 245 (3rd Cir. 2004).

20 *United States v. Choiniere*, 517 F.3d 967 (7th Cir. 2008), *cert. denied*, 130 S.Ct. 193 (2009). Support for the *Hanlester* interpretation of the anti-kickback statute's *scienter* requirement can be found in the U.S. Supreme Court decision *Bryan v. United States*, 524 U.S. 184 (1998), which interpreted the term "willfully" in a non-health-care context. *But see United States v. Starks*, 157 F.3d 833 (11th Cir. 1998)(contrary to *Hanlester*, a kickback violation does not require knowledge of the anti-kickback statute in particular, as long as defendants knew their conduct was illegal).

21 *United States v. Franklin-El*, 554 F.3d 903, 911 (10th Cir. 2009).

22 51 F.3d 1390 (9th Cir. 1995).

23 Bureau of National Affairs, *Defendants' Perception of Their Conduct: Vagueness and Scienter*, BNA Health Law & Business Series, §1500.04 (2010).

24 358 Fed.Appx. 140, 142 (11th Cir. 2009) (unpub.).

25 490 F.3d 541, 549-550 (6th Cir. 2007).

26 *Id.* (internal citations omitted).

27 Senator Ted Kaufman (D-DE) estimates that "[f]raud perpetuated against both public and private health plans costs between $72 and $220 billion annually, increasing the cost of medical care and health insurance and undermining public trust in our health care system." http://kaufman.senate.gov/press/press_releases/release/?id=5e8767a9-e711-4f7a-8a52-27ad23e8fb53 (Oct. 28, 2009).

28 *Mistretta v. United States*, 488 U.S. 361, 368 (1989). 28 U.S.C. §991(a).

29 28 U.S.C. §994(a)(1).

30 Pub. L. No. 111-148, at §10606(a)(2)(B).

31 "In section 3612 of the Methamphetamine Anti-Proliferation Act of 2000, Congress directed the Sentencing Commission to increase the methamphetamine guidelines if the offense created a substantial risk of harm to human life or the environment. *See United States v. Pinnow*, 469 F.3d 1153, 1156 (8th Cir. 2006). *See also United States v. McElheney*, 630 F.Supp.2d 886, 893 (E.D. Tenn. 2009)("Courts have also recognized the Guidelines for child pornography are the result of congressional mandates rather than empirical analysis and have accorded them less weight as a result."). *See generally* Benson Weintraub and Benedict P. Kuehne, *The Feeney Frenzy: A Case Study in Actions and Reactions in the Politics of Sentencing*, 16 FED. SENTENCING REP. 114 (Dec. 2003).

32 "Carrying out its charge, the Commission fills an important institutional role: It has the capacity courts lack to 'base its determinations on empirical data and national experience, guided by a professional staff with appropriate expertise."' *Kimbrough v. United States*, 128 S. Ct. 558, 574 (2007) (citations omitted); *Rita v. United States*, 127 S. Ct. 2456, 2464 (2007) ("The Commission's work is ongoing. The statutes and the Guidelines themselves foresee continuous evolution helped by the sentencing courts and courts of appeals in that process... The Commission will collect and examine the results. In doing so, it may obtain advice from prosecutors, defenders, law enforcement groups, civil liberties associations, experts in penology, and others. And it can revise the Guidelines accordingly."); *United States v. Booker*, 543 U.S. 220, 264 (2005) ("[T]he Sentencing Commission remains in place, writing Guidelines, collecting information about actual district court sentencing decisions, undertaking research, and revising the Guidelines accordingly.").

33 *Chevron, USA v. Natural Resources Defense Council*, 467 U.S. 837, 844 (1984).

34 75 Fed. Reg. 41927-03 (July 19, 2010).

35 *Id.* at (4).

36 Pub. L. No. 111-148 at §10606(a)(2)(B).

37 *United States v. Olis*, 429 F.3d 540, 545 (5th Cir. 2005); *United States v. Rutkoske*, 506 F.3d 170 (2nd Cir. 2007).

38 543 U.S. 220 (2005).

39 *United States v. Zolp*, 479 F.3d 715, 718 (9th Cir. 2007).

40 William W. Wilkins and John R. Steer, *Relevant Conduct: The Cornerstone of the Federal Sentencing Guidelines*, 41 S.C.L.REV. 495, 495 (1990).

41 USSG §1B1.3.

42 USSG §2B1.1.

43 *United States v. McBride*, 362 F.3d 360, 375 (6th Cir. 2004)("loss is often a proxy for culpability"). *Cf., United States v. Hubel*, 625 F.Supp.2d 845 (D. Neb. 2009) ("The Guidelines' quantity-driven, "market-oriented" approach is *not a proxy for culpability in every case*, nor does it always correlate to the purposes of sentencing under 18 U.S.C. § 3553(a).")(emphasis added).

44 This is particularly prevalent, for example, in global pharmaceutical markets involving arbitrage and the price differentials occasioned by use of the Wholesale Acquisition Cost ("WAC") and Average Wholesale Price ("AWP") set by the manufacturers. *See* Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Drug Markets*, 5 YALE J. HEALTH POL'Y LAW AND ETHICS 193 (2005).

45 *United States Hicks*, 217 F.3d 1038, 1048 (9th Cir. 2000)(collecting cases).

46 *See* USSC, Sourcebook of Federal Sentencing Statistics (2009) at Table 55 (sentencing appeals constituted 57.1 percent of all criminal appeals).

47 *See Kimbrough v. United States*, 552 U.S. 85 (2007)(sentencing court's policy disagreement with [former] crack cocaine guideline permits a *Booker* variance).

48 *United States v. Emmenegger*, 329 F.Supp.2d 416, 427-28 (S.D.N.Y.2004).

49 Benson Weintraub, WHITE COLLAR CRIME: HEALTH CARE FRAUD (WEST) (2009-2010 ed.) at §15:8 (footnote omitted) (text available on Westlaw®)

50 *United States v. Nachamie*, 121 F.Supp.2d 285, 293 (S.D.N.Y. 2000)("The intended loss figure is the capped amount that Medicare typically pays per procedure code, reduced by 20%.").

51 USSG §2B1.1, comment. (n. 3(A)).

52 Pub. L. No. 111-148 at §10606(b)(1)-(2).

53 *Id.* at §10606(a)(3)(A)(i).

54 *Id.* at §10606(a)(2).

55 The Bureau of Justice Statistics (BJS) is a component of the Office of Justice Programs in the U.S. Department of Justice. Its statutory mission is to collect, analyze, publish, and disseminate information on crime, criminal offenders, victims of crime, and the operation of justice systems at all levels of government. BJS was established by Congress in 1979.

56 Benson B. Weintraub & Benedict P. Kuehne, *The Feeney Frenzy: A Case Study in Actions and Reactions in the Politics of Sentencing*, 16 FED. SENTENCING REP. 114 (Dec.2003).

57 *See* Note 8, *supra*.

58 *See e.g.*, J. Kelly Strader, *White Collar Crime and Punishment: Reflections on Michael, Martha, and Milberg Weiss*, 15 GEO. MASON. L. REV. 45, 102 (2007)(stating that "because white collar criminals have extremely low recidivism rates, restraint through incarceration arguably provides only marginal social benefit").

59 *Cf., In Re Zyprexa Products Liability Litigation*, 489 F.Supp.2d 230, 243 (E.D.N.Y. 2007) ("Sentencing increasingly considers restorative needs of the criminal and victim rather than rigid "'just deserts'." *See* Model Penal Code Sentencing, Tent. Draft No. 1 (April 9, 2007) (not yet adopted by ALI), p. 27 ("The goal of proportionality in punishment is ubiquitous....").

COMPENSATED ON-CALL COVERAGE: WHAT'S NEW AND WHAT'S FMV?

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For a variety of reasons, the prevalence of compensated on-call coverage arrangements has been increasing for several years.[1] As the number of such arrangements has increased, the complexity of considerations related to structuring them and determining their fair market value ("FMV") has also increased.

Just a few years ago, the idea of compensating physicians to be on-call was somewhat novel, and structuring compensation arrangements for on-call coverage was akin to venturing into an unknown "wild west." Now, arrangements for compensating physicians for on-call coverage are the subject of multiple advisory opinions from the Office of the Inspector General of the United States Department of Health and Human Services (the "OIG"), as well as of considerable federal rulemaking and commentary. The result is that there is an array of regulatory guidance to consider when structuring and determining the compensation to be paid for on-call coverage, with much of it focused on the importance of assuring that the compensation is FMV[2] for the services provided.

In addition, as greater numbers of physicians have begun to receive compensation for providing on-call coverage, the pool of both anecdotal and statistical data concerning the "going rate" for on-call coverage has increased, providing new bases for claims and opinions regarding what constitutes FMV for on-call services. Hospitals and physicians increasingly share news of on-call pay at the proverbial "water cooler," while the publishers of well-known physician compensation surveys such as Sullivan Cotter & Associates, Inc. have begun publishing annual compilations of on-call compensation rates. However, heightened media coverage and physician attention to the burdens associated with providing on-call coverage, as well as the consequences of failing to do so, have increased not only the *volume* but also *variety* of arrangements under which some form of compensation is provided to physicians who furnish on-call coverage, which makes valid comparisons among arrangements (and, thus valid conclusions about FMV that are based on such comparisons) more difficult.

The purpose of this article is to discuss the new and emerging influences and trends in the prevalence and structures of on-call arrangements, and how these influences and trends affect FMV compensation in such arrangements.

OIG Advisory Opinions

To date, the OIG has issued several Advisory Opinions concerning compensation arrangements for on-call coverage. These Advisory Opinions provide the most topically specific of the available government commentary regarding regulatory concerns related to compensation for on-call coverage. Although OIG Advisory Opinions are specific to the facts and circumstances that are submitted by their requestors, and, therefore, may not be "relied upon" by parties other than the requestors, the OIG Advisory Opinions concerning compensation arrangements for on-call coverage provide useful guideposts for assessing the government's general concerns and areas of regulatory focus with respect to compensation arrangements for on-call coverage.

Advisory Opinion 07-10

In OIG Advisory Opinion 07-10,[3] the OIG examined an on-call coverage arrangement under which a hospital provided *per diem* compensation for physicians providing on-call coverage. The OIG warned that the practice of paying physicians to provide on-call coverage may implicate the Federal Anti-Kickback Statute ("AKS")[4] because the existence of such payment practices creates a risk that physicians may demand such compensation as a condition of doing business at a hospital, and that on-call coverage compensation could be misused by a hospital to entice physicians to join or remain on the hospital's medical staff or otherwise to generate additional business for the hospital. The OIG also warned that an arrangement under which physicians are paid *per diem* compensation for providing on-call coverage will not fit within the AKS's safe harbor[5] for personal services and management contracts if the total payments to the physicians vary each month based on the number of shifts worked, since the monthly variation in compensation means that aggregate compensation is not "set in advance" as required to comply with the requirements of the safe harbor.[6]

Nonetheless, the OIG indicated that *per diem* compensation arrangements may withstand scrutiny under the AKS if the *per diem* compensation is: (i) FMV; (ii) for actual and necessary services; and (iii) without regard for referrals or other business generated by the parties.[7] OIG then set forth specific guidance regarding acceptable and unacceptable methods for establishing the FMV of on-call compensation. Among the unacceptable methods mentioned by OIG (collectively, "Compensation Methods Subject to Scrutiny") are those based on:

- "lost opportunity" when they do not reflect *bona fide* lost income;

- payment structures that compensate physicians when no identifiable services are provided;
- aggregate payments that are disproportionately high compared to the physician's regular medical practice income; and
- payment structures that compensate the on-call physician for professional services for which s/he receives separate reimbursement from insurers or patients, resulting in the physician being paid twice for the same service.

The method that the requesting hospital in Advisory Opinion 07-10 used to establish FMV, and that OIG apparently accepted as valid, was based on:

- the actual *burden* on the physician who is providing call coverage, including whether the on-call coverage is on weekdays or weekends, and the likelihood of a physician having to respond to a call event when on call;
- the likelihood that the physician will have to provide care for an uninsured patient; and
- the severity of illness that physicians of a specialty typically encounter when on call and the degree of inpatient care that they must typically provide to patients admitted from the emergency department.

Advisory Opinion 09-05

In OIG Advisory Opinion 09-05,[8] the OIG examined a different structure of arrangement under which a hospital would *not* provide *per diem* compensation to physicians for providing on-call availability, but instead, would provide reimbursement to on-call physicians for professional services rendered to patients for whom there is no alternative payor source (*i.e.*, uninsured patients). Advisory Opinion 09-05 does not represent any significant change in the government's position with respect to compensation for on-call coverage; rather, it reflects OIG's recognition of an expansion in the types on-call coverage arrangements being implemented in the marketplace.[9]

In issuing this advisory opinion, the OIG reiterated its reasoning why compensation arrangements related to the provision of on-call coverage implicate the AKS, and again stressed that the key inquiry that is undertaken by the OIG to determine whether an on-call coverage arrangement passes muster is whether the compensation provided is consistent with FMV in an arm's-length transaction for actual and necessary items or services. The OIG also restated the four "Compensation Methods Subject to Scrutiny" from Advisory Opinion 07-10 and underscored that these are problematic compensation structures because of their potential to disguise kickback payments. However, the OIG ultimately indicated that although the arrangement at issue in Advisory Opinion 09-05 *could* generate prohibited remuneration and warrant prosecution if the requisite intent to induce or reward referrals were present, the proposed arrangement would not warrant administrative sanctions under the AKS because certain characteristics of the arrangement assured that it presented a low risk of abuse. The foremost of these characteristics was the fact that the hospital was able to certify that the planned payments to the physicians were consistent with FMV based on the following factors:

1. The arrangement would allow payments only for tangible and quantifiable services that physicians render pursuant to their on-call duties (*i.e.*, payment would only be made for actual time spent providing services in the emergency department);
2. The payments were not based on "lost opportunity";
3. Physicians would only receive payments when they could document that no other payment source was available for the professional services rendered, so as to eliminate the possibility of the physician being paid twice for the same service; and
4. The rates to be paid to the physicians were tailored to reflect the value of services actually provided and were determined using a valuation methodology that took into account actual facts and circumstances, such as: patient acuity levels for emergency department patients in the relevant specialty at the relevant hospital; marketplace fees for services across public, private and self-payers; the hospital's payor mix; and the probable physician time commitment associated with the service.

Common Themes in the OIG Advisory Opinions

- OIG Advisory Opinions 07-10 and 09-05 (collectively, the "Advisory Opinions") each address a different type of on-call coverage arrangement, but contain similar themes and guidance from the OIG with respect to the OIG's mode of scrutiny for on-call compensation arrangements. In both advisory opinions, the OIG indicated that:
- The OIG recognizes that there are legitimate reasons why hospitals may find it necessary to provide compensation to physicians in connection with on-call coverage.
- Regardless of whether legitimate reasons exist for compensating physicians for on-call coverage, compensated on-call coverage arrangements implicate the AKS to the extent that they carry the potential to disguise prohibited payments for referrals. Moreover, on-call coverage arrangements will not fit within the AKS safe harbor for personal services and management contracts when total compensation fluctuates based on shifts worked or volume of call events, because aggregate compensation in such cases is not "set in advance."

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- Each arrangement involving compensation for on-call services will be evaluated by the OIG based on the totality of its specific facts and circumstances.
- The OIG's key inquiry when scrutinizing compensation for on-call coverage is whether the compensation is: (i) consistent with FMV in an arm's-length transaction; (ii) for actual and necessary items or services; and (iii) not determined in a manner that takes into account the volume or value or referrals or other business generated between the parties.
- The OIG views any arrangement based on one or more of the four "Compensation Methods Subject to Scrutiny" as problematic and potentially inconsistent with FMV.

Other Regulatory Considerations

The Advisory Opinions provide general guidance to help avoid AKS scrutiny by assuring that arrangements by hospitals to compensate physicians in connection with on-call coverage are carefully structured to fit the facts and circumstances, and are consistent with FMV. In addition to the Advisory Opinions, there is other regulatory guidance that is influencing the structure of on-call arrangements, including:

- Provisions of the Emergency Medical Labor and Treatment Act ("EMTALA")[10] that permit hospitals to allow on-call physicians to schedule elective surgery during the time that they are on call and/or to have simultaneous on-call duties;[11] and
- Changes to EMTALA that are set forth in the 2009 Inpatient Prospective Payment System ("IPPS") Final Rule,[12] and that permit hospitals to participate in a formal community call plan ("CCP") under which they may share on-call physicians, provided that certain conditions are met.[13]

The Trends in On-Call Coverage Arrangements

Together, the Advisory Opinions and changes to EMTALA regulations, coupled with other factors such as heavy news reporting of shortages of on-call physicians and changes in the practice patterns of specialist physicians, have contributed not only to increases in the prevalence of compensated on-call arrangements, but also the complexity and variety of such arrangements.

Subspecialty Coverage Arrangements

Several years ago, compensation for on-call coverage was generally limited to call panels in a few select specialties, such as neurosurgery and trauma surgery. These specialties shared common characteristics: they were the subject of severe physician shortages, and they were associated with very high burdens for those who take call. In the present environment, hospitals routinely provide compensation for on-call services in a variety of different specialties that are associated with a variety of different burdens. The expanding universe of compensated on-call coverage arrangements now encompasses physicians of a large number of specialties and subspecialties.

In light of the Advisory Opinions and other sources of guidance concerning the government's view on compensation for on-call coverage, establishing FMV for on-call coverage in less common specialties and subspecialties requires consideration of a number of factors, including:

- the degree to which there is a legitimate need for on-call coverage at the specialty or subspecialty level (*i.e.*, is it necessary and commercially reasonable to pay a hematologist/oncologist to be on call for the emergency department?);
- the fact that physicians of unique specialties and subspecialties may number only one or two on a medical staff and may be expected to individually provide continuous (*i.e.*, 24 hours per day and 365 days per year) or near continuous on-call coverage;
- the fact that although a subspecialty physician may be the only provider of subspecialty services on a medical staff, s/he may be part of a larger specialty department and required to participate in the general specialty call panel. If this is the case, the subspecialty physician may on certain days be required to provide simultaneous (*i.e.*, concurrent) on-call coverage for patients needing general specialty services as well as for those needing subspecialty services; and
- based on all of the factors above, marketplace data concerning what other physicians are paid for clinical services and/or on-call coverage in the physician's specialty at other hospitals may be of limited value for determining FMV for specialty or subspecialty on-call coverage at the subject hospital, and reliance on such data may result in one or more Compensation Methods Subject to Scrutiny.

On-Call Coverage by Employed Physicians

Uncertainty about the future of private practice medicine is prompting physicians of many specialties to select hospital employment over independent practice. A number of articles are being written on this topic, there has been a significant increase in the number of transactions involving private practice physicians who are seeking hospital employment. As the number of hospital-employed physicians increases, it has become common for call panels to contain one or more physicians who are hospital employees. The existence of hospital employees on a compensated call panel necessitates

careful evaluation of the FMV of on-call compensation, including specific consideration for:

- whether (as well as the extent to which) the employment agreement requires the employee physician to provide on-call coverage as part of employment duties. Often, physician employment agreements require performance of a *minimum* number of on-call days. When this is the case, hospitals must consider whether call panel compensation (*i.e.*, any compensation under a compensated on-call coverage agreement that is separate from the employment agreement) should apply only to days of coverage that are *in excess* of the days of coverage that the physician is required to provide by the terms of employment. This is to assure that the employee physician is not paid twice (*i.e.*, under both the employment agreement and the on-call coverage agreement) for providing the same services, and to ensure that total compensation to the physician does not exceed FMV.
- whether either: (i) the compensation being paid for specialty call coverage in the marketplace (*i.e.*, what other hospitals are apparently paying), and/or (ii) what a hospital pays to non-employee physicians on the same call panel, is a reasonable barometer for FMV of the on-call coverage that is to be provided by the employed physician. Many existing on-call coverage arrangements, and much of the published survey data concerning such arrangements, reflect agreements with "independent contractor physicians" who are responsible for paying their own costs and expenses, including their own malpractice insurance premiums, payroll taxes, retirement contributions and health insurance premiums. The rates that these independent contractor physicians receive for their services reasonably include allowances for the payment of such costs. When physicians are hospital employees, such costs and benefits are typically borne by the hospital as part of the employment package. As such, paying the same *per diem* rates to employee and non-employee physicians on the same call panel may suggest duplicative (and greater than FMV) compensation to the employed physicians.

Arrangements Involving Concurrent Call Coverage for Multiple Hospitals

Local shortages of physicians in certain specialties and/or subspecialties have led some hospitals that share common ownership or corporate affiliation to enter into "concurrent" on-call coverage arrangements – *i.e.*, arrangements for one physician to provide on-call specialty coverage simultaneously for several affiliated hospitals during each coverage day. With the proliferation of "chain" hospitals, concurrent coverage arrangements have become fairly common. With recent changes to the EMTALA regulations, which allow hospitals to meet their on-call obligations through CCPs, there may be additional increases in the prevalence of concurrent on-call coverage arrangements as otherwise unaffiliated hospitals begin to explore the option of sharing on-call physicians.

Although there are a variety of methods being used to compensate physicians for services provided in connection with on-call coverage, the most common method is the payment of a *per diem* rate. Determining FMV for *per diem* compensation in connection with concurrent on-call coverage requires consideration of a number of factors that generally include the following:

- Physicians who provide concurrent on-call coverage for multiple hospitals may bear some additional burden (in comparison to their counterparts who provide on-call coverage at one facility at a time) because of the relatively high frequency and probability of calls during each coverage period when a physician covers multiple hospitals. This increased call burden may reasonably warrant higher *per diem* compensation rates for physicians who provide concurrent on-call coverage for multiple hospitals than for their counterparts who provide on-call coverage at just one facility at a time.
- The degree of "forbearance" for a physician providing a single day of concurrent on-call coverage is less than the degree of forbearance for a physician who provides a total of two days of on-call coverage by covering one hospital each day. One day of concurrent on-call coverage means one day that a physician is restricted from traveling and engaging in social activities that may compromise his or her ability to rapidly respond to a call, regardless of the frequency or probability of call events during that day. On the other hand, single-facility on-call coverage on two separate days means that there are two days that a physician is restricted from traveling and engaging in social activities that may compromise his or her ability to respond to a call, regardless of the frequency or probability of call events during each of those days. Therefore, in order to assure that an on-call physician is not paid twice for the same service, hospitals should consider that the FMV of *per diem* compensation for concurrent call coverage for multiple facilities is *less* than the sum of the FMV *per diem* rates for single-facility coverage at each facility.
- As suggested in the Advisory Opinions, patient payor mix affects the FMV of compensation for on-call services in proportion to the frequency of events to which the on-call physician will have to respond. When the relevant patient population is characterized by a high proportion of poorly

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reimbursing payors (*e.g.*, Medicaid, charity, self-pay[14], etc.) such as Medicaid and uninsured patients, the degree to which on-call physicians will be exposed to these poorly reimbursing payors will depend on the frequency with which they are called to provide patient care services. Therefore, determining the FMV of compensation for a physician who provides concurrent on-call coverage for multiple hospitals reasonably entails consideration of the percentage of poorly reimbursing payors in relation to the frequency of call events at each of the relevant hospitals.

- Overall, the FMV of *per diem* compensation for concurrent on-call coverage is affected by a variety of factors, and should be determined based on careful consideration of the specific facts and circumstances pertaining to the planned arrangement. Anecdotal and survey data regarding what other hospitals pay is not necessarily definitive of FMV for a concurrent call coverage arrangement, and should be carefully scrutinized to determine whether it is an appropriate basis for determining compensation in any specific arrangement.

On-Call Coverage Arrangements Involving "Per Diem Plus" Compensation

As the breadth of specialties for which hospitals provide compensation for on-call services has expanded, the variety and complexity of the on-call compensation structures that are being observed in the marketplace have increased. Although *per diem* compensation for on-call availability remains the most common form of compensation in compensated on-call coverage arrangements, alternative forms of compensation are increasingly being offered either in lieu of or in addition to *per diem* compensation.

Some hospitals are paying "activation fees" in lieu of *per diem* compensation when the frequency of call events in a specialty is very low. Activation fees are one-time, fixed-fee payments that are triggered whenever a physician is required to respond to a call event by presenting to the hospital.

The FMV for activation fees varies based on many of the same factors that influence the FMV for *per diem* payments, such as the likelihood of a physician having to respond to a call event when on call, the likelihood that the on-call physician will have to provide care for an uninsured or otherwise poorly paying patient, and the severity of illness that physicians of a specialty typically encounter when on call. However, for any specialty and hospital, the FMV of an activation fee may be substantially higher than the FMV of the alternative *per diem* rate for on-call availability, since activation fees "concentrate" the physician's compensation for on-call burdens into relatively infrequent, discrete payments, while *per diem* rates spread the compensation over multiple days of on-call availability.

Regardless, the aggregate compensation paid by a hospital under an activation fee model is likely to be *less than* the aggregate compensation paid under a *per diem* compensation model, so long as the frequency of call events that require activation of the on-call physician is very low. For this reason, the selection of activation fee compensation over *per diem* compensation may yield significant cost savings for hospitals in cases where it is necessary to provide compensation to physicians to secure on-call coverage that is required to comply with a regulatory standard, but the frequency with which call events actually occur in the specialty at the hospital is very low.

Other compensation methods that are frequently being used in lieu of or in addition to *per diem* payments include:

1. provision of in-kind compensation, such as coverage of the physician in the hospital's self-insurance plan, payment of the physician's professional liability insurance premiums and/or payment of the physician's dues or premiums to professional organizations and benefit associations; and
2. reimbursement for professional services rendered to uninsured patients while on call.

When one or more of these other forms of compensation are provided in addition to *per diem* compensation, the FMV of each form of compensation that is to be received by the physician should be determined in light of all other forms of compensation that the physician will receive in connection with the requisite on-call coverage.

By way of example:

- If a physician will receive *per diem* compensation for on-call availability, *plus* reimbursement from the hospital for professional services rendered to uninsured patients while on call, a poor hospital payor mix has little bearing on the FMV of the *per diem* rate, even though poor payor mix would have significant bearing if there were no reimbursement for services to uninsured patients, since the risk that the physician will have to render professional services without reimbursement has been removed.
- If a physician will receive *per diem* compensation for on-call availability, *plus* in-kind compensation such as payment of his or her professional liability insurance premiums, then the dollar value of the in-kind compensation must be taken into account when

determining the FMV of the *per diem* compensation. This is necessary to assure that the physician is not paid twice for the same service and that total compensation received by the physician in connection with the on-call coverage does not exceed FMV.

Conclusion

In the current regulatory environment, in which much scrutiny is being given to relationships between healthcare providers in hopes of ferreting out disguised Medicare fraud and abuse, defining FMV and assuring that physician compensation arrangements are consistent with it is important for protecting both hospitals and physicians from costly federal litigation, sanctions, and/or possible exclusion from federal healthcare programs. As the prevalence of hospitals paying for on-call coverage increases, and the breadth of specialties in which hospitals offer compensation to secure on-call coverage expands, the variety and complexity of issues to consider when determining the FMV for compensated call coverage increase. Hospitals and physicians should both be mindful of these issues when negotiating compensation agreements for on-call services.

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Endnotes

1 These reasons include the requirements imposed on hospitals by the Emergency Medical Treatment and Labor Act ("EMTALA"), and a decline in the willingness of physicians to provide emergency department on-call coverage due to negative perceptions about the effect of on-call coverage on physician lifestyle, the number of uninsured patients that a physician will encounter when on call, and the risk of malpractice suits stemming from care provided in emergency settings when the physician has no prior knowledge of the medical status of the patient being treated.

2 As defined in the International Glossary of Business Valuation Terms, "fair market value" means the price, expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arm's length in an open and unrestricted market, when neither is under compulsion to buy or sell and both have reasonable knowledge of the relevant facts. As defined by the Centers for Medicare & Medicaid Services for compliance with Medicare fraud and abuse laws, fair market value means the value in arm's-length transactions, consistent with the general market value, when "general market value" means the compensation that would be paid as a result of *bona fide* bargaining between well-informed parties when neither party is otherwise in a position to generate business for the other party. (See 42 C.F.R. § 411.351)

3 Dated September 20, 2007.

4 42 U.S.C. § 1320-7b. The AKS broadly proscribes any arrangement by which anyone knowingly and willfully offers, pays, solicits or receives any remuneration, including any kickback, bribe or rebate, directly or indirectly, in cash or in kind, to induce the purchase, lease, ordering or arranging for, or recommending the purchase, lease, or ordering, of any good, service or item for which payment may be made in whole or in part by a federal healthcare program such as Medicare.

5 The government has promulgated certain "safe harbors" by setting forth lists of requirements that, if met, will assure that an arrangement will not be subject to government action under the AKS. To benefit from the protection of a safe harbor, an arrangement must comply with all requirements of the safe harbor.

6 The safe harbor for personal services and management contracts is set forth in 42 C.F.R. § 1001.952(d) and includes the requirement that the aggregate compensation to be paid under the contract is set in advance, is consistent with FMV in arm's-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or other business otherwise generated between the parties for which payment may be made in whole or in part under federal healthcare programs.

7 In addition to specifically identifying the three requirements, the OIG noted the existence of guidance set forth in its Supplemental Compliance Program for Hospitals (70 Fed. Reg. 4858, 4866 (Jan. 31, 2005)) that "The general rule of thumb is that any remuneration flowing between hospitals and physicians should be at fair market value for actual and necessary items furnished or services rendered based upon an arm's-length transaction and should not take into account, directly or indirectly, the value or volume of any past or future referrals or other business generated between the parties."

8 Dated May 14, 2009.

9 Each OIG Advisory Opinion is specific to the set of facts and circumstances that are submitted to the OIG by the requestor. The facts and circumstances that are contemplated in Advisory Opinion 09-05, most notably including the structure of the compensation arrangement, are different from those contemplated in 07-10.

10 42 U.S.C. 1395dd. Enacting regulations are codified at 42 CFR 489.24 and 42 CFR 489.20 in subsections (l), (m), (q) and (r). In general terms, EMTALA requires hospitals that participate in Medicare to assure that any patient who comes to the emergency department requesting examination or treatment for a medical condition be provided with an appropriate medical screening examination to determine if an emergency medical condition exists, and if an emergency medical condition is determined to exist with respect to that patient, that the patient be provided with any necessary stabilizing treatment, or else be transferred to another hospital under a protocol that meets certain statutory and regulatory criteria. The EMTALA statute and related regulations specifically require hospitals that participate in Medicare to maintain a list of on-call physicians who are available to provide stabilizing treatment after an initial screening examination has been performed.

11 42 CFR 489.24(j)(2).

12 73 FR 48434 (August 19, 2008).

13 The IPPS FY 2009 Final Rule added a provision to 42 CFR 489.24(j)(2)(iii) to permit hospitals to meet EMTALA obligations by participating in a CCP. The CCP must contain certain elements for a participating hospital to meet EMTALA obligations, such as having a clear delineation of when each of the participating hospitals is responsible for on-call coverage, including time period and specialty/service.

14 A variety of statistical data suggests that self-pay patients typically pay less and take longer to pay than commercial insurers and other third party payors who are viewed as favorable payors.

The Editorial Board of *The Health Lawyer* is pleased to provide this update of presentations made at the Annual Emerging Issues in Healthcare Law Conference, held in Phoenix February 2010 as well as an update to an article published in the October 2010 issue of *The Health Lawyer*. This is an additional benefit provided to Section members to keep you apprised of new developments in healthcare law. We hope that you find these updates useful.

UPDATE TO MEDICARE & MEDICAID CONTRACTORS: INSIDE OUT

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Since the ABA Health Law Section's conference on Emerging Issues in Healthcare Law last February, there have been several recent developments in the Recovery Audit Contractor (RAC) program. Of particular importance is the expansion of the RAC program to Medicare Parts C and D and Medicaid, pursuant to the Patient Protection and Affordable Care Act (PPACA). PPACA mandated the expansion of the RAC program to Medicare Part C (Medicare Advantage plans) and Part D (Prescription Drug coverage) by December 31, 2010. This is also the date by which states were required to have contracted with one or more RACs to perform audits of Medicaid providers. States are expected to implement their RAC programs by April 1, 2011. CMS recently issued a letter indicating that state Medicaid Directors needed to submit a State Plan Amendment ("SPA") to CMS which either attests that the state will establish a Medicaid RAC program by December 31, 2010, or that the state will seek an exemption from the requirements. CMS has indicated that exemptions will only be granted under the most compelling circumstances.

Another important component being discussed about the Medicaid RAC program is the contingency fee payment to the contractors. PPACA requires that Medicaid RACs only be paid on a contingent basis from amounts recovered or amounts specified by the state for identifying underpayments. Currently, the highest contingency fee rate for the Medicare RACs is 12.5 percent. CMS will not dictate the contingency fee rates, but a maximum rate for the Medicaid RACs will be set by CMS in the Federal Register no later than December 31, 2013. This rate will apply to any Medicaid RAC contracts with a period of performance beginning on or after July 1, 2014. These contingency fee rates should be reasonable and take into account factors such as effort on the part of the RAC, number of participants in the state's Medicaid program and the number of Medicaid RACs engaged by the state. Although CMS has listed factors to be considered, states are given flexibility in choosing the manner in which they implement the Medicaid RAC program.

States are also required to have an adequate appeals process in order to handle appeals from adverse audit decisions made by the Medicaid RACs. So long as a state's existing administrative appeals process is able to accommodate Medicaid RAC appeals, CMS is not requiring states to adopt a new administrative review process.

The Medicare RAC program has also seen changes in recent months with the addition of medical necessity reviews in all four RAC regions. The RACs have been increasing the number of procedures and issues subject to medical necessity reviews. During the RAC demonstration project around 50 percent of the identified overpayments were related to medical necessity issues. Medical necessity reviews will continue to be a highly targeted area by the RACs and as such providers need to be proactive in their approach to compliance.

In connection with the Medicaid Integrity Program ("MIP"), CMS recently implemented policies applicable to Audit Medicaid Integrity Contractors ("Audit MICs") addressing the audit look-back period and timeframes for responding to documentation requests. Previously, Audit MICs were instructed to follow the state's look back policy when conducting an audit. CMS recently established a five year audit look-back period for Awudit MICs, which took effect October 1, 2010. The issuance of the Notification Letter at the start of a MIC audit is the trigger for the five year timeframe. Therefore, if a provider receives a Notification Letter in November 2010, the look-back period for the records requested and claims under review may date back to November 2005.

CMS also approved a policy expanding the timeframe for providers to respond to record requests by an Audit MIC. Originally, providers had 10 business days to submit the required documentation. CMS revised this timeframe to allow 30 business days to respond. Audit MICs are also authorized to grant a 15 business day extension at a provider's request.

Providers and their counsel can stay apprised of updates on the various contractors in the audit landscape by visiting the CMS website at http://www.cms.gov/.

HEALTH PLANS 2011: REGULATORY UPDATE

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Since our October 2010 article,[1] regulators have made two significant changes to healthcare reform requirements for 2011: delaying W-2 reporting for one year and allowing plans to change insurance companies without losing grandfathered status.

W-2 Reporting Delayed

While the Patient Protection and Affordable Care Act ("PPACA")[2] required employers to report the cost of employer-provided health coverage on each employee's W-2 form beginning with W-2 forms issued for the 2011 taxable year,[3] the Internal Revenue Service has now indicated that such reporting is optional until the 2012 taxable year.[4]

Grandfathered Plans and Insurance Companies

The initial set of interim final regulations regarding "grandfathered" status under PPACA indicated that a group health plan would lose its grandfathered status if it changed insurance companies or entered into a new policy, certificate or contract of insurance.[5] However, the regulators recently reversed course and announced that a group health plan would not lose its grandfathered status if it changed insurance companies, policies, certificates or contracts of insurance, provided that the plan did not make any of the other changes listed in the interim final regulations that would cause a plan to lose its grandfathered status.[6]

Future Updates

Additional regulations and guidance on PPACA's impact on health plans are expected throughout 2011, and we expect to provide information on these 2011 developments in *The Health Lawyer* in late 2011.

Endnotes

1 Howard Bye and Erin Lennon, *Health Plans 2011: Healthcare Reform Begins*, *The Health Lawyer*, October 2010, at 47.

2 Pub. L. No. 111-148, 124 Stat. 119.

3 PPACA § 9002.

4 I.R.S. Notice 2010-69, 2010-44 I.R.B. 576.

5 75 Fed. Reg. 34,538, 34,558 (June 17, 2010) (Treas. Reg. § 54.9815-1251T(a)(1)(ii)) (parallel provisions at 75 Fed. Reg. at 34,562 (29 C.F.R. § 2590.715-1251(a)(1)(ii)(DOL/EBSA)) and 75 Fed. Reg. at 34,566 (45 C.F.R. § 147.140(a)(1)(ii)(HHS))).

6 75 Fed. Reg. 70,114, 70,120 (November 17, 2010) (Treas. Reg. § 54.9815-1251T(a)(1)(ii)) (parallel provisions at 75 Fed. Reg. at 70,121 (29 C.F.R. 2590.715-1251(a)(1)(ii)(DOL/EBSA)) and 75 Fed. Reg. 70,121 (45 C.F.R. § 147.140(a)(1)(ii)(HHS))).

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Volume 23, Number 3
February 2011

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For more information on any of these programs, call the Section at 312/988-5532 or visit the Section web site at www.abanet.org/health

January 26, 2011
Recent Program Integrity Initiatives in Light of PPACA: MICs, MACs, RACs, and ZPICs
(Teleconference)

February 15, 2011
Litigating the Qui Tam Case: Three Dimensional Chess
(Teleconference)

February 17, 2011
Stark Law Basics
(Teleconference)

February 23-26, 2011
12th Annual Conference on Emerging Issues in Healthcare Law
The Ritz-Carlton, New Orleans
New Orleans, LA

March 9, 2011
Elder Law: What Attorneys Representing Elderly Clients Need to Know
(Teleconference)

March 17, 2011
Fundamentals of Tax-Exempt Healthcare Organizations
(Teleconference)

April 21, 2011
Anti-Kickback Law Basics
(Teleconference)

May 11-13, 2011
The 21st Annual National Institute on Health Care Fraud
Eden Roc Renaissance Miami Beach
Miami Beach, FL

May 18-20, 2011
ERISA Basics
Millennium Knickerbocker Hotel Chicago
Chicago, IL

May 19, 2011
Reimbursement & False Claims Act Fundamentals
(Teleconference)

June 16, 2011
Physician-Legal Issues Conference
Chicago, IL

June 16, 2011
Fundamentals of Medical Staff & Peer Review Issues
(Teleconference)

July 21, 2011
Healthcare Antitrust Fundamentals
(Teleconference)

August 18, 2011
FDA Public Health Clinical Trials Fundamentals
(Teleconference)

October 17-18, 2011
9th Annual Washington Healthcare Summit
Ritz-Carlton, Pentagon City
Arlington, VA

February 22-24, 2012
13th Annual Conference on Emerging Issues in Healthcare Law
Hilton San Diego Bayfront
San Diego, CA