
UBHLA
UNIVERSITY OF BALTIMORE HEALTH LAW ASSOCIATION

UBHLA HOLDS CAREER PANEL

The newly formed University of Baltimore Health Law Association kicked off the new school year with its first large event on September 2, 2008. Four distinguished members of the health care legal community came to UB to discuss their distinct areas of practice, and the different career paths a health law student can take.

Meg Garrett, Esq, spoke candidly about her journey to becoming Senior Counsel for Johns Hopkins Health Care System. Ms. Garrett began her service in health care as a nurse, and eventually made the choice to switch careers, head to law school, and juggle the demands of motherhood at the same time. Ms. Garrett deals with a multitude of issues impacting health care in both academic medical center and not-for-profit hospital settings. She spends time handling risk management, patient care, and medical staff legal issues. Ms. Garrett noted that having a clinical background in health care is beneficial to students aspiring to practice health law, but it is not a necessity.

Also in attendance was Lisa Ohrin, Esq., the Deputy Director of the Division of Technical Payment Policy within the Centers for Medicare and Medicaid Services ("CMS"). Ms. Ohrin spends the majority of her time developing and writing fraud and abuse policy and regulations related to the physician self-referral law and handles a variety of statutory and regulatory Medicare payment issues. Ms Ohrin also teaches courses at the UB School of Law and the UMB School of Law. Ms. Ohrin's knowledge and expertise is built upon 14 years of a wide variety of health law practice areas. Ms. Ohrin spent time working with an integrated hospital system, a national long term care provider, a private law firm, the University of Maryland School of Law (as the director of the school's Health Law program), and a Harvard teaching hospital. Because there are so many different opportunities in health law, Ms. Ohrin pointed out it is easy to make a switch to a different practice area, and she has been happy to take advantage of the variety of knowledge and skills she has gained.

To provide perspective on yet another practice area of health law, Jeffrey Pecore, Esq., President of the MSBA Health Law Section and a partner in private practice with Pecore & Doherty, spoke with students regarding the endless possibilities afforded to those interested in the field. Mr. Pecore urged students to attend the MSBA Health Law Section meetings to stay abreast of the issues in Health Law today, and to get to know other local lawyers working in the field. He noted that he followed the "traditional" practice path of joining a large firm after graduating from law school, switching to another large firm, and later opening his own private practice. He expressed that in his days as a student, "health care law" as a field was not yet fully defined. He therefore gained his knowledge of the unique issues pertaining to the health care industry simply by the experience of working with one health care client after another. Soon enough, Mr. Pecore was exclusively working with such clients, thus, as he quipped, "sort of falling into health law."

Finally, Richard Bardos, Esq spoke about his experiences as a prosecutor of Medicaid fraud and abuse by health care providers. Mr. Bardos, Assistant Attorney General, is the, Deputy Director for the Medicaid Fraud Control Unit for Maryland's Office of the Attorney General. Mr. Bardos began his legal career immersed in litigation and criminal law as a Maryland State Attorney. He too quipped that he "fell into health law": as time passed, he was assigned to more and more cases involving health care parties, and he eventually settled there. Mr. Bardos was open about his career path and reassured students that not knowing exactly what one wants to do is not an uncommon thing, and can often allow a young attorney the flexibility to "fall into" a practice area that he or she loves.

A cocktail reception followed the panel discussion in the Student Center gallery, where students, faculty, and members of the health law community mingled and enjoyed wine, beer, and hors d'oeuvres. Hopefully the success of this semester's career panel and the work of the UB Health Law Association is just the first step in strengthening and building the presence of this important field in our law school.

- Kathleen Haggerty

PET TURTLES: A PUBLIC HEALTH RISK

While a pet turtle may seem cute and harmless, small turtles may actually harbor harmful bacteria. The FDA, in 1975, banned the sale of baby turtles with a carapace length of less than 4 inches. (*21CFR 1240.62)*. The FDA instituted the ban when 250,000 infants and small children became infected with a form of *Salmonella* associated with small turtles. *Salmonella* can be found on the shell and outer surface of the baby turtles. A study conducted shortly after the ban estimated that the prohibition prevented 100,000 *Salmonella* infections in children each year since its implementation. (Cohen, ML JAMA, 1980; 243; 1247-9). In spite of the ban, small turtles are still sold in pet stores. The Centers for Disease Control and Prevention estimates that a significant increase in the number of turtle associated *Salmonella* cases has occurred within the past few years.

While public health officials continue to support the ban, turtle farmers argue that small turtles carry no greater public health risk than other reptiles. Additionally, turtle farmers argue that a new procedure developed by researchers at Louisiana State University minimizes, and possibly eliminates, *Salmonella* from newborn turtles. (NPR, May 17,2007). Utilizing a novel cleaning machine, the eggs are sanitized with a bleach water solution. Researchers contend that the cleansing process minimizes the *Salmonella* infection rate in small turtles to less than 1 percent.

Turtle farmers successfully lobbied members of Congress to introduce legislation concerning the prohibition. In February 2007, Rep. Alexander introduced the *Domestic Pet Turtle Market Access Act of 2007*. The bill, H.R. 924, would prohibit the FDA from restricting the sale of small turtles that met certain requirements. Specifically, small turtles treated utilizing the cleansing process could be sold as pets. In addition, a turtle farmer or other retailer could sell small turtles as pets so long as information concerning the risk of *Salmonella* infection from turtle exposure was disclosed to buyers. After introduction, this bill was referred to the House subcommittee on health. Thus far, the farmer's attempts to lift the prohibition on the small turtles have been unsuccessful.

-Karen Weathersbee

Analyzing Remuneration That Does Not Fall Under the Non-monetary Compensation Exception of the Physician Self-Referral Regulations

When it comes to physician self-referral regulations, one thing remains certain and consistent over time: the rules are complex and their interpretation is not an easy task. This is certainly not to say that the rules are arbitrary: they are undoubtedly grounded in public policy and seek to counter program abuse. Nor is it to say the complexity of the rules is arbitrary. The rules are complex because the universe of abusive arrangements is complex. Compensation and ownership/investment arrangements in the health care industry have grown so sophisticated that it takes a voluminous set of regulations in order to sufficiently counter fraud and abuse.

Given the complexity, the Centers for Medicare and Medicaid Services—the agency responsible for developing Medicare fraud and abuse policies—should be applauded for their earnest efforts to provide guidance to the industry. One look through their regulations and one immediately finds detailed explanations of what is meant by certain provisions and why CMS agrees or disagrees with certain comments.

Despite their concerted efforts of clarification, many provisions remain unclear: to wit, remuneration that does not fall under the non-monetary compensation exception found in 42 C.F.R. § 411.357(k). In an industry that is constantly advancing and requires a great deal of continuing education in order for practitioners to stay abreast of advancements, the question often arises whether free training or education creates a compensation arrangement, thus implicating a further physician self-referral analysis. This article analyzes such scenarios and explores the position that CMS has taken on this issue. Unfortunately, CMS has not explicitly set forth factors, which indicate remuneration or non-remuneration. Rather, they have mentioned three vague criteria, which practitioners must balance against each other.

The Law

Under section 1877 of the Social Security Act (42 U.S.C. §1395nn), a physician may not refer a Medicare patient for certain designated health services ("DHS") to an entity with which the physician (or an immediate family member of the physician) has a financial relationship, unless an exception applies. Section 1877 also prohibits the entity furnishing the DHS from submitting claims to Medicare, the beneficiary, or any other entity for Medicare DHS that are furnished as a result of a prohibited referral.

The umbrella of "financial relationships" covers ownership/investment interests and compensation arrangements between physicians and DHS entities. In section 1877(h)(1)(A) of the Act, a compensation arrangement is defined as "any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity other than an arrangement involving only remuneration described in subparagraph (C)." Remuneration is defined in Section 1877(h)(1)(C) of the Act as, "any payment, discount, forgiveness of debt, or other benefit made directly or indirectly, overtly or covertly, in cash or in kind." The Act further identifies certain types of remuneration, which, if provided, would not create a compensation arrangement subject to the physician self-referral prohibition. Such remuneration includes forgiveness of amounts owed for inaccurate or mistakenly performed tests or procedures and correction of minor billing errors; the provision of items, devices, or supplies that are used solely to collect, transport, process, or store specimens for the entity providing the item, device, or supply; and payments made by an insurer to a physician to satisfy a claim if the health services are not furnished, and the payment meets criteria set forth in Section 1877(h)(1)(c)(iii). *See, also*, the definition of "remuneration" at 42 C.F.R. § 411.351. Finally, the regulations list, among a whole host of exceptions, a compensation arrangement that does not constitute a financial arrangement: non-monetary compensation that costs less than $300 per year and satisfies certain requirements.

Although the Act and its companion regulations in 42 C.F.R. § 411.350 through 411.357 identify remuneration which is not "compensation," there is nothing in the statutory or regulatory text (i.e. not including explanatory text) which identifies arrangements which are not "remuneration." However, CMS has lightly touched on this issue in the explanatory text accompanying its Phase II, Interim Final Rule (*see* 69 Fed. Reg. 16,114 (Mar. 26, 2004)) and its in public dialogue with the industry, suggesting that there may be certain arrangements which CMS would not consider to be "remuneration" for purposes of the physician self-referral prohibition. In the explanatory text of the regulations, CMS discusses benefits provided to physicians that cannot fit into

certain exceptions: the non-monetary compensation exception, because the benefits are worth more than $300; the medical staff incidental benefits exception, because the benefits are worth more than $25 per occurrence; and the fair market value exception, because the benefits do not involve a written contract. CMS specifically addresses one such benefit, free CME, and establishes two factors by which to measure the existence or nonexistence of remuneration. "Free CME, could constitute remuneration to the physician, depending on the *content of the program* and the *physician's obligation to acquire CME credits*." (69 Fed. Reg. 16,114 (Mar. 26, 2004)).

CMS has provided one more measure of remuneration in a letter to the American Medical Association, exclaiming that "[they] do not consider [a certain arrangement] to be [remuneration] if it is *primarily for the benefit of the hospital's patients*." (*available at* www.ama-assn.org/ama1/pub/upload/mm/455/cmsletter.pdf). Additionally, CMS noted that "[an arrangement] that is not primarily for the benefit of the hospital's patients is considered [remuneration]."

As such, practitioners are provided with three basic guidelines by which to ascertain whether certain arrangements are remuneration, thus requiring a further physician self-referral analysis. However, the problem remains that such guidelines have been drawn very vaguely and only with respect to a few set of facts as presented by the American Medical Association and other commenters. CMS has not elaborated upon its position by delineating characteristics of the content of the program or the physicians' obligation to acquire CME credits which would indicate the presence of remuneration. Furthermore, they have not defined "primarily for the benefit" or articulated factors which CMS would consider in determining whether something is "primarily" for the benefit of the patients. As it stands, given the vague parameters, practitioners can only glean by comparison an idea of whether their health care clients' arrangement creates a compensation relationship.

Certainly, practitioners may seek guidance from CMS, either through an informal inquiry or through a request for an advisory opinion; and this they would be well advised to do. But given the fact that there does not exist a "bright line rule," practitioners will have to engage in a balancing test of sorts in persuading CMS that an arrangement is primarily for the benefit of the patients. Unfortunately, as we know from constitutional and antitrust cases, which routinely (or notoriously) invoke balancing tests, anything goes with such analyses: decisions typically depend more on the leanings of the reader rather than the soundness of the argument.

Letter to the American Medical Association

With that said, a deeper examination of the dialogue between CMS and the American Medical Association may provide helpful insight into such balancing test. The American Medical Association wrote an informal inquiry as to whether free continuing medical education ("CME") provided by hospitals to their physicians on-site constituted a compensation arrangement. CMS replied that on-site CME would not be considered remuneration if it is primarily for the benefit of the hospital's patients. Deconstructing the scenario of on-site CME, we find a few notable features regarding the program content, obligation to earn CME credits, and patient benefit. The benefit conferred by the hospital—continuing medical education—enables physicians to stay abreast of medical advancements so that they can provide quality patient care; it provides general information regarding medical advancements; and it is typically sponsored by professional associations (as opposed to for-profit product companies). Additionally, the CME there was to be provided onsite (as opposed to at a remote location such as a beta site training facility): CME sessions have historically been provided on-site at no charge. Finally, physicians are required to earn CME credit in order to practice medicine. The content of the program, the obligation to earn CME credits, and the benefit to the patient there could certainly be factors that would weigh in favor of non-remuneration.

An opposite set of features may weigh in favor of remuneration: for example, where the benefit is training on how to use a specific product; where the training occurs off-site, involves multiple all-day sessions; and where sessions are conducted and sponsored by for-profit product companies.

Although the content of the program and the obligation to obtain CME is important and relevant, the degree of benefit to the patients is paramount to the analysis. In CMS's letter, they posited that some on-site CME would be considered remuneration:

that which is not primarily for the benefit of the hospital's patients. In other words, despite an obligation to earn CME credits or program content, which would weigh in favor of non-remuneration, if the CME is not primarily for the benefit of the patients, then it constitutes remuneration.

As mentioned earlier, CMS has not defined "primarily." The term "primarily" suggests a more-likely-than-not standard, again invoking the balancing test. Benefits attained for the physicians that are less than 50% would tip the scales in favor of non-remuneration. The term "primarily" also suggests that both the hospitals and the patients may stand to benefit from an arrangement simultaneously. Under the "primarily for the benefit" standard, the physicians and hospital may benefit a great deal. Training sessions likely improve the reputation of the facility in the community; they further the physician's goals of becoming qualified to use the technologies in which the facilities have invested; and they even may induce sales for the product vendors and manufacturers. This may entirely be the case, yet the benefits to the patients can still outweigh the benefits to the physicians and hospitals. The standard does not demand *de minimus* or incidental benefit on the part of the physician; rather it requires the patients to benefit, at least, just slightly more.

Conclusion

As such, until CMS is presented with the occasion to establish clear guidelines, practitioners should analyze remuneration in light of CMS's brief discussion in the Phase II, Interim Final Rule, as well as their position set forth in their letter to the American Medical Association. By utilizing a balancing test, one should consider the content of the program, the obligation to earn CME, and the benefits of the patients measured against those of the physicians and hospitals.

-Anna Jacobs

ABOUT UBHLA

UBHLA is a student-run organization dedicated to the advancement of health care law at UB and the professional development of students in all areas of health care law.

UBHLA was established in 2008 by a small group of law students who saw an unexplored opportunity to enrich the University of Baltimore law school with a health law organization. The ultimate goal of UBHLA is to serve as a health care law resource for students, the university, and the legal community. We seek to develop a dynamic bank of health law resources for students; to promote the development of a health law curriculum at the university; and to provide the legal community with a generation of committed health law practitioners. The organization is dedicated to keeping members aware of current issues and opportunities related to health law.

With the enthusiastic support of the UB faculty, administration, and student body, we hope to cultivate interest in health care law through engaging lectures, career panels, community events, and an electronic newsletter. We invite you to become involved today to become a part of an exciting organization and connect with a career in health law. Feel free to explore our website for more information about the group at www.ubalt.edu/healthlaw.

Newsletter Submissions

If you are interested in submitting an article or information about an upcoming meeting for publication in the newsletter, please e-mail your information to kweathersbee@yahoo.com

Calendar

November 4th, 2008

Maryland State Bar Health Law Section; 5:30 PM UMB School of Law

November 9th-11th, 2008

Fundamentals of Health Law, American Health Lawyers Association, Chicago, IL

November 17th-18th, 2008

ABA's Washington Healthcare Summit, Ritz Carlton, Arlington, VA

Contributors

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Karen serves as Secretary of UBHLA. Karen is a third year law student. Her essay on quarantine was selected as the winner of the ABA's 2008 Gellhorn-Sargentich Law Student Essay Competition.

KATIE HAGGERTY

Katie is a second year law student. Katie serves as Chair of the UBHLA Film Committee. Katie received her undergraduate degree from Boston University.