Compensation Valuation in an Age of Transparency

By Ann S. Brandt, HealthCare Appraisers Inc.

The life sciences industry is dealing with a series of global challenges related to increasing competition, escalating costs, and expanding regulatory requirements. Regulations, focusing on requirements for transparent interactions between life sciences organizations (LSOs) and health care providers (HCPs), continue to evolve as they are implemented by governments and industry associations throughout the world. In the United States, the Physician Payments Sunshine Act[1] requires manufacturers of drugs, medical devices, and biologicals that participate in U.S. federal health care programs to report certain payments and items of value given to physicians and teaching hospitals. The European Federation of Pharmaceutical Industries and Associations (EFPIA) has issued a common transparent framework for pharmaceutical companies to report transfers of value to HCPs throughout the European Union (EU), while the MedTech Europe[2] Code of Ethics, which applies to its medical device and medical technology membership, clarifies and distinguishes appropriate activity between HCPs and member companies. Furthermore, anti-corruption laws (e.g., The Foreign Corrupt Practices Act (FCPA)[3] in the United States and the U.K. Bribery Act[4]), which provide criminal penalties for violations, are now more easily enforced with the implementation of the new transparency requirements.

Relationships Between Health Care Professionals and Life Sciences Companies

Because of the rather symbiotic relationship between physicians, LSOs, and the products these companies develop,[5] global scrutiny of relationships and transactions between HCPs and LSOs has increased. Yet, for many valid reasons, LSOs routinely engage HCPs to provide training, speaking, product testing, research, and other services related to their products.

Experienced HCPs offer a level of expertise and understanding that cannot be duplicated by any other group of professionals. Their clinical knowledge and experience is often critical to the development, commercialization, and effective use of LSO products and services. Furthermore, research indicates that clinicians pay more attention to what other clinicians say about a drug, device, or treatment than to any other source of information. LSOs engage the services of experienced HCPs to deliver informational programs to their counterparts in the community.

In recognition of the potential for conflicts of interest in these types of arrangements, regulators throughout the world are implementing laws to prevent inappropriate financial relationships between HCPs and LSOs. New regulations are emerging that focus on various types of *service* arrangements to determine whether they may be linked to prescribing practices or to usage patterns involving the LSOs products. Of particular significance is whether the fees paid to HCPs are based on the services rendered (i.e., speaking, consulting, training, conducting research, etc.), or are paid as an inducement to prescribe the LSO's products and/or services. As a result, global transparency laws seek to expose *all* payments made to HCPs by LSOs, or their third-party intermediaries, in an effort to identify those which may directly or indirectly relate to payment for referrals. For obvious reasons, this task is somewhat onerous, one which is compounded by the massive volume of data being generated as a result of the new transparency laws. In the near term, it appears that the focus of most investigations may be limited to payments that appear to be outside of the norm (i.e., outliers). Notwithstanding, data mining algorithms are becoming more sophisticated, which could result in a meaningful increase in prosecutions for violation of country-specific and/or global anti-corruption laws.

U.S. Regulatory Environment

Physician Payments Sunshine Act (Sunshine Act)

The Sunshine Act, which was included as Section 6002 of the Patient Protection and Affordable Care Act of 2010 (ACA),[6] requires manufacturers of drugs, biological products, medical devices, and medical supplies to track and report to the U.S. Department of Health and Human Services (HHS) certain payments and other transfers of value[7] that they provide to physicians[8] and teaching hospitals. By requiring life sciences companies to record and report these payments or transfers of value, the Centers for Medicare & Medicaid Services (CMS) is striving to promote transparency and reduce the potential for conflicts of interest that HCPs or teaching hospitals might face as a result of their relationships with manufacturers.

Even though the ACA was signed into law in 2010, the final rules pertaining to the Sunshine Act were not finalized until February 2013, at which time CMS announced that companies would be required to begin data capture on August 1, 2013, and submit their first federal reports by March 31, 2014. After three reporting cycles, it is clear that the Sunshine Act is having significant financial and operational impact. Multi-functional aggregate spend systems have been implemented at many of the global companies that dominate the sector. Similarly, small and mid-sized LSOs are examining the compensation arrangements they have with speakers, consultants, educators, and advisory board members. Compliance departments throughout the industry continue to examine potential points of failure while they develop policies and procedures for standardizing their relationships with HCPs. Furthermore, there appears to be a growing consensus among LSOs, that in this age of increasing transparency, the need for enterprise-wide fair market value (FMV)-compliant compensation plans are of paramount importance.

[G]lobal transparency laws seek to expose all payments made to HCPs by LSOs, or their third-party intermediaries, in an effort to identify those which may directly or indirectly relate to payment for referrals.

State Laws

The number of states that have implemented their own disclosure requirements independent of those required by the federal government continues to grow. These states include California,[9] Connecticut,[10] the District of Columbia,[11] Louisiana,[12] Maine,[13] Massachusetts,[14] Minnesota,[15] Nevada,[16] Vermont,[17] and West Virginia.[18] Although the federal Sunshine Act preempts corresponding state law requirements, the future of these generally broader state requirements remains uncertain.

Global Regulatory Environment

In addition to an increasing number of country-specific transparency laws (e.g., France, Slovakia, Australia, Columbia, etc.) and organizational codes of ethics (Eucomed, PhRMA, IFPMA, EFPIA, etc.), several countries, including the United States, have developed anti-corruption laws that include significant penalties for non-compliance, even when the violations occur outside of the country's geographic boundaries (e.g., the "U.K. Bribery Act, the U.S FCPA[19]). These laws are particularly important for LSOs, because in many countries, most health care professionals are government employees. Thus, nearly every interaction with health care professionals may potentially expose a company to criminal and/or civil liability under applicable anti-corruption laws.

Foreign Corrupt Practices Act

Enacted as a result of investigations by the Securities and Exchange Commission (SEC) in the 1970s, the FCPA prohibits U.S. companies from directly or indirectly making payments to

The number of states that have implemented their own disclosure requirements independent of those required by the federal government continues to grow.

foreign officials for the purpose of getting or keeping business. The FCPA has dual enforcers—the Department of Justice (DOJ) and the SEC—both of which have been aggressively enforcing the FCPA against companies and individuals.

The 1998 enactment of certain amendments to the FCPA expanded the anti-bribery provisions to foreign companies and persons making payments within the United States to obtain or retain business.

U.K. Bribery Act (Bribery Act)

The Bribery Act, which went into effect in July 2011, imposes criminal liability for a variety of bribery offenses. The unique features of the Bribery Act include that it (1) applies to all bribery, whether in the public or private sector; (2) applies to both the giving and receiving of bribes; and (3) creates a new corporate offense if a corporation fails to prevent bribery.[20] Enforcement of the Bribery Act is the responsibility of the Serious Fraud Office (SFO).

Arguably, one of the most significant elements of the Bribery Act involves the fact that simply having a presence in the United Kingdom, whether a subsidiary or just an office, will create jurisdiction. The Bribery Act applies to both U.K. companies and foreign companies with operations in the United Kingdom, *even if offenses take place in a third country and are unrelated to U.K. operations*.

It is beyond the scope of this article to describe the details of every applicable law and regulation. Notwithstanding, it is important to understand that the regulatory environment is becoming increasingly complex and that expanding transparency requirements may significantly impact the opportunities for prosecution related to bribery offenses throughout the world.

Valuing HCP Compensation Arrangements

When assessing the FMV of compensation within the context of the life sciences industry, it should be noted that compensation earned by a health care professional in her specialty practice may not be directly comparable to compensation associated with providing speaking, consulting, training, or product development services to a LSO. In fact, for compliance purposes, U.S. regulators have indicated that the FMV of compensation for clinical services may differ from the FMV of compensation for administrative services. The salient point appears to be that depending on the facts and circumstances of the arrangement, the compensatory *value* of clinical work may be higher or lower than that of nonclinical work.

Classifying HCPs Based on Experience and Expertise

Generally, HCPs are engaged by LSOs because they possess certain specialized expertise and experience that cannot be duplicated by the LSO's own employees (e.g., expertise and experience in treating patients with a specific disease state). These HCPs may include a broad range of professionals from the local-level practitioner to the internationally acclaimed "thought leader" who has published hundreds of peer-reviewed journal articles, held leadership positions in numerous professional societies, and spoken at conferences throughout the world. To accurately and reliably assign HCPs into relatively homogeneous "Tiers" of similarly qualified professionals, the unique qualifications of each HCP must be evaluated in terms of the key criteria or "Attributes" of the role for which the HCP is being engaged to perform. For example, the specific skills and experience required of a medical researcher engaged by an LSO to perform bench research related to small molecules are typically very different from those required of an orthopedic surgeon who is engaged to provide clinical training related to the use of a navigation system for total knee replacements. The quantification of relevant differences in skills, experience, and role requirements is critical to the development of an effective and reliable methodology to classify or stratify HCPs into appropriate Tiers for the purpose of determining the FMV of compensation.

Developing Stratification Models

The Attributes used to stratify HCPs can vary widely and depend on the LSO and/or the group or department engaging the HCP. Furthermore, LSOs may find it necessary to develop several different "Stratification Models" each based on different

combinations of Attributes. Another element to consider in the development of a Stratification Model involves the determination of the appropriate number of Tiers to incorporate into its design. Within the United States, the most common approach involves the use of a four-Tier Stratification Model to classify HCPs based on experience and expertise, (a) international level; (b) national level; (c) regional level; and (d) local level. Whereas, in other countries a two or three-Tiered Stratification Model may suffice. Notwithstanding, the key requirement in developing a valid and reliable Stratification Model is that selected Attributes must be *operationally defined and objectively measured.*

Global Differences in the Availability of HCP Information

As mentioned previously, evolving global transparency laws have resulted in the requirement for FMV-compliant compensation arrangements for HCPs throughout the world. However, the availability of information related to the expertise and experience of individual HCPs varies rather dramatically between countries. For example, the primary source of information regarding the experience and expertise of U.S.-based HCPs generally is a detailed curriculum vitae (CV). Whereas, in the United Kingdom, a CV generally is quite short (usually a maximum of two sides of a standard sheet of paper), and therefore, contains only a summary of the HCP's employment history, qualifications, education, and training. In other parts of the world (e.g., China), a CV may only be a short biographical paragraph.

Unfortunately, the information required to accurately stratify HCPs into appropriate Tiers (e.g., number of publications in peer-reviewed journals, number of leadership positions in professional organizations or societies, number of invited speaking engagements on a national level, etc.), may not be available in summarized CVs or short biographical paragraphs. This is especially problematic in less developed countries where specialized medical training may be quite different than it is in other parts of the world. One strategy to overcome the lack of required information about the expertise and experience of each HCP, when determining appropriate compensation, is to include the items used in the Stratification Model as part of the "on-boarding" process. In this case, the HCP can provide the appropriate answer for each item/Attribute, and then sign the document; thereby, *attesting* to the answers, while facilitating the stratification process.

Determining the FMV of Compensation

Once a valid and reliable Stratification Model is developed and its underlying analytics and item weights are established, FMV compensation ranges are then determined.

In utilizing the market approach to value physician service arrangements in the life sciences industry, it must be noted that specific market information is not always readily accessible. For example, few sources of data are available anywhere in the world for specialized nonclinical services, such as consulting, research, or speaking. By contrast, multiple sources of published data exist in the United States relating to physician compensation for clinical services (e.g., the Medical Group Management Association (MGMA), American Medical Group Association (AMGA), Sullivan, Cotter and Associates Inc. (SCA), etc.). Furthermore, physician compensation and payer systems vary widely from country to country; therefore, it is important to be aware of the specific issues and limitations that may be encountered when considering market information.

When assessing the FMV of compensation within the context of the life sciences industry, it should be noted that compensation earned by a health care professional in his or her specialty practice may not be directly comparable to compensation associated with providing speaking, consulting, training, or product development services to a LSO.

The use of general surveys identifying payments to HCPs *by other LSOs* should be critically evaluated since there is usually no reason to believe that these payments ever met the FMV standard. In fact, it is highly likely that HCP compensation ranges obtained by surveying other LSOs, may represent "tainted" values that have been influenced by referral relationships. As such, there may be significant bias in those values such that they are not reliable in establishing FMV of the agreements.

Conclusion

Changes in the regulatory landscape within the United States and throughout the world are having a profound impact in the way LSOs are doing business. Anti-bribery and transparency laws are having a significant effect on compensation arrangements between LSOs and HCPs. Ensuring that HCP compensation arrangements are within FMV is an effective and easily implemented way to facilitate compliance. However, to be effective, the methodology used to determine the FMV of HCP compensation arrangements must be objective and applied consistently. The valuation of HCP compensation arrangements generally requires knowledge of (1) the type, level, and extent of the services to be provided and (2) the skills and experience of each HCP. This information will facilitate the development of

Ensuring that HCP compensation arrangements are within FMV is an effective and easily implemented way to facilitate compliance.

a Stratification Model, which can be effectively used to classify HCPs into homogeneous categories (i.e., Tiers) based on expertise and experience. Once developed, the Stratification Model will provide an objective and repeatable mechanism to evaluate each HCP to determine the FMV of compensation. The availability of benchmark compensation data, as well as the level of information included in a typical CV, varies widely among countries; therefore, in countries outside of the United States, it is critical to have a good understanding of certain country-specific information, including (a) the regulatory environment, (b) the dynamics of the health care system, (c) how HCPs are compensated, and (d) the availability of valid compensation-related data sources.

About the Author

Ann S. Brandt, PhD, Partner, serves as the leader of the life sciences service line at HealthCare Appraisers Inc. Working primarily with medical device, pharmaceutical, and biotechnology companies, Dr. Brandt and her team of valuation professionals determine the fair market value of U.S. and global transactions including health care provider (HCP) compensation, intellectual property, royalty and licensing arrangements, as well as transactions related to data acquisition/sales and clinical trials. Dr. Brandt has worked with many life sciences companies to ensure that their global compensation arrangements comply with regulatory requirements related to the fair market value standard. Dr. Brandt has more than 25 years of health care experience as a valuation professional, clinician, consultant, strategist, and professor. She is an experienced presenter and has authored articles and book chapters on a variety of health care valuation topics.

Thanks go out to the leaders of the Life Sciences Practice Group for sponsoring this feature article: Kristian Andrew Werling, McDermott Will & Emery LLP, Chicago, IL (Chair); **Stefanie A. Doebler**, Covington & Burling LLP, Washington, DC (Vice Chair—Publications); **Ryan S. Johnson**, Fredrikson & Byron PA, Minneapolis, MN (Vice Chair—Membership); **Andy Lemons**, Hester & Lemons LLC, Atlanta, GA (Vice Chair—Strategic Planning and Special Projects); **Nicole A. Liffrig Molife**, Latham & Watkins LLP, Washington, DC (Vice Chair—Research & Website); **Jackie Olson**, Apple Inc, Sunnyvale, CA (Vice Chair— Educational Programs).

For more information about the Life Sciences Practice Group, visit www.healthlawyers.org/PGs or follow them on Twitter @AHLA_LS.

Endnotes

1 78 Fed. Reg. 9458-9528 (Feb. 8, 2013).
2 MedTech Europe is an alliance of European medical technology industry associations. It was founded in October 2012 and currently has two members: EDMA, representing the European in vitro diagnostic industry, and Eucomed, representing the European medical device industry.
3 15 U.S.C. §§ 78dd-1, *et seq.* (1977).
4 2010 UK Bribery Act, *available at:* http://www.legislation.gov.uk/ukpga/2010/23/pdfs/ukpga_20100023_en.pdf.
5 *I.e.* physicians who provide compensated services, *including, but not limited to*, speaking, advisory boards, consulting, product development, etc. to LSOs, may also be referral sources for these very products and services.
6 Patient Protection and Affordable Care Act, 42 U.S.C. § 18001, et seq. (2010).
7 Payments under $10 are excluded only if the aggregate amount paid to HCPs is under $100 annually.
8 The Sunshine Act defines "physician" as a medical doctor, doctor of osteopathy, dentist, podiatrist, optometrist, or chiropractor who is legally authorized to provide services within the scope of his or her license. However, many LSO's are including a much broader range of HCPs within their compensation tracking programs.
9 Cal. Health & Safety Code §§ 119400–119402.
10 Public Act No. 10-117 (S.428), §§ 93–94.
11 D.C. Code Ann. § 48-833.0148–833.09 and D.C. Mun. Reg. tit. 22, §§ B1800–B1805, B1899.
12 La. Rev. Stat. §§ 42:1115–115(A).
13 Me. Rev. Stat. §§ 151.01, 151.44, 151.47, 151.461, 10A.071, subd. 1(b).
14 105 Mass. Code Regs. § 970.00.
15 Minn. Stat. §§ 151.01, 151.44, 151.47, 151.461, 10A.071, subd. 1(b).
16 Nev. Admin. Code § 639.616.
17 Vt. Stat. Ann. tit. 18 §§ 4631a, 4632, as revised by No. 128 (S.88), §§ 32-33 (Vt. May 27, 2010).
18 W. Va. Code § 16-29H-8.
19 The Foreign Corrupt Practices Act of 1977, as amended, 15 U.S.C. §§ 78dd-1, *et seq.*
20 Bribery Act 2010, § 12(5).