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Fair Market Value and Compensation Arrangements in an Age of Transparency

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The life sciences industry is dealing with a series of global challenges relating to increasing competition, escalating costs and expanding regulatory requirements. New regulations and requirements related to transparent interactions between life sciences companies ("LSCs"), physicians, allied health providers and others (collectively, "Healthcare Professionals" or "HCPs"), are being implemented by governments and industry associations throughout the world. Anti-corruption laws (*e.g.,* The Foreign Corrupt Practices Act[1] in the U.S. and the U.K. Bribery Act are now more easily enforced with the implementation of the new transparency requirements.

Relationships between Healthcare Professionals and Life Sciences Companies

One of the most significant areas of global scrutiny involves the relatively symbiotic relationship between physicians, life sciences companies ("LSCs") and the products these companies develop (*i.e.,* physicians who provide services to, and are compensated by LSCs, may also be referral sources for the healthcare goods and services provided by LSCs). Yet, LSCs regularly engage physicians and others (*i.e.,* the HCPs) to advise, consult, teach, speak or conduct research related to their products and services. Payments to HCPs for these types of services, which can total millions of dollars per year, have become routine expenses for LSCs.

Experienced HCPs offer a level of expertise and understanding that often 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 LSC products and services. Furthermore, research indicates that clinicians pay more attention to what other clinicians say than to what sales reps say about a drug or device. Therefore, when LSCs want to educate HCPs about new treatments, products and their applications, they often 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, regulators throughout the world are implementing laws to prevent inappropriate financial relationships between HCPs and LSCs. 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 LSCs' products. Of particular significance is whether the fees for these *services* appear to be in excess of fair market value for the services rendered. Worldwide interest in transparency and fair market value are very much a response to the realities that accompany the globalization of healthcare; therefore, it must be assumed that these requirements will become part of the daily demands of doing business for LSCs.

[1] 15 U.S.C. §§ 78dd-1, *et seq*.(1977).

The Regulatory Environment within the U.S.

The Physician Payments Sunshine Act (the "Sunshine Act")

The Sunshine Act, which was included as Section 6002 of the Patient Protection and Affordable Care Act of 2010 (PPACA), 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[2] that they provide to physicians[3] 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. The requirements of the Sunshine Act have resulted in an industry-wide focus on well-defined FMV-compliant compensation plans that are consistently applied across the enterprise.

State Laws

Prior to the implementation of the Sunshine Act, a number of state laws were implemented to impose limits and reporting requirements on interactions between HCPs and LSCs. These laws, enacted in Massachusetts,[4] Vermont,[5] California,[6] the District of Columbia,[7] Minnesota,[8] and West Virginia,[9] generally are broader in scope than the federal Sunshine Act. Although the federal Sunshine Act preempts corresponding state law requirements, the future of these state laws remains unknown.

The Worldwide Regulatory Environment

In addition to country specific transparency laws (*e.g.,* France and Slovakia) and organizational codes of ethics (Eucomed, PhRMA, IFPMA, EFPIA, etc.), several countries, including the U.S., 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 Foreign Corrupt Practices Act ("FCPA")). These laws are particularly important for LSCs, because in many countries, many HCPs are government employees. Thus, nearly every interaction with a HCP may potentially expose an LSC to criminal and civil liability under applicable anti-corruption laws.

The stakes are getting higher and the penalties are becoming more onerous as increasing numbers of countries are implementing transparency laws. A well-defined and FMV-compliant compensation plan,

[2] Payments under $10 are excluded only if the aggregate amount paid to healthcare professionals is under $100 annually.

[3] 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 LSC's are including a much broader range of HCPs within their compensation tracking programs.

[4] MASS. GEN. LAWS ch. 111N, § 2

[5] VT. STAT. ANN. tit. 18, §§ 4631a(b)(1), 4632(a)(2), 4632(b)(1)

[6] CAL. HEALTH & SAFETY CODE § 119402(e)

[7] D.C. CODE § 48-833.01

[8] MINN. STAT. § 151.47(1)(f))

[9] W. VA. CODE § 16-29H-8

which is applied consistently throughout the enterprise, may prove to be an effective and relatively easy way to mitigate some of the risks associated with emerging transparency and bribery laws.

Valuing HCP Compensation Arrangements

HCPs generally provide three categories of services for LSCs: (i) consulting/advisory services; (ii) research services; and (iii) speaking/education services. For the most part, a specific HCP is engaged by an LSC to perform services because he/she possesses certain expertise and experience that cannot be duplicated by LSC employees. For example, HCPs with extensive clinical practice experience in working with patients with specific diseases or disorders can provide significant value to LSCs in the development and evaluation of products. Furthermore, HCPs tend to pay more attention to what their colleagues have to say about the efficacy of a particular treatment or device than they do to someone with little to no clinical experience. However, when assessing the FMV of compensation within the context of the life sciences industry, it should be understood that compensation earned by a healthcare professional in his or her specialty practice may not be directly comparable to compensation associated with providing speaking, consulting or research services to a LSC.

The valuation of HCP compensation arrangements within the life sciences industry requires knowledge of the type, level, and extent of the services to be provided as well as the expertise and experience required of the HCP. For example, the skills and experience required of an HCP who is engaged to provide consulting services related to basic research in early stage molecule development may be far different than the HCP who is engaged to assist in obtaining regulatory approval for a drug or device. Therefore, the process of quantifying relevant differences in skills and role requirements, and developing an effective and reliable methodology to stratify HCPs into homogeneous groups in order to determine the FMV of compensation, can be challenging.

Stratifying HCPs

In determining the FMV of compensation, a stratification model is typically developed to classify HCPs into homogeneous groups or tiers (the "Tiers") based on level of experience, expertise and the unique requirements of the role/activities for which the HCP is being engaged. For example, the skills and experience required of the medical researcher engaged by an LSC to perform *basic research* are typically very different from those required of an orthopedic surgeon who is engaged to provide clinical training in the use of a knee replacement navigation system. Similarly, differences in level of expertise and influence are evident when comparing the expertise of the orthopedic surgeon who uses the navigation system in his/her clinical practice to the nationally renowned orthopedic surgeon who developed key algorithms that form the basis of the navigation system.

There are two interrelated analyses required when determining the FMV of HCP compensation (i) development of the stratification model and its associated tiers; and (ii) determination of the FMV compensation payable at each tier.

The criteria or attributes used to stratify HCPs can vary considerably depending on the specific requirements of the position for which the HCP is to be engaged. Commonly considered stratification attributes include, but are not limited to:

- Educational credentials and specialized training;
- Professional certifications;
- Leadership experience;
- Academic appointments;
- Research experience and funding history;
- Invited presentations on both a national and international level;
- Publication history;
- Service on editorial boards; and
- Experience in working with the FDA or other regulatory agency.

Additional attributes, specific to some unique requirements of the position for which the HCP is engaged, are generally developed through discussions with the LSC and key constituents involved in HCP selection. For example, an HCP who is engaged to provide expertise in basic science research may need to possess require very specific skills and experience, and may need extensive leadership experience and clinical certifications. Whereas, an LSC engages a HCP to provide presentations to international professional groups would probably want to secure the services of an internationally known thought leader who possesses a high level of status in the professional community as evidenced through, among other things, extensive leadership, research and publication experience.

When developing a HCP stratification model, the LSC, must also consider number of tiers to incorporate into its design (each tier is associated with a different level of compensation). For HCPs based in the U.S. a three or four tiered model is most often implemented, for example.

- Tier I: International-level
- Tier II: National-level
- Tier III: Regional-level
- Tier IV: Local-level

It is also important to note that when developing stratification models for HCPs residing (and being paid) outside of the U.S., tiers and associated compensation levels may be different than they are in the U.S. Furthermore, the non-U.S. HCP's curriculum vitae ("CV"), which is often the primary source of information regarding the experience and expertise of the HCP, may not include the same level of information as seen in the CVs of U.S.-based HCPs. Therefore, in order to build a useful stratification model, it is generally advisable to review a representative sample of HCP CVs from each country to be included in the analysis prior to finalizing the model.

Determining Appropriate Compensation Levels

Once the number of stratification tiers is determined, the FMV compensation rate associated with each tier will need to be calculated. For U.S.-based HCPs, compensation data can be derived from a variety of sources. However, the use of published surveys that include values from multiple health care industry segments (*e.g.,* private clinical practice, hospital-based practice, etc.) may be more accurate in addressing the potential over-compensation bias that may occur when market comparables are obtained solely from similar relationships between healthcare providers and life sciences companies.[10]

Once the appropriate surveys are selected (*e.g.,* MGMA, AMGA, Sullivan Cotter, etc.), identified benchmark compensation earned by HCPs (based on specialty), will serve as the basis for determining the FMV of compensation.[11] For example, when determining the FMV compensation for a nephrologist, survey data relating to nephrology compensation is used as a benchmark within the analysis. Similarly, when determining the FMV compensation for medical physicists, it is important to utilize benchmark survey data for medical physicists with the same credentials as required for the position. Therefore, if the LSC requires the services of Ph.D. certified medical physicists, then it would be *inappropriate* to utilize benchmark compensation data for master's degree physicists who are not certified.

The determination of FMV compensation for HCPs residing and working outside of the U.S., requires an understanding of how HCPs are compensated in each country. For example, (i) Are all the physicians employed? (ii) Are only physician specialists employed? (iii) Do employed physicians also maintain independent private practices? Furthermore, in most cases, benchmark compensation data for specific clinical specialties will not be available in many countries outside of the U.S. Rather, governments and NGOs report physician compensation based on just two categories, generalists and specialists. Additionally, data may only be reported every few years, making meaningful comparisons to current rates quite difficult. Accordingly, it is important to adjust compensation benchmarks to account for changes in the price level of the subject country. This adjustment is especially important for countries that have experienced significant changes in price level in recent years (*e.g.*, the inflation rate in Vietnam in 2011 totaled 18.7%). To the extent possible, it is advisable to apply CPI adjustments reported for *healthcare expenditures*, as this statistic is commonly tracked by national statistical agencies. Due to the varying ways healthcare systems are run among different countries, the application of a healthcare-specific CPI adjustment may mitigate the risk of inaccuracies in the compensation calculations for HCPs residing and working outside of the U.S.

[10] In determining the FMV of HCP compensation arrangements within the life sciences, surveys that query LSCs in terms of what they pay HCPs *may* be influenced by referral relationships and may not be indicative of market compensation rates under the FMV standard (*i.e.,* such arrangements may represent "tainted" values). As such, there may be significant bias in those values such that they are not reliable in establishing FMV of compensation arrangements.

[11] In addition to general sources of compensation data, benchmark data can be obtained from a broad range of specialized data sources (*e.g.,* the American Dental Association and the American Association of Physicists in Medicine).

In Conclusion

Changes in the regulatory landscape within the U.S. and throughout the world are having a profound impact in the way LSCs are doing business. Anti-bribery and transparency laws are having a significant impact on compensation arrangements between LSCs and HCPs. Ensuring that compensation arrangements with HCPs are within FMV is an effective and easily implemented way to mitigate risk. In order to be effective, the methodology used to determine the FMV of HCP compensation arrangements must be objective and applied consistently. Once developed, the stratification model will provide an objective and repeatable mechanism to evaluate an HCP's credentials and determine the appropriate level of compensation. The availability of benchmark compensation data, as well as the level of information included in a typical HCP's CV, varies widely among countries. Therefore, in order to determine FMV compensation for HCPs outside of the U.S., it is important to understand (i) the regulatory environment in each country; (ii) the structure of HCP compensation in each country; and (ii) valid sources of benchmark compensation.

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