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Manufacturer Payment Sunshine Provisions Under PPACA: New Reasons to Substantiate Payments as Fair Market Value

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Reporting Provisions Under PPACA

The Patient Protection and Affordable Care Act (PPACA)[1] contains a number of provisions that are aimed at combating healthcare fraud and abuse. Among them are provisions that will require manufacturers and distributors of pharmaceutical, medical device, biological, and medical supply products that operate in the United States (Manufacturers) to report to the Secretary of the U.S. Department of Health and Human Services (HHS Secretary) payments or transfers of value (Payments) that they make to physicians and teaching hospitals (Covered Recipients).[2] Under these "Sunshine Provisions," Payments that must be reported include, among others:

- Consulting fees;
- Compensation for services other than consulting;
- Honoraria;
- Gifts;
- Entertainment;
- Food;
- Travel;
- Education;
- Research;
- Charitable contributions;

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- Royalty and license payments;
- Current or prospective ownership or investment interests;
- Direct compensation for serving as faculty or a speaker for a medical education program; and
- Grants.

The reporting obligation for Manufacturers begins on March 31, 2013. Reporting is due on the ninetieth day of each year and must be in accordance with procedures that are to be issued by the HHS Secretary by October 1, 2011. Failure to comply with reporting obligations as required by the Sunshine Provisions subjects Manufacturers to significant monetary penalties.[3]

With respect to each Payment, the information that must be included in reporting generally includes:

- The name of the Covered Recipient;
- The business address of the Covered Recipient;
- The specialty and National Provider Identifier (NPI) of the Covered Recipient if the Covered Recipient is a physician;
- The amount of the Payment;
- The date(s) on which the Payment was provided to the Covered Recipient;
- A description of the form of the Payment, such as whether it is:
  (1) Cash or cash equivalent;
  (2) In-kind items or services; and/or
  (3) Stock, stock options, or any other ownership interest, dividend, profit, or other return on investment.
- A description of the nature of the Payment, such as whether it constitutes a consulting fee, compensation for services other than consulting, honoraria, etc.,
- The name of any drug, device, biological, or medical supply for which marketing, education, or research is related to the Payment; and
- any other information that the HHS Secretary determines appropriate (e.g., in future regulations).

By September 30, 2013, and on June 30 of each calendar year (CY) thereafter, the HHS Secretary will make the reported information (excluding NPIs and certain proprietary information)[4] available to the public.

State Preemption and the Sunshine Provisions

The Sunshine Provisions follow the legislation and regulations of several states that already regulate Payments by drug, device, and supply manufacturers.[5] The Sunshine Provisions will preempt state law that requires reporting of the same type of information as the Sunshine Provisions.[6] However, the Sunshine Provisions will *not* preempt state law that requires:

- Disclosure of more information than is required to be disclosed by the Sunshine Provisions;
- Disclosure by persons or entities other than Manufacturers;
- Disclosure of Payments to persons or entities other than Covered Recipients; or
- Disclosure to a federal, state, or local governmental agency for public health surveillance, investigation, or other public health or health oversight purposes.

In essence, the Sunshine Provisions preempt state law that is similar to or less expansive, but do not preempt state law that is more restrictive or of greater breadth. Therefore, persons or entities that meet the definition of a Manufacturer or Covered Recipient can expect that beginning in 2013, most Payments greater than $10 or exceeding $100 in the aggregate in a CY[7] must be reported to the Secretary and will eventually be made public, regardless of applicable state law. Persons or entities that make or receive Payments in a manner that brings them under the jurisdiction of state law that is broader or more restrictive than the Sunshine Provisions will be subject to additional regulations that may make issues related to Payments more complex. For example, entities that make Payments or are contemplating making Payments to one or more physicians in Massachusetts may not only be subject to reporting requirements imposed by the Sunshine Provisions, but also to Massachusetts state law that altogether prohibits most Payments that are of more than nominal value unless such Payments are:

(1) Compensation or reimbursement made to a healthcare practitioner for providing bona fide services;

(2) Reasonable; and

(3) Based on fair market value (FMV).[8]

Substantiating FMV When Payments Are in the "Sunshine"

The Sunshine Provisions are part of a larger government scheme that is aimed at reducing unnecessary and potentially fraudulent use of medical products. The overall scheme includes not only the reporting requirements of the Sunshine Provisions, but also heightened government scrutiny and enforcement activity related to the relationships between the entities that meet the definition of Manufacturers and the persons or entities that meet the definition of Covered Recipients, and vigorous investigation, prosecution, and/or sanctions when such arrangements are determined to implicate the federal Anti-Kickback Statute (AKS),[9] False Claims Act (FCA),[10] or other federal prohibitory statutes.[11]

Beginning with a Special Fraud Alert in 1994,[12] HHS has taken a firm stance that any Payments from entities that fit the definition of Manufacturers to persons or entities that fit the definition of Covered Recipients may implicate the AKS and other federal prohibitory statutes if the Payments are more than nominal in value and exceed the FMV of any legitimate service rendered to the payor by the recipient.[13] Subsequent government fraud alerts, rulemaking commentary, and civil and criminal actions all have underscored that Payments from a Manufacturer to a Covered Recipient are likely to be scrutinized as disguised incentives or rewards for the recommendation or use of a Manufacturer's

products, *unless* the Payments can be substantiated as FMV for reasonable and bona fide transfers of items or services.[14] Against this backdrop, the Sunshine Provisions:

(1) Create transparency about the Payments flowing from Manufacturers to Covered Recipients;

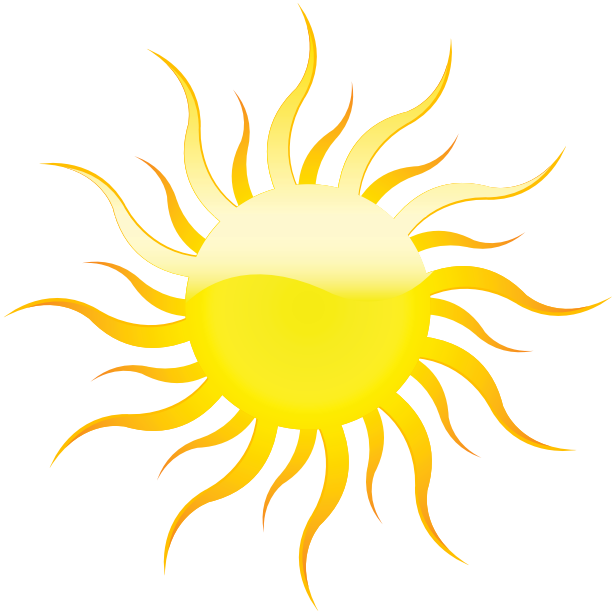
(2) Make inappropriate Payments seemingly easier for the government and public to identify; and

(3) Raise the possibility of more vigorous enforcement activity relating to the AKS and FCA, as well as of state law that restricts or prohibits certain Payments by Manufacturers.

The transparency required by the Sunshine Provisions means that the key (and the rub) for avoiding unpleasant and potentially costly government scrutiny, investigations, and/or litigation may be the ability to clearly substantiate Payments as FMV for legitimate transfers of items or services. Substantiating Payments as FMV requires some understanding of how experts (including government experts) define FMV and arrive at a determination of FMV in situations involving payments to physicians, and how the existence of the Sunshine Provisions may affect the data and methods that one may reasonably use to establish FMV.

In the non-healthcare world, FMV is commonly defined as 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 a compulsion to buy or sell, and both have reasonable knowledge of the relevant facts.[15] In the context of healthcare transactions, valuators generally defer to the definition of FMV that the Centers for Medicare & Medicaid Services (CMS) has promulgated in reference to financial interests of physicians who are in a position to make referrals. This definition of FMV is the value in arm's-length transactions, consistent with the general market value, when "the general market value" means the compensation that would be paid as a result of bona fide bargaining between well-informed parties to the transaction when neither party is otherwise in a position to generate business for the other party.[16]

The definition ascribed to the general market value can complicate the process of substantiating FMV in healthcare transactions. Although a simple review of the compensation paid in similar transactions may reasonably establish FMV in non-healthcare transactions, it rarely does so in the context of healthcare transactions because, generally, one or more parties in the comparable healthcare transactions are healthcare providers that are in a position to "refer" business to the other part(ies) in the transaction. As such, a simple comparison to what other parties have paid for an apparently similar item or service may fail the test of general market value. For this reason, even though the Sunshine Provisions may result in unprecedented public access to information regarding the nature and value of Payments in the healthcare marketplace, Manufacturers, as well as Covered Recipients, who also are subject to prosecution under the AKS (or a state anti-kickback statute) or to sanctions by the Office of Inspector General under the Civil Monetary Penalty Statute, should be wary of relying on such information as the sole basis for substantiating



FMV in a transaction, even when they believe that such information may relate to transactions that are substantially similar .

The FMV of Payments by Manufacturers is more reasonably substantiated by comparison to payments made for similar items or services in transactions that do not involve healthcare providers who are in a position to generate business for the entity that is making the payments. Hence, and by way of example, even if the Sunshine Provisions result in public knowledge that some Manufacturers previously have paid up to $500 per hour for consulting services by practicing physicians who specialize in cardiology, one should not assume that $500 per hour constitutes FMV for cardiology consulting services. However, if the subject cardiology consulting services are reasonably comparable to medical director services that some cardiologists have provided for corporate health programs at large entities that are not Manufacturers, and market data indicates that these large entities that are not Manufacturers routinely pay approximately $500 per hour for their cardiology consulting services, $500 may well be substantiated as FMV.

Valuation experts typically will rely on one of three generally accepted valuation approaches to determine the FMV of an item or service. These are the:

(1) Market approach;

(2) Cost approach; or

(3) Income approach.

The market and cost approaches are preferred over the income approach for valuing Payments for consulting or other services by physicians.[17] Both the market and cost approaches require the identification and comparison of transactions that are similar to the subject transaction. Because the duties, desired physician qualifications, and circumstances related to services arrangements with physicians are diverse, identification of reasonable comparables can be difficult and usually requires some understanding of the details of the potentially comparable arrangements.

The Sunshine Provisions will result in public access to a substantial amount of information regarding the nature and value of Payments for consulting, speaking, and other physician service arrangements. This information may assist in the identification of comparables and aid in the determination of FMV. However, to the extent that the information that is reported under the Sunshine Provisions provides only a high-level overview of transactions and/or does not capture many specific details of arrangements, the information will not necessarily support conclusions regarding FMV. When employing either the cost or market approach, FMV needs to be established (or at least defensible) on the basis of amounts paid in contexts that are clearly similar to the subject transaction. Furthermore, for purposes of meeting the AKS safe harbor for personal services contracts and/or complying with other legal and regulatory guidance that applies to healthcare transactions, the comparable transactions should be commercially reasonable and not influenced by party's ability to otherwise generate business for the other party.

Conclusion

The transparency required by the Sunshine Provisions will increase the importance of Manufacturers such as pharmaceutical, biologic, medical device, and medical supply manufacturers being able to substantiate that their Payments to physicians and teaching hospitals are consistent with FMV. At the same time, such transparency may increase the pool of data that may be considered when analyzing or drawing conclusions regarding the FMV of Payments. Both Manufacturers and Covered Recipients should be cautious, however, about using Payment data that others report to establish FMV. Based on the definition of FMV that is generally used to gauge regulatory compliance in healthcare transactions, FMV for Payments should be determined and defensible based on market data pertaining to transactions that are:

(1) Determined to be similar to the transaction giving rise to the Payment, after consideration of all material facts and circumstances;

(2) At arm's length; and

(3) Untainted by the potential for referrals or other business between the parties to the transaction.

Data reported under the Physician Sunshine Provisions may not meet these requirements in all cases.

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1 Pub. L. No. 111-148, to be codified in various sections of 42 U.S.C. (PPACA).

2 PPACA Section 6002; Manufacturers defined at Section 6002, 1128G(e)(9); Covered Recipients defined at Section 6002, 1128G(e)(6).

3 PPACA Section 6002, 1128G(c) (Penalties for Non-Compliance).

4 Provisions regarding public availability of reported data (PPACA Section 6002, 1128G(c)(1)(C)) state that the data available to the public on an internet website will exclude NPIs (Section 6002, 1128G(c)(1)(C)(viii)). Other provisions provide for delayed publication of Payments made pursuant to product research or development agreements or to clinical investigations, each of which may be proprietary (Section 6002, 1128G(c)(1)(E)).

5 The states where state law already regulates Payments by entities that meet the definition of Manufacturers include California, Connecticut, Maine, Massachusetts, Minnesota, Nevada, Vermont, and West Virginia. The District of Columbia also has enacted legislation of this type.

6 The Sunshine Provisions contain a specific section addressing state law preemption: Section 6002, 1128G(d)(3).

7 The definition applicable to Payments excludes the transfer of anything of a value less than $10, unless the aggregate amount that a Manufacturer transfers to a Covered Recipient exceeds $100 in a calendar year (PPACA Section 6002, 1128G(e)(10)(B)(i). The definition also excludes certain other transfers such as product samples, loan of a covered device for a short period of time, discounts (including rebates), in-kind items used in the provision of charity care, etc.) (Section 6002, 1128G(e)(10)(B)(ii)-(xii).

8 105 CMR § 970.000.

9 42 U.S.C. § 1320a-7b.

10 42 U.S.C. § 3729-3733.

11 The U.S. Department of Justice has announced plans to pursue actions against Manufacturers under other U.S. laws, including the Foreign Corrupt Practices Act (15 U.S.C. § 78dd-1, *et seq.*) when appropriate.

12 *OIG Special Fraud Alert: Prescription Drug Marketing Schemes* (Issued Aug. 1994), republished at 59 Fed. Reg. 65372 (Dec. 19, 1994).

13 *Id.,* 65376.

14 *See Artificial Joint Makers Settle Kickback Case*, N.Y. Times, Sep. 28, 2007; Press Release, United States Department of Justice, *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring* (Sep. 27, 2007) (discussing government claims against Zimmer Inc.; Depuy Orthopedics Inc.; Biomet Inc.; Smith and Nephew Inc.; and Stryker Orthopedics Inc., and announcing that the U.S. Attorney's Office for the District of New Jersey had negotiated deferred prosecution agreements with four of the five named companies, and an non-prosecution agreement with Stryker Orthopedics, Inc.), *available at* www.justice.gov/usao/nj/press/2007releases.html.

15 International Glossary of Business Valuation Terms.

16 42 C.F.R. § 411.351 (setting forth CMS' definition of FMV, to be applied with respect to physicians' referrals to healthcare entities with which they have financial relationships). The definition is also consistent with similar fair market value guidance related to the AKS.

17 The income approach entails conversion of anticipated economic benefits (such as future income streams to the payor of the compensation as a result of paying the compensation) into a present single amount. The income approach is not the preferred method for determining FMV in the context of arrangements between Manufacturers and Covered Entities for the services of physicians because: (1) the future income streams resulting from compensation arrangements with physicians may be tied to and/or a proxy for the volume or value of the physician's future referrals or business generation for the payor of the compensation, and (2) compensation that is influenced by the volume or value of the physician's future referrals or generation of business for the payor of the referrals is suspect under the AKS.