

No Safe Harbor of \$500 Per Hour for Determining FMV of Physician Payments in the Life Sciences Industry

Pharmaceutical and medical device companies are facing increasing scrutiny by federal regulatory enforcement agencies. The OIG has long taken the position that compensation to physicians that exceeds the fair market value (“FMV”) of legitimate services rendered implicates the federal Anti-kickback Statute. Therefore, the focus of scrutiny is often on the array of compensated relationships that exist between physicians and such companies, including speaking and consulting engagements. Since federal scrutiny raises concerns not only for companies engaging physician consultants, but also for physician consultants and their employers, academic institutions and other organizations that employ physicians are increasingly implementing policies to monitor and/or impose restrictions on compensated consulting engagements involving their employed physicians. These restrictions include requiring documentation that any remuneration is consistent with FMV.

Establishing defensible FMV compensation rates for physician consulting services requires more work than simply establishing parity with rates paid by peer group companies. Since many existing compensation relationships are between companies which manufacture healthcare products and physicians who are in a position to prescribe, use or recommend these products, existing arrangements may be “tainted” by the intent to provide remuneration for referrals. Therefore, ascertaining the FMV of physician consulting services requires the use of an appropriate valuation methodology that:

- (i) accounts for specific facts and circumstances of the contemplated arrangement; and
- (ii) can be applied without reliance on “tainted” marketplace values.

FMV Pitfall

A 2007 government action against five manufacturers of hip and knee implants resulted in four of the companies entering Deferred Prosecution Agreements (“DPAs”).

The DPAs contained a provision stating:

[T]he Company agrees to make Payments to Consultants at a fair market value hourly rate...of no more than \$500 per hour for time actually expended by a Consultant performing Consulting Services. In the event the Company wishes to make Payments to a Consultant at a higher [h]ourly [r]ate...the Company must obtain...a fair market value analysis conducted by an independent organization...

Some have interpreted the \$500 hourly rate as a form of a *safe harbor* payment for physician services. We do not believe that the government intended to provide universal guidance as to the FMV of compensation rates payable to physicians. The FMV of any specific physician compensation arrangement may be more than, or less than, \$500 per hour.