

Fair Market Value Issues in Financial Arrangements with Research Physicians

*Research Compliance Conference
June 3-6, 2012*

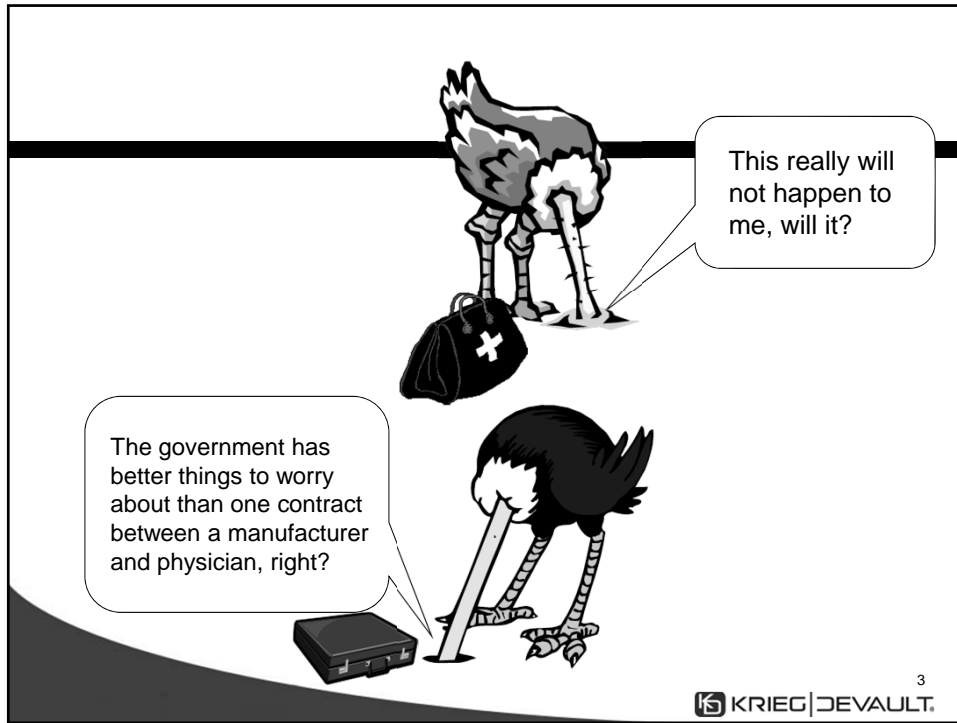


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Why Is Documenting Fair Market Value and Commercial Reasonableness Important?

- Fines and Penalties, including 3 times the amount paid by Medicare/Medicaid for service, \$10,000 fine per payment, etc.
- Exclusion from Medicare/Medicaid Programs.
- Intermediate Sanctions.
- Damage to reputation.
- Corporate Integrity Agreements/Deferred Prosecution Agreements.
- Shareholder lawsuits
- Imprisonment.



Tell That to the Parties Involved in the Following Recent Cases:

- DePuy Orthopaedics
- Biomet
- Caremark
- Smith & Nephew
- Stryker Orthopaedics
- Bristol-Myers Squibb
- Astra Zeneca
- Pharmacia
- Merck-Medco
- Pfizer
- Schering-Plough
- Advance PCS
- MedTronic
- Novartis Nutrition



2007 Settlements with Orthopedic Device Companies

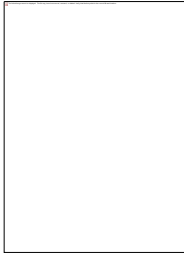
- 5 Companies, \$311M – Largest Settlement was \$169.5M
- Monitor Expense – \$28 - \$52M
- Information is being gathered
- Focus will switch to physician consultants – See March 22, 2008 article “New Focus of Inquiry Into Bribes: Doctors” attached as Exhibit A.



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“If you don’t focus on doctors, this is a problem that will never end.”


Lewis Morris, Chief Counsel to the Office of Inspector General

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2009-2010 Orthopedic Physician Settlements

- OIG alleged physicians sought and received “consulting payments” in exchange for using devices.
 - 10/20/09: Robert Diaz, M.D. \$65,000 and excluded for 3 years
 - 2/16/10: Harvey Montijo, M.D. \$650,000
 - 10/21/10: Steven Lancaster, M.D. \$101,000

ANTI-KICKBACK STATUTE (42 U.S.C. § 1320a-7b)

It is illegal to knowingly or willfully:

- Offer, pay, solicit, or receive remuneration;
- Directly or indirectly;
- In cash or in kind;
- In exchange for:
 - Referring an individual; or
 - Furnishing or arranging for a good or service; and
- Payment may be made by Medicare or Medicaid.



UNITED STATES V. GREBER

THE “ONE PURPOSE” RULE

If one purpose of the remuneration is to induce referrals, the statute is violated, even if the payment was also intended to compensate for professional services.

THREE NECESSARY ELEMENTS

Intentional Act

**Direct or Indirect
Payment of
Remuneration**

**To *Induce* the Referral
of Patients or Business**

WHAT IS REMUNERATION?

- Extremely Broad Scope, whether in cash or in kind, and whether made directly or indirectly, including:
 - Above or below market credit arrangements;
 - Above or below market rent or lease payments;
 - Above market consulting fees;
 - Bribes;
 - Discounts;
 - Furnishing of supplies, services or equipment either free, above or below market;
 - Kickbacks;
 - Gifts;
 - Rebates; and
 - Waivers of payments due.

CAUTION

**Almost Any Benefit
By and Between
Pharma/Device
Manufacturers and
Medical Providers Can
Be Considered
Remuneration**

ANTI-KICKBACK STATUTE

SAFE HARBOR FOR PERSONAL SERVICES AND MANAGEMENT CONTRACTS

- Written Agreement signed by parties
- Term of at least one year
- Agreement must specify **aggregate payment** and such payment must be **set in advance**
- Compensation must be **reasonable, fair market value** and determined through **arms' length negotiations**
- Must set exact services required to be performed



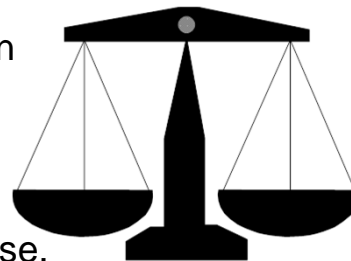
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ANTI-KICKBACK STATUTE

SAFE HARBOR FOR PERSONAL SERVICES AND MANAGEMENT CONTRACTS, *cont'd*

- Compensation must not be determined in a manner that takes into account volume or value of referrals
- All arrangements must be in **one** contract.
- The arrangement must serve a commercially reasonable business purpose.



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ANTI-KICKBACK STATUTE

SAFE HARBOR FOR PERSONAL SERVICES AND MANAGEMENT CONTRACTS, *cont'd*

If the Agreement does not contemplate full-time services, it must also specify:

- The **exact** schedule of intervals;
- Their **precise** length; and
- The **exact** charge for such intervals.

Note: Many consulting arrangements may not have exact schedules.

ANTI-KICKBACK STATUTE

SAFE HARBOR FOR PERSONAL SERVICES AND MANAGEMENT CONTRACTS

Most Research and Consulting Arrangements will not be Safe-Harbor protected because:

1. Aggregate compensation set in advance, and
2. Exact schedule of services.

ANTI-KICKBACK STATUTE

EMPLOYMENT SAFE HARBOR

Payments made by employer to employee under bona fide employment relationship with employer for employment in furnishing of any item or service for which payment may be made under Medicare or Medicaid are excepted from the Anti-Kickback Statutes' prohibitions.



ANTI-KICKBACK STATUTE

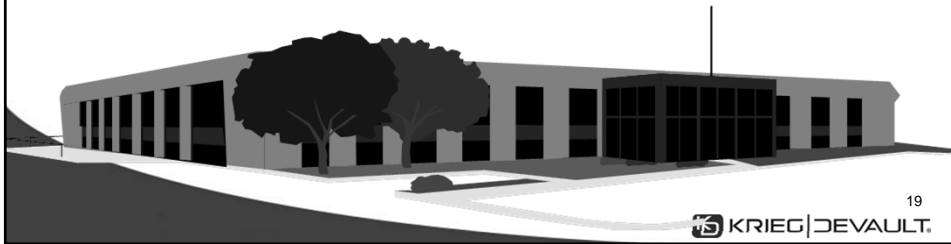
EMPLOYMENT SAFE HARBOR, *cont'd*

If payments under employment arrangements are not fair market value, payments above fair market value could be construed to be outside of employment compensation.

ANTI-KICKBACK STATUTE

SAFE HARBOR FOR RENTAL OF OFFICE SPACE

- Written Agreement
- 1 Year
- **Fair Market Value**
- Identify space used



ANTI-KICKBACK STATUTE

SAFE HARBOR FOR EQUIPMENT RENTAL

- Written Agreement
- Identify Specific Equipment
- Schedule of Usage
- 1 Year Term
- **Fair Market Value**



WHAT IS FAIR MARKET VALUE?

Fair market value is “the value in arm’s-length transactions, consistent with the general market value.”



WHAT IS FAIR MARKET VALUE?

“General Market Value” means the price that an asset would bring as a result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as a result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.

42 C.F.R. § 411.351

WHAT IS FAIR MARKET VALUE?

Key points:

- Referrals between the parties cannot be considered.
- Fair market value is determined upon the sale or when the service agreement is executed.
- Local market conditions are factors (i.e., lack of a specialty in the market, depressed real estate market).
- Proximity of real estate to the lessor (hospital) cannot be considered, but costs of developing or improving real estate should be considered.
- Expertise of physician for personal services.



DOCUMENTATION OF FAIR MARKET VALUE/COMMERCIAL REASONABLENESS

For every physician contract, fair market value/commercial reasonableness is the biggest issue.



DOCUMENTATION OF FAIR MARKET VALUE/COMMERCIAL REASONABLENESS

Types of Arrangements in Device/Pharma Industry where FMV is Important:

- Consulting agreements
- Royalty agreements
- Product development agreements
- Service agreements
- Teaching or education agreements
- CME (continuing medical education) agreements
- Promotional agreements (speaker agreements)
- Marketing agreements
- Fellowships or payments to fellows

DOCUMENTATION OF FAIR MARKET VALUE/COMMERCIAL REASONABLENESS

Types of Arrangements in Device/Pharma Industry where FMV is Important (*Continued*):

- Preceptorship agreements
- Grants
- Honoraria
- Charitable contributions
- Speaking engagements
- Clinical trials
- Clinical data collection
- Lease agreements with HCPs
- Author for hire agreements

FAIR MARKET VALUE

All Device/Pharma Arrangements can fit into one of the following three categories:

- Employment Agreements
- Consulting/Independent Contractor Services
- Royalty Payments

GENERAL FMV PRINCIPALS

Market Data:

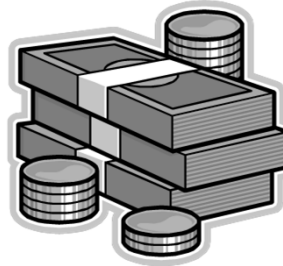
1. Determine what competitors are paying (anti-trust risks)
2. Opinion letter from compensation analyst
3. Third party surveys
4. National experts



GENERAL FMV PRINCIPALS

Although there are exceptions, most compensation arrangements should be evaluated by:

- Hours worked
- Compensation per hour



GENERAL FMV PRINCIPALS

NOTE: In Orthopedic device Settlements, ALL arrangements needed to be substantiated based upon hourly rate and no compensation above \$500 per hour.

GENERAL FMV PRINCIPALS

Typical third party surveys include:

- Sullivan, Cotter & Associates, Inc. - Physician Compensation and Productivity Survey;
- HayGroup - Physicians Compensation Survey;
- Hospital and Healthcare Compensation Service - Physician Salary Survey Report;
- Medical Group Management Association - Physician Compensation and Productivity Survey;
- ECS Watson Wyatt - Hospital and Health Care Management Compensation Report
- William M. Mercer - Integrated Health Networks Compensation Survey

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EXHIBIT B

Summarized below is the market survey data establishing the fair market value of pay for Family Practice Physician (without OB). This market data has been obtained from independent third party compensation surveys.

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SURVEY DATA FAMILY PRACTICE (WITHOUT OB)

Survey	Survey Match	Region	Total cash compensation		
			25th %ile	50th %ile	75th %ile
Sullivan	Family Practice without OB/GYN	National	124,524	142,906	165,378
	Family Practice without OB/GYN	Regional	126,276	144,842	172,331
Hay	Family Practice	National	129,647	149,880	163,306
	Family Practice	Regional	129,896	151,337	182,249
HHCS	Family Practice	National		165,966	
MGMA	Family Practice without OB	National	131,527	153,874	186,886
	Family Practice physician	National	125,810	139,730	165,897
Average			\$ 127,796	\$ 152,376	\$ 172,741
approach/hour			\$ 61	\$ 73	\$ 83

Additional information:

A 20 to 30% premium can be applied to total cash in lieu of benefits. A 25% premium applied to the 50th percentile would equal approximately:

\$ 190,471 per year
\$ 92 per hour
\$ 733 per day

Surveys: Regional data included where available. Data updated to 7/1/02.

Sullivan, Cotter & Associates, Inc. - 2001 Physician Compensation and Productivity Survey Report
HayGroup - 2001 Physicians Compensation Survey
Hospital and Healthcare Compensation Service - 2002 Physician Salary Survey Report
Medical Group Management Association - Physician Compensation and Productivity Survey 2000
ECS Watson Wyatt - 2001/2002 Hospital and Health Care Management Compensation Report

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Table 1: Physician Compensation

	Phys	Med Pracs	Mean	Std. Dev.	25th %tile	Median	75th %tile	90th %tile
Allergy/Immunology	145	79	\$309,751	\$153,367	\$207,565	\$261,396	\$383,152	\$513,974
Anesthesiology	3,522	168	\$406,154	\$152,493	\$307,324	\$404,996	\$484,642	\$609,557
Anesthesiology: Pain Management	164	59	\$502,024	\$223,360	\$380,008	\$436,059	\$547,226	\$839,499
Anesthesiology: Pediatric	140	10	\$426,988	\$91,987	\$371,958	\$424,705	\$469,955	\$577,850
Cardiology: Electrophysiology	217	93	\$571,508	\$205,091	\$429,808	\$532,380	\$667,270	\$864,141
Cardiology: Invasive	506	125	\$499,486	\$227,523	\$359,012	\$467,715	\$608,911	\$748,081
Cardiology: Invasive-Interventional	630	150	\$553,890	\$223,998	\$403,145	\$526,454	\$672,528	\$815,799
Cardiology: Noninvasive	600	107	\$444,220	\$189,898	\$309,469	\$431,740	\$544,123	\$700,736
Critical Care: Intensivist	99	30	\$326,070	\$140,383	\$251,829	\$306,225	\$371,159	\$489,847
Dentistry	78	21	\$174,305	\$52,836	\$135,120	\$157,787	\$211,832	\$260,202
Dermatology	296	118	\$451,853	\$214,874	\$289,281	\$392,885	\$569,237	\$780,004
Dermatology: Dermatopathology	5	4	-	-	-	-	-	-
Dermatology: Mohs Surgery	801	60	\$700,461	\$285,589	\$460,585	\$610,707	\$924,817	\$1,186,410
Emergency Medicine	801	60	\$284,673	\$86,095	\$230,232	\$277,297	\$326,570	\$408,470
Endocrinology/Metabolism	357	161	\$228,232	\$64,298	\$181,273	\$211,400	\$259,515	\$331,897
Family Practice (with OB)	939	146	\$211,063	\$76,047	\$160,152	\$186,742	\$248,254	\$305,710
Family Practice (without OB)	5,635	709	\$207,916	\$86,693	\$156,903	\$189,402	\$239,837	\$305,372
Family Practice: Amb Only (No Inpatient Work)	463	76	\$193,390	\$62,367	\$151,432	\$176,717	\$227,825	\$295,725
Family Practice: Sports Medicine	100	49	\$250,439	\$111,160	\$176,386	\$219,768	\$282,150	\$403,271
Gastroenterology	846	191	\$496,874	\$208,757	\$342,309	\$463,955	\$609,572	\$813,232
Gastroenterology: Hepatology	45	10	\$355,248	\$137,262	\$239,994	\$392,110	\$472,611	\$647,593
Genetics	8	6	-	-	-	-	-	-
Geriatrics	112	50	\$188,885	\$69,077	\$150,000	\$183,623	\$218,392	\$281,335
Hematology/Oncology	504	126	\$444,510	\$208,843	\$301,301	\$381,892	\$527,398	\$781,062
Hematology/Oncology: Oncology (Only)	61	28	\$456,625	\$211,947	\$305,286	\$432,777	\$577,672	\$716,107
Hospice/Palliative Care	28	19	\$198,091	\$37,135	\$173,261	\$196,262	\$219,381	\$252,038
Hospitalist: Family Practice	214	66	\$227,823	\$86,835	\$190,842	\$224,747	\$261,898	\$304,441
Hospitalist: Internal Medicine	3,368	336	\$225,630	\$67,149	\$191,065	\$220,144	\$267,305	\$305,721
Hospitalist: IM-Pediatric	20	9	\$217,014	\$61,292	\$184,535	\$200,000	\$229,267	\$355,938
Hospitalist: Pediatric	157	41	\$179,078	\$44,996	\$148,815	\$171,617	\$201,828	\$227,916
Infectious Disease	200	85	\$243,059	\$91,951	\$176,823	\$219,556	\$291,889	\$376,143
Internal Medicine: General	3,763	510	\$225,305	\$91,039	\$167,483	\$205,379	\$259,686	\$330,266
Internal Medicine: Amb Only (No Inpatient Work)	300	56	\$209,960	\$66,357	\$163,397	\$202,067	\$258,362	\$295,394
Internal Medicine: Pediatric	130	48	\$220,739	\$68,534	\$170,526	\$201,336	\$257,703	\$324,083
Nephrology	284	78	\$326,729	\$153,544	\$229,191	\$306,046	\$377,662	\$470,669
Neurology	635	187	\$276,421	\$118,887	\$201,931	\$249,867	\$315,958	\$420,735
Obstetrics/Gynecology: General	1,755	338	\$312,257	\$122,668	\$230,300	\$281,190	\$342,561	\$432,004
OB/GYN: Gynecology (Only)	195	100	\$245,350	\$114,502	\$165,554	\$225,000	\$307,338	\$397,258
OB/GYN: Gynecological Oncology	55	29	\$421,803	\$163,244	\$306,674	\$382,794	\$480,218	\$621,801
OB/GYN: Maternal & Fetal Med	105	43	\$473,316	\$172,024	\$360,825	\$446,886	\$607,361	\$807,361
OB/GYN: Reproductive Endocrinology	10	7	\$333,824	\$73,438	\$292,062	\$334,895	\$378,672	\$455,665
OB/GYN: Urogynecology	23	16	\$351,799	\$98,051	\$260,992	\$321,565	\$450,000	\$495,015
Occupational Medicine	95	67	\$21,312	\$92,042	\$173,332	\$201,880	\$247,450	\$336,001
Ophthalmology	357	116	\$377,465	\$185,289	\$251,940	\$330,784	\$462,418	\$632,104
Ophthalmology: Corneal & Ref Surgery	11	6	\$494,387	\$231,213	\$351,900	\$406,708	\$602,206	\$1,008,824
Ophthalmology: Pediatric	26	16	\$312,495	\$97,385	\$246,989	\$313,782	\$379,953	\$448,933
Ophthalmology: Retina	44	21	\$601,817	\$268,740	\$443,068	\$558,262	\$741,714	\$1,099,493
Orthopedic (Nonsurgical)	38	25	\$235,206	\$90,998	\$161,242	\$204,172	\$322,029	\$382,917
Orthopedic Surgery: General	857	251	\$539,354	\$269,601	\$372,437	\$497,088	\$668,642	\$825,044
Orthopedic Surgery: Foot & Ankle	80	58	\$493,545	\$199,613	\$360,094	\$451,171	\$607,395	\$749,710
Orthopedic Surgery: Hand	189	85	\$275,945	\$242,029	\$394,737	\$510,039	\$703,067	\$962,145
Orthopedic Surgery: Hip & Joint	138	72	\$675,156	\$287,849	\$469,744	\$589,272	\$826,944	\$1,179,805
Orthopedic Surgery: Spine	53	23	\$559,422	\$446,221	\$446,221	\$567,438	\$662,863	\$763,047
Orthopedic Surgery: Pediatric	140	83	\$760,782	\$451,196	\$454,117	\$648,233	\$864,250	\$1,329,042
Orthopedic Surgery: Sports	43	23	\$609,614	\$168,308	\$510,039	\$651,235	\$891,739	\$829,903
Orthopedic Surgery: Trauma	222	93	\$645,692	\$290,542	\$423,026	\$583,443	\$811,116	\$1,000,000
Orthotolaryngology: Sports Medicine	461	162	\$411,689	\$178,471	\$293,793	\$370,631	\$489,694	\$647,119
Otorhinolaryngology: Pediatric	19	10	\$342,046	\$158,250	\$231,183	\$321,015	\$431,737	\$587,729

GENERAL FMV PRINCIPALS

Key Concepts with Exhibit B:

1. Range established (25 %, 50%, and 75%)
2. Specialty is matched
3. Hourly rate is determined by percentile
4. Surveys are averaged to negate disparity
5. Premium added to base in lieu of benefits (assuming physician is independent contractor)



KEY FACTORS IN APPLICATION OF PERCENTILE

How does Physician compare with other physicians in same specialty?

- National/Regional reputation
- Articles published
- Speeches presented
- Productivity (worked RVUs)
- Opportunity Costs
- Supply v. Demand
- Unique Specialty/Subspecialty
- Experience



THOUGHT LEADERS/GENERAL FMV PRINCIPALS

National Experts/Thought Leaders

- Evidence of above-normal compensation
- Established fee schedule
- Frequency of above-normal compensation
- Unique skills/experience
- Speaking/writing/research experience
- Highly specialized services

Research Arrangement Example

FACTS

Orthopedic Device Company seeks to engage nationally recognized orthopedic surgeon to evaluate new hip replacement device. Company seeks physician to perform physical review of device and use of device in ten patient hip replacements with monitoring and evaluation of device post-surgery for one year. Because the device has not been approved by the FDA, the surgical procedures in which the device is used cannot be paid for by Medicare or other third party payors. Company believes that the following number of hours will be committed by orthopedic surgeon to perform evaluations and to provide written feedback:

Research Arrangement Example

(cont.)

Service	Estimated Number of Hours
Device evaluation	20 hours
Pre-surgical evaluation of 4 hours/patient, including obtaining patient informed consent	40 hours
4 hours per surgery	40 hours
4 hours per patient post-surgical evaluation	40 hours
Written report with detailed analysis	20 hours
TOTAL NUMBER OF HOURS ESTIMATED	160 hours

Benchmark Data

	25 th	50 th	75 th	90 th
Annual Cash Compensation ¹	\$372,437	\$497,088	\$658,842	\$825,044
Hourly Rate (÷ 2,000 hours)	\$186.22	\$248.54	\$329.42	\$412.52
Hourly Rate + 25% for expenses and benefits	\$232.78	\$310.68	\$411.78	\$515.63

¹2011 Medical Group Management Association Physician Compensation and Productivity Survey.

Research Arrangement Example

Orthopedic surgeon is considered to be a ***thought leader*** because surgeon has published numerous articles regarding hip implant specifications and has spoken at numerous national conferences on the subject. Surgeon has stated that he is typically paid \$600 per hour.



Research Arrangement Example

If Orthopedic surgeon and device manufacturer concur that \$600 per hour is reasonable and a monthly stipend is desired, then monthly stipend can be calculated as follows:

$$160 \text{ hours} \times \$600 = \$96,000 \div 12 = \$8,000$$



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RESEARCH CONSULTING/INDEPENDENT CONTRACTOR ARRANGEMENTS

1. Hourly payment (with maximum number of hours in contract)
2. Annual payment (determined by projected number of hours multiplied by Fair Market Value hourly rate)



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RESEARCH CONSULTING/INDEPENDENT CONTRACTOR ARRANGEMENTS

If Annual Payment method is used, need to track hours to make sure consistent with contract.



RESEARCH CONSULTING/INDEPENDENT CONTRACTOR ARRANGEMENTS

Duties and Responsibilities:

Require physician to complete a time card, (written statement of services rendered and amount of time dedicated to such services).

Time Sheet Exhibit C

PHYSICIAN: «FirstName» «LastNames», «Title» MEDICAL DIRECTOR OF: «JobTitle»

PAY PERIOD: _____
 For a complete listing of duties please reference the Medical Director Agreement.
 Please indicate time in half hour increments.

DUTIES	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
A. Provide program assistance, guidance, and recommendations																															
B. Provide medical guidance and direction																															
C. Provide educational services and/or conferences																															
D. Administrative duties																															
E. Be available to discuss and review treatment																															
F. Be a physician liaison																															
G. Meet regularly with Clinic staff. Attend meetings as requested																															
H. Other																															

GRAND TOTAL: _____ Approved by: _____
 «FirstName» «LastNames», «Title» Date

* In addition to the above, please generally describe the services performed this month.

RESEARCH CONSULTING/INDEPENDENT CONTRACTOR ARRANGEMENTS

Actual consulting services should be performed.

Good:

- Analyze drug/device and provide written analysis to Company.
- Give speech on behalf of Company.
- Review and develop written reports/analysis
- Write articles for Company.

RESEARCH CONSULTING/INDEPENDENT CONTRACTOR ARRANGEMENTS

Questionable:

- Compensation paid just to sign up patient in clinical trial not tied to or evaluated based upon time.
- Paid “consulting fee” to sit in an audience to listen about a new product/service.
- Pay physician to participate on large panel (15 members+) when fewer members would be reasonable (i.e., 5 members).
- Pay physician to “shadow” when there is no legitimate business need for shadowing.

ROYALTY PAYMENTS

- Appraisals
- Focus on Actual Sales
- Aggregate payment should not exceed a specified percentage of actual sales

ROYALTY PAYMENTS

Questionable Arrangements:

- Flat fee or Guaranteed fee
- Royalties paid beyond patents
- Royalties paid even though no product sold

RESEARCH CONSULTING/INDEPENDENT CONTRACTOR ARRANGEMENTS

One Example:

Company desires to train 30 physicians of various specialties who will provide research services about a particular disease state or device or drug. Training to occur at central location (i.e., Chicago).



RESEARCH CONSULTING/INDEPENDENT CONTRACTOR ARRANGEMENTS

Example FMV Questions:

- Q. How many physicians are reasonably needed?
- Q. How are physicians selected?
- Q. What does Company pay each physician to attend training session?
- Q. What does Company pay the trainer?
- Q. What expenses can the Company pay for?

EXAMPLE

HOW MANY?

- Why is this a FMV issue?
- Needs Assessment
 - Project need
 - Amount of research services reasonably anticipated
 - Flexibility of physicians selected
 - Demand for research services
 - Supply of physicians with requisite skills



EXAMPLE

HOW ARE PHYSICIAN'S SELECTED?

- Reputation
- Past Interaction
- Past Research Projects
- Flexible Schedule
- Specialist in Disease State
- Geographic Diversity
- Specialty
- Familiar with Company's Products
- Past Speeches/Articles



EXAMPLE

WHAT DOES COMPANY PAY?

- Fixed amount for each physician
- Varied amount based on specialty
- Individually negotiated amount
- Determine time that is compensable
 - Travel
 - Preparation
 - Training Time

EXAMPLE

WHAT DOES COMPANY PAY?

Bottom Line: Company **MUST** have documented reason for compensation decisions that are **DEFENSIBLE!**

Bad Rationale: Because that is what everyone is doing.



EXAMPLE

WHAT DOES COMPANY PAY?

Reasonable Documentation:

- Time sheets
- Sign-in sheets
- Invoice from Physician
- Benchmark data
- Rationalize payment based upon hourly rate

EXAMPLE

PAID EXPENSES

Good:

- Reasonable coach airfare
- Midsize rental car
- Reasonable hotel
- Reasonable meals/per diem
- Modest social events – Focus on networking

Bad or Questionable:

- Spouse's expenses paid
- First class airfare
- Luxury rentals/limousines
- Expensive resort
- Luxury restaurants
- Spa or golf payment/reimbursement

DOCUMENTATION GUIDELINES

Pharma/Device companies should establish a structured approval and documentation process for all physician contracts.

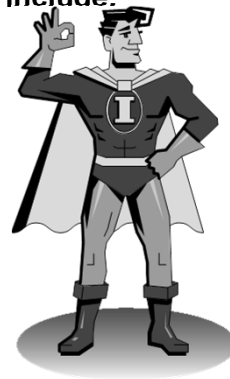


DOCUMENTATION GUIDELINES

One example is using the Board of Trustees, or a committee of the Board of Trustees (i.e., Executive Committee).

Documentation submitted for approval can include:

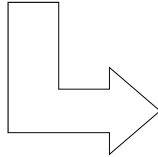
1. Fair Market Value/Commercially Reasonableness Documentation (Survey, Checklist, Competing Offers)
2. Proof of Legal Review
3. Officer's Certificate (see [Exhibit D](#))
4. Copy of contract (or contract review memo disclosing the material components of the contract.)



CONTRACT APPROVAL

Exhibit D

Officer's Certificate



OFFICER'S CERTIFICATION

I, _____, [President] _____ of [Name of Organization] hereby certify that to the best of my knowledge, the following matters are true for the _____ by and between [Name of Organization] and _____ dated _____, 2005 (the "Arrangement"):

1. There are no other arrangements, written or oral, with _____ except as written in the Arrangement;
2. The payments pursuant to the Arrangement represent the fair market value of the services to be rendered thereunder;
3. No payment has been or will be made, to the professional referenced herein outside of the terms and conditions of the Arrangement unless such outside payment is also consistent with [Name of Organization]'s policies; and
4. I, as the _____, shall ensure that the services required under the Arrangement are rendered prior to making each payment thereunder.

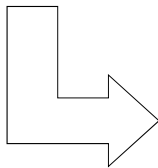
Date: _____ Signature: _____

* Can be signed by CEO, VP or President.

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CONTRACT APPROVAL

Contract Review Memo



PHYSICIAN CONTRACT REVIEW MEMO*

Name of Physician or Group with who contract is being sought: _____

Type of contract (i.e., Medical Director, Employment Agreement, Practice Location Agreement): _____ ("Contract")

Specialty: _____

_____ Contracting Entity (check all that apply):

List all Entities

Name and Title of Administrator completing Physician Contract Review Memo: _____

*Signature of above Administrator: _____ Date: _____

Pursuant to the terms of the proposed contract, the physician/group will do the following: _____

Term: The Contract will commence and end on the date of service provided _____

Renewal terms, if any, are as follows: _____

Describe i) why the Contract is Fair Market Value and ii) method of compensation. (Be very detailed, including a calculation as to how the annual compensation was determined. For example, if the documented Fair Market Value per hour rate is \$100.00, and 100 hours are expected from the physician/group, then a \$10,000 annual payment is warranted.) *Attach all supporting Fair Market Value documentation, including Physician Recruitment Checklist if applicable. In addition to the Fair Market Value documentation, if Physician is to be compensated above the 50th percentile, attach a memo explaining why Physician should be compensated above the 50th percentile (relevant factors may include specialty, board certifications or eligibility, years in practice, etc.) NOTE: NO CONTRACT SHALL BE APPROVED IF DESIRED COMPENSATION IS ABOVE 90th PERCENTILE.*

Administrator responsible for monitoring performance of all aspects of Contract by physician/group (listed administrators are limited only to the following: CEO, COO, SVP, VP): _____

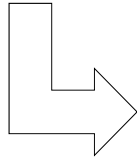
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CONTRACT APPROVAL

Contract Review Memo (Page 2)



State why the Contract is needed (including those needs that further charitable purpose):

Billing: Does the contract cover professional patient care services to be performed by the physician? Yes No If YES, will bill, either directly or by a contracted billing company, for the professional patient care services and retain revenue? Yes No

In addition to the above, this contract is needed and furthers the _____ charitable service because *(initial all that apply)*: _____ the contract benefits the community by improving patient access to quality medical services; _____ the contract will further the _____ mission; _____ the contract will improve an existing area of service.

[Legal staff to complete the following portions of this memo]
Has the Contract been reviewed and approved by legal counsel?
Yes No

State exception upon which contract is based *(legal staff must initial one)*:
 Bona fide employment relationship
 Personal services arrangement
 Rental of office space
 Rental of equipment
 Other: _____

If the contract was reviewed by in-house counsel, the signature that follows is a representation that _____ in-house counsel believes that the contract satisfies, in all material respects, _____ policy on hospital physician financial relationships and applicable laws governing such relationships.
(signature of _____ lawyer)

Has an Officer's Certificate been executed and delivered to the legal office? *(legal staff must initial one)*
Yes No

If not, please explain why: _____

[Chief Financial Officer, or designee, to complete the remaining portion of this memo]

Has the Contract been reviewed and approved by Finance?
Yes No

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DOCUMENTATION GUIDELINES

Because of the inherent risk with physician contracts, the Company should establish a Committee that should i) be involved in the approval process, and ii) oversee process for approval of physician contracts.



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DOCUMENTATION GUIDELINES

For every contract, the following documents should be maintained in a central file:

- **Executed** and copy of contract
- Fair market **current** value/commercial reasonableness documentation that formed the basis for the contract
- Documentation of legal review
- Officer's Certificate (see [Exhibit D](#))



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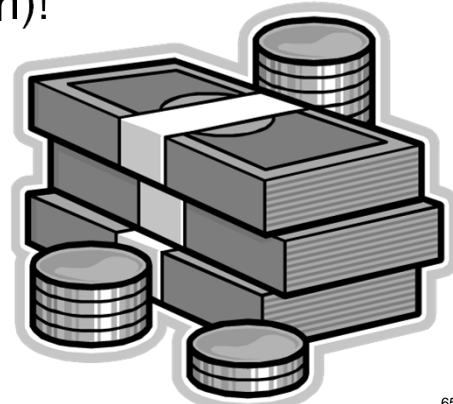
DOCUMENTATION GUIDELINES

- Time Report for actual and commercially reasonable services performed
- Payment records consistent with:
 - Time worked
 - FMV hourly rate
- W-2/1099 reflects all compensation paid

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BOTTOM LINE:

It is all about the Money
(and documentation)!



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Questions

