

Be Careful What You Say: Physician Affiliation Tricks of the Trade to Reduce Your Risk

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Entities that provide care to patients cannot operate with physicians and other providers. The opposite is also true. The sanctity of arrangements between these parties is protected by healthcare regulation. These laws and regulations create stressful working environments that challenge most legal and compliance professionals brave enough to enter the healthcare industry.

The best way to manage risk is to:

1. Understand the steps of the process;
2. Understand where others have run into compliance challenges along the path; and
3. Implement processes to thwart risk as best possible.

Physician Affiliation Process

The process for healthcare systems who enter into affiliations with physicians has numerous points in which need and approval is documented. Each of the steps can be summarized into five areas:

Physician Contracting Process



Determination of Need

Before any contractual relationship is conjugated, the healthcare system must document need for the arrangement. This documentation can be as simple as referencing the laws

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requiring the position (e.g., Clinical Laboratory Improvement Amendments (CLIA) requirements for a physician lab director to direct the technical and scientific operations of a lab) to as complicated as developing a complex model for the healthcare system and physician(s) to work together to operate in the most efficient and cost-effective manner to meet community need related to patient care.

The template necessary to document need varies based on the type and complexity of the arrangement. Here is a simple example related to documenting the need for a medical director.

MEDICAL DIRECTOR PLANNING WORKSHEET			
Department:			
Supervising Director:			
Proposed Hours per Month:			
Number of Physicians on Medical Staff Participating in Program:			
	Yes	No	Reasoning
Is the directorship required by law?			State law:
Is there another medical director that can perform the services?			If yes, why are the services not combined?

Process Execution

Once the need for the arrangement is documented, the healthcare system needs to make operational decisions to further document the commercial reasonableness of the arrangement. Within healthcare, nurses commonly use Situation, Background, Assessment, and Recommendation (“SBAR”) to share information between parties when treating patients.² A number of hospitals use this same method to share information about physician alignment arrangements.

As part of the SBAR situation analysis, the budgetary assessment is important. A pro forma model for revenue generating relationships such as employment agreements allows healthcare system’s management to understand potential shortfalls caused by expenses

² SBAR was originally developed by Michael Leanord, MD at the Colorado Permanente Medical Group around patient safety. [SBAR Tool: Situation-Background-Assessment-Recommendation | Institute for Healthcare Improvement](#)

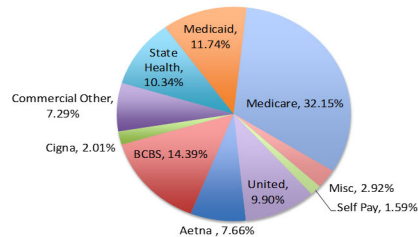
that might exceed collections. The budgetary analysis should include proforma income statements and other financial analysis and such analysis absolutely cannot take into account the value or volume of referrals of the contemplated agreements.

Practice Name:

Specialty:

Volume & Revenue Impact

Pro Forma Analysis



Payor Mix				
Payor	Volume %	wRVUs		
			Pmt per wRVU	Revenue
Aetna	7.66%	2,000.00	65.00	\$ 130,000.00
BCBS	14.39%	4,000.00	100.00	\$ 400,000.00
Cigna	2.01%	550.00	105.00	\$ 57,750.00
Commercial Other	7.29%	2,000.00	50.00	\$ 100,000.00
State Health	10.34%	3,000.00	35.00	\$ 105,000.00
Medicaid	11.74%	3,300.00	30.00	\$ 99,000.00
Medicare	32.15%	9,200.00	60.00	\$ 552,000.00
Misc	2.92%	800.00	68.00	\$ 54,400.00
Self Pay	1.59%	450.00	70.00	\$ 31,500.00
United	9.90%	3,000.00	120.00	\$ 360,000.00
Total	100.00%	28,300	66.77	\$ 1,889,650

Combined 2021 and 2022 Collection Rate	\$ 66.77
Y1 wRVUs	\$ 32,195
Y1 NPSR	\$ 2,149,760

Clinical & Administrative Staff					
Current			Projection		Comments
Position	Name	FTE	Wages Est.	FTE	Wages
Director/Office Manager		1.00	\$ 65,000	1.00	\$ 68,250
Director		1.00	\$ 50,000	1.00	\$ 52,500
Director		1.00	\$ 50,000	1.00	\$ 52,500
Office Manager		1.00	\$ 39,520	1.00	\$ 41,496
Receptionist		1.00	\$ 37,440	1.00	\$ 45,760
Medical Assistant		1.00	\$ 37,440	1.00	\$ 47,840
Medical Assistant		1.00	\$ 37,440	1.00	\$ 47,840
Medical Assistant		1.00	\$ 37,440	1.00	\$ 47,840
Total		8.00	\$ 354,280	8.00	\$ 404,026

Physician Compensation					
Tax Return Compensation			Projection		
Position	Provider	FTE	Salary	Proj. Comp	wRVUs
Physician	Doctor 1	1.00	\$ 100,000	\$ 641,776	10,696
	Bonus			\$ 64,178	
Physician	Doctor 2	1.00	\$ 100,000	\$ 901,693	15,028
	Bonus			\$ 90,169	
Physician	Muhammad Haq	1.00		\$ 350,000	6,471
	Doctor 3			\$ 35,000	
Total Providers (Physicians)		3.00	\$ 200,000	\$ 2,082,816	32,195

	Year 1	Year 2	Year 3
Revenue			
Doctor 1	10,696	10,696	10,696
Doctor 2	15,028	15,028	15,028
Doctor 3	6,471	8,812	11,565
wRVUs	32,195	34,536	37,289
Billing Report Total Payments	\$ 2,149,760	\$ 2,306,073	\$ 2,489,897
Net Patient Service Revenue	\$ 2,149,760	\$ 2,306,073	\$ 2,489,897
Expenses			
Clinical/Administrative Staff	\$ 404,026	\$ 412,107	\$ 420,349
Benefits (Clinical/Administrative)	68,684	70,058	71,459
Pension Profit Sharing	-	-	-
Payroll Taxes - Staff	40,403	41,211	42,035
Professional Fees	11,864	12,101	12,343
Billing Expense	107,488	109,638	111,831
Advertising/Promotion	15,000	7,500	5,000
Office Supplies	16,501	16,831	17,167
Medical Supplies	164,039	167,320	170,667
Dues and Subscriptions	14,100	14,382	14,670
Computer Expense	18,000	18,360	18,727
Purchased Services	-	-	-
Bank & Credit Card Fees	-	-	-
Permits/Licenses/Fees	-	-	-
Postage	-	-	-
Misc.	-	-	-
Malpractice/ Insurance	23,508	23,978	24,458
Utilities	3,078	3,140	3,203
Telephone and Answering Services	18,564	18,935	19,314
Depreciation & Amortization	-	-	-
Repairs/Maintenance/Security	4,037	4,118	4,200
Equip. Leases/Repairs/Maintenance	-	-	-
Rent	177,654	181,208	184,832
Taxes & Licenses	-	-	-
Total Expenses*	\$ 1,086,947	\$ 1,100,886	\$ 1,120,253
Total Revenue Less Total Expense	\$ 1,062,813	\$ 1,205,188	\$ 1,369,644
Physician Compensation			
Base Compensation	1,893,469	1,893,469	1,893,469
Bonus	189,347	189,347	189,347
Additional Compensation	-	-	-
Additional Compensation (Net Practice)	-	-	-
Benefits	134,913	137,611	140,363
Payroll Taxes	85,223	86,927	88,666
CME	12,000	12,000	12,000
Total Physician Compensation	\$ 2,314,952	\$ 2,319,354	\$ 2,323,845
EBITDA	\$ (1,252,138)	\$ (1,114,167)	\$ (954,201)
Build-out Cost (one time fee)	30,037	-	-
Depreciation & Amortization	1,283	1,283	1,283
Interest	-	-	-
Potential Renovations/Buildout	35,000	-	-
Net Income/(Loss)	\$ (1,318,458)	\$ (1,115,450)	\$ (955,484)
Net Income/(Loss) Per Physician	\$ (439,486)	\$ (371,817)	\$ (318,495)

Where there are financial shortfalls as in the example above, the commercial reasonableness of the arrangement is particularly important to document including, but not limited to, the following:

- a description of the business purpose of the contemplated transaction;
- a description of the national, regional, and local economic considerations that influence the contemplated agreements;
- an overview of the non-financial considerations impacting the contemplated transaction (e.g., community need, gaps in coverage, expansion of care and coverage, new services lines, operational synergies, etc.); and
- description of alternative solutions considered by the healthcare system to address the need.

Supporting Documentation

Regulatory requirements include proper documentation of fair market value (“FMV”) that supports the compensation to be paid and ties to final executed agreements. Further, the Stark Law notes that the agreement must be arms-length³, which generally assumes some level of negotiation. A challenge exists in both trying to negotiate in an arms-length way that passes regulatory muster while making sure any negotiated remuneration is consistent with FMV.

A valid determination of FMV should:

- Consider multiple sources of information;
- Account for all services provided to and by the provider;
- Recognize any external factors such as recruiting challenges, payor mix, patient acuity, etc.; and
- Take into account any payments received outside of the arrangement.

Given the complex regulatory laws involved in physician affiliations which require FMV, healthcare systems should be working with valuation firms to support FMV and obtaining legal advice regarding structuring the arrangement in a compliant manner.

Approval Process

Once all supporting documents are compiled, the arrangement requires final approval from the body in the organizational governance structure that has the right to approve the arrangement. Failure to follow the healthcare system’s approval process can be used by the Department of Justice to find a knowing violation. While healthcare systems can have different approval structures, a best practice for regulatory compliance is to have a Compensation Committee that is composed of legal, financial, and operational professional at an executive level.

Execution and Monitoring

It is important to have systems, policies, processes, and procedures in place in order to maintain compliance for arrangements between organizations and actual sources or recipients of health care business or referrals and that involve, directly or indirectly, the offer, payment or provision of anything of value (“Focus Arrangements”). The best summary of recommended processes is found in Corporate Integrity Agreements (“CIAs”) between the

³ Fair market value is generally defined as “the value in an arms-length transaction, consistent with the general market value of the subject transaction.” 42 CFR § 411.351.

Office of Inspector General (“OIG”) and entities that have entered into a civil settlement with the OIG. In particular, the CIA between the OIG and Alliance Parent in 2021⁴ provides an excellent template of the types of systems, policies, processes, and procedures a healthcare system should have in place for ensuring compliance with both the Anti-Kickback Statute and the Stark Law which are reasonably designed to ensure that Focus Arrangements do not violate those laws including:

- **Creating and maintaining a centralized tracking system** for all existing, new, and renewed arrangements, with a plan to audit and monitor all Focus Arrangements;
- **Documenting the names and positions of covered person(s)** involved in the negotiation, review, and approval of all Focus Arrangements;
- **Tracking all remuneration to and from all parties** to Focus Arrangements to ensure that the parties are complying with the financial terms of the focus arrangements and that the Focus Arrangements are commercially reasonable;
- **Documenting all FMV determination(s)** for any Focus Arrangement, including the FMV amount or range and corresponding time period(s), the date(s) of completion of the fair market valuation(s), the individuals or entities that determined the fair market value amount or range, and the names and positions of the focus arrangements covered person(s) who received or were otherwise involved with the FMV determination(s);
- **Tracking service and activity logs** to ensure that parties to the arrangement are performing the services required under the applicable Focus Arrangement(s);
- **Monitoring the use of** leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s);
- **Establishing and implementing a written review and approval process for Focus Arrangements**, the purpose of which is to ensure that all new and existing renewed Focus Arrangements do not violate the Anti-Kickback Statute or Stark Law and that includes at least the following: (i) a legal review of all Focus Arrangements by counsel with expertise in the Anti-Kickback Statute of the Stark Law as applicable; (ii) process for specifying and documenting the business need or business rationale for all Focus arrangements, and (iii) a process for determining and documenting the FMV of the remuneration specified in the Focus Arrangement.

⁴ [Alliance Parent, Inc. Corporate Integrity Agreement](#)

- **Internal review and approval of existing, new and renewed Focus Arrangements**, including those policies that identify the individuals required to approve each type or category of focus arrangement, the internal controls designed to ensure that all required approvals are obtained, the processes for determining and documenting the business need or business rationale for all Focus Arrangements, the processes for determining and documenting the FMV of the remuneration specified in the Focus Arrangement, and the processes for ensuring that all Focus Arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute and Stark Law;
- **Require the Compliance Officer to annually review of and report** to the Compliance Committee on the Focus Arrangements' tracking system, internal review and approval process, and other Focus Arrangements systems, process, policies, and procedures; and
- **Implementing effective responses** when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including systems, process, policies and procedures that address disclosure of such violations and quantification and repayment overpayments when appropriate.