feature focus

Risk Assessments and Compliance

Editor's note: The following articles are focused on issues related to risk assessments for hospitals, rehabilitation facilities, homecare, and skilled nursing facilities.

The first article, Risk management: Are your physician financial relationships out of control? was written by John P. Krave, JD. John is a partner in the Los Angeles law office of Davis Wright Tremaine, LLP. He may be reached by telephone at 213/633-6800 and by e-mail at johnkrave@dwt.com.

The second article, Identify risks, evaluate controls, remediate weaknesses, and repeat! (for IRFs, CORFs, and ORFs) was written by Christine Bachrach and Tedra Bonar. Christine Bachrach is Senior Vice President and Compliance Officer at HealthSouth Corporation in Birmingham, AL and may be reached by telephone at 205/-970-5853 or by e-mail at Christine.Bachrach@healthsouth,com.

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Risk management: Are your physician financial relationships out of control?

By John Krave, JD

For all the resources devoted to hospital risk management in an operational sense, it is ironic that many hospitals fail to devote adequate financial and human resources to the one institutional risk that is entirely controllable: the facility's direct or indirect financial relationships with referring physicians. In our experience, every hospital has such relationships, yet few catalogue and assess these relationships to avoid violating state Medicaid and federal Medicare laws that prohibit bribes and kickbacks (anti-kickback laws) in connection with patient referrals and certain self-interested referrals (Stark Laws). The Stark Law has indirect application to the referral of Medicaid patients. Even facilities that have extensive legal compliance programs often neglect to maintain a central listing of their physician relationships and to review them at regular intervals to ensure their ongoing legality in light of changes in state or federal law. In our experience, the problem is especially acute among hospital systems, resulting in inconsistent contracting practices and compliance standards.

The Stark Law (42 U.S.C §1395nn) offers a template for a review of facility financial relationships. Simply stated, the Stark Law prohibits physicians from referring patients for certain "designated health services" (DHS) to any person or entity with which they have a "financial relationship," except where the arrangement qualifies for an express exemption. The law is of direct and immediate relevance because "designated

health services" include inpatient and outpatient hospital services, as well as most radiology, laboratory, and other diagnostic procedures. As a result, while it is almost always necessary for a hospital to structure its financial relationships with referring physicians to qualify for a Stark exemption, many facilities have informal compensation arrangements that trigger the statute but remain undocumented in violation of the law. The other byproduct of hospital oversight is the facility's continued participation in hoary "evergreen" relationships, often in the form of joint ventures or medical directorships, that violate the criminal anti-kickback laws, which prohibit the payment of direct or indirect remuneration in exchange for patient referrals. For these reasons, the cataloguing and assessment of such relationships is advisable, even if a facility is not among the "Lucky 500" selected by CMS to prepare required comprehensive reports of their financial relationships later this year.

Because of their informality and often relatively small dollar volume, a significant percentage of providers are unable to even identify the full range of such relationships at their facility. A simple three-step inquiry rooted in Stark Law definitions may assist in the identification and assessment of physician relationships that pose potential risk to hospitals.

Step 1. Does the hospital have a financial relationship with the physician? The Stark Law's definition of "financial relationship" serves as a baseline for a review of physician arrangements. The term has the following applications:

- A financial relationship may result from a physician's ownership or investment interest in the entity to which he or she makes a referral of designated health services (the "Referral Target"). Such interest may be direct or indirect, and may arise through debt, equity, or other means. The restriction often affects physician referrals to a limited partnership or other provider joint venture in which he or she holds an ownership interest.
- A financial relationship exists where a physician has a compensation arrangement with the Referral Target. Compensation arrangements include any relationship involving remuneration between a physician (or a member of the physician's immediate family) and the Referral Target. The remuneration in a financial relationship may be direct or indirect, in cash, or in kind. Hospitals should regard any circumstance in which they are remunerating a physician, regardless of context or amount, as constituting a financial relationship which requires periodic assessment.

The great majority of ownership or investment interests will be documented to some extent, and Stark law compliance should be readily apparent based on transaction documents. It is noteworthy that the Stark Law generally exempts physician ownership in a "whole hospital" if he or she is a member of its medical staff. (Ownership of a hospital department or other sub-unit does not, on the other hand, qualify for exemption.)

If the hospital and physician are co-owners of a joint venture, even if initially structured or approved by legal counsel, the facility should review the arrangement at least annually to ensure that the business is operating in accordance with its original purpose and documentation. More important, the hospital and its legal counsel should periodically review individual ventures to ensure that their structure and operation comply with frequent changes in the Stark Law or government regulatory interpretations, as well as with advisory opinions concerning the Anti-kickback Law issued by the Office of Inspector General (OIG) of the Department of Health and Human Services. Recent proposed changes to the Stark Law interpretations of "per-click" leasing arrangements merit particular attention.

A different problem affects compensation arrangements: Hospitals often overlook them or fail to recognize the breadth of their Stark Law obligations in this regard. Many hospitals are large, de-centralized operations typified by "left hand/right hand" management issues, particularly in the context of comparatively small outlays that, when viewed in isolation, are insignificant line items in a much larger departmental budget. Given such circumstances, it is not difficult to see how relatively minor or temporary payments for call coverage or medical directorships can escape notice. Ill-informed managers may also be under the impression that relatively minor payouts or benefits to physicians do not require accounting.

The most effective cure for the problem is maintenance of a centralized log of all physician arrangements, updated on a monthly or quarterly basis. At minimum, the chief executive officer, chief financial officer, and facility compliance officer should maintain current and updated copies of the log. As in the case of ownership and investment interests, facilities should also periodically review compensation arrangements for their legal currency. For example, the Centers for Medicare and Medicaid Services (CMS) has proposed to revise its Stark Law interpretation of percentage-based compensation rules and payment for services provided "under arrangement."

Step 2. Does the hospital have its compensation arrangements with physicians in a written document? As a starting point for the second step of its analysis, the hospital should inquire whether it has a written contract or other writing to document the purpose and terms of all physician compensation arrangements to which it is party. Indeed, the great majority of compensation arrangements between physicians and hospitals require a written agreement between the parties in order to qualify for a Stark Law exemption, regardless of whether the facility is remunerating the physician, or the converse.

Continued on page 25

Even in the case of such minor items as incidental benefits to medical staff members, the limits are so low and the Stark Law exceptions so narrow that hospitals should, as a matter of policy, mandate file memos to document the purpose for the arrangement and the rationale for concluding why it qualifies for a Stark Law exemption. For example, Phase II of the Stark Law regulations exempt certain incidental benefits by a hospital to its medical staff, provided such items are used only in connection with the care for hospital patients and are limited in value to $25 per occurrence of the benefit, adjusted for inflation. Although no contract is required, the required use of a file memo will at least mandate centralized control of such practices and will compel attention to detail required for compliance.

The following are among the more common relationships that are required to be in writing:

- **Personal services arrangements,** including medical directorships, provider-based physician contracts (e.g., radiology, pathology, emergency department), coverage agreements, and arrangements in which the hospital provides management or billing services to the physician's practice;
- **Space leases,** including space within the hospital or a hospital-owned medical office building, or an arrangement in which a physician is leasing space to the hospital;
- **Equipment leases,** including any arrangement in which the hospital or physician lease any type of equipment to the other; and
- **Recruitment or retention arrangements,** including any circumstance in which the hospital remunerates the physician or a sponsoring group to recruit the practitioner to its service area, or less often, to retain a physician within its service area.

If the hospital lacks a written contract with respect to any of the foregoing, the arrangement is unlikely to qualify for a Stark exemption, in which event the subject physician may not refer Medicare patients to its facilities for inpatient or outpatient services or other DHS.

Step 3. If the hospital and physician have a written contract to cover a physician relationship, does it qualify for a Stark Law exemption? The threshold analysis is uncomplicated; the Stark Law exceptions for personal services arrangements, equipment leases, and space leases are similar and require the following:

- **Written agreement.** The written contract must be executed by the parties and cover all aspects of an arrangement. For example, a simple "Memorandum of Lease" describing the leased premises and basic rent is usually inadequate for an office space lease, because the parties have doubtless agreed on indemnities, representations and warranties, allocation of expenses, repairs and maintenance, eminent domain rights and countless other details integral to the arrangement.
- **Legitimate business purposes.** The lease or services agreement may not cover more space, equipment, or services than are reasonable under the circumstances. For example, a hospital may not lease an unnecessary amount of office space from a referring physician for the purpose of enhancing the rental payments, regardless of whether the basic rent reflects fair market value. Hospitals may not "featherbed" by providing "make work" administrative positions for key physicians, even if compensation is fair market value for the position.
- **Fair market consideration.** The agreement must establish fair market rent or compensation determined in a manner independent of the value or volume of referrals between the parties. Hospital files should include memoranda demonstrating the basis for this conclusion in specific instances. Consultation with legal counsel is often advisable due to the complexity of the issue.
- **Compensation set in advance.** Rent or compensation must be determinable in advance, either by use of a fixed amount or establishment of a formula that does not vary in accordance with referral value or volume. CMS has proposed a revised rule with respect to equipment leases where rent is determinable on a "per click" basis.
- **Term of at least one year.** The purpose for this requirement is to ensure that the parties are not permitted to adjust rent or compensation based on referrals. Most commentators have concluded that parties may provide for earlier termination if the contract precludes them from re-contracting until expiration of the original one-year period.
- **Commercial reasonableness.** Independent of other considerations, the arrangement must be commercially reasonable, even if there were no referrals between the parties.
- **No requirement for referrals.** The agreement cannot require either party to refer or order business from the other under any circumstances, either pursuant to express terms or by implications. The arrangement must also meet any other requirements established by the Secretary of Health and Human Services to protect against payment abuse. The changing nature of such requirements (e.g., the evolution in the "per click" leasing requirements) compels periodic review of particular arrangements.

Storm signals should arise for any personal services arrangement or equipment or space lease that does not meet the foregoing requirements. The facility should take immediate measures to bring such arrangements into compliance. For all other compensation arrangements, as well as ownership and investment interests, hospital files should catalogue the applicable Stark Law exception and the rationale in favor of compliance. When in doubt, legal consultation is advisable. ■

Continued on page 26

 ...continued from page 25

Identify risks, evaluate controls, remediate weaknesses, and repeat! (for IRFs, CORFs, and ORFs)

By Christine Bachrach and Tedra Bonar

In several past articles in *Compliance Today*, we have been provided with many excellent examples of how to conduct a risk assessment. This article is also about compliance/regulatory risk assessment, but is focused on the specifics surrounding the determination and documentation of risks, controls, and remediation activities for inpatient rehabilitation facilities (IRFs), comprehensive outpatient rehabilitation facilities (CORFs) and outpatient rehabilitation facilities (ORFs).

Risk identification

The first and one of the most important steps in the risk assessment process is identifying the risks. Many risks apply to all healthcare providers, but some risks apply only to a particular care setting. Risks can be identified from several sources, including government resources such as the OIG Work Plan, CMS's Conditions of Participation, CMS Claims Processing Manuals, OIG Advisory Opinions, and recent court cases and decisions. In addition, interviews with key management personnel, operational data and reports, previous organization risk-assessment activity, and industry journals provide valuable information. No one source is entirely comprehensive, and as many sources as possible should be consulted to make the list as all-inclusive as possible.

The process begins by pinpointing all of the main categories of risk for the organization. This will help ensure that all stakeholders are included in the process. Interviews or group brainstorming will provide input to the compliance office regarding the risks that may be high priority, based upon the perception and activity from regulatory agencies. Eventually, the risks can be put into sub categories within each of your main categories.

Some risks that are specific to IRFs, ORFs and CORFs are listed in Tables 1-3.

As with any risk assessment, additional categories will become part of the review and may include: Anti-kickback and Stark laws, state and federal licensure, credentialing, Certificate of Need requirements

Table 1

Care Setting: Inpatient Rehabilitation Facilities (IRFs)				
Category	Sub-Category	Sub-Sub Category	Risk	Why is this a risk?
Hospital billing integrity	Medical necessity	Medicare admissions criteria	Patient admission does not meet medical necessity criteria	Medicare Benefit Policy Manual, chapter 1, Inpatient hospital services covered under Part A and Medicare Claims Processing Manual, section 140.1.1
		3-hour "Rule"/ Guideline (therapy services)	Failure to furnish intensive therapy services during IRF stay	This is not in any regulation (See *Matthews v. HealthSouth* – "intensive rehabilitative services" is not idefined in Medicare statutes and regulations.") However, CMS has suggested that Peer Review Organizations (PROs) in the claims-screening process (*Hooper v Sullivan*) should automatically kick claims to an MD for review for medical necessity, if a claim does not contain 3 hours of therapy per day.
	Services performed within scope of practice	Licensed personnel	Licensed personnel (PTA/ATC) furnishes treatment not permitted by state scope of practice rules	42 CFR 482.56
		Unlicensed personnel	Unlicensed personnel (e.g., rehab tech) furnishes treatment not permitted by state rules	See your state specific laws.
	Case-level payment adjustments	Early transfers	Delaying discharge dates in order to avoid early transfer payments for Medicare patients	Medicare Claims Processing Manual, Section 140.2.3
		Interrupted stays	Improperly billing for two separate and distinct stays when a Medicare patient is discharged and readmitted within 3 days	Medicare Claims Processing Manual, Section 140.2.3
		Short stays	Delaying discharge dates in order to avoid short stay payments for Medicare patients	Medicare Claims Processing Manual, Section 140.2.3

Table 1 continued

Care Setting: Inpatient Rehabilitation Facilities (IRFs) *continued*				
Category	**Sub-Category**	**Sub-Sub Category**	**Risk**	**Why is this a risk?**
	Coding	IRF - CMGs,ICD-9, HIPPS, FIM, PAI, IGCs	Late submission/ filing of PAI	Medicare Claims Processing Manual, Section 140.1.4
			Inaccurate diagnosis coding placed on PAI leading to incorrect co-morbidity tier	Medicare Claims Processing Manual, Section 140.1.2
			Inaccurate FIM score placed on PAI	FIM score placed on IRF Patient Assessment Instrument (PAI) drives CMS payments. See The Inpatient Rehabilitation Facility Patient Assessment Instrument Training Manual 04/01/04- *www.cms.hhs.gov /InpatientRehabFacPPS/downloads /irfpaimanual040104.pdf*
			Integration of codes into Case Mix Group is inaccurate	Medicare Claims Processing Manual, Section 104.2.2
		IRF- Discharge disposition	Incorrect assignment of discharge disposition	This can affect amount of payment made to the IRF.
Professional billing integrity	Billing for non-employed providers	None	Inappropriately billing for inpatient services performed by non-employed providers (e.g., nurse practitioners, radiologists, etc.)	Depending upon the contract and situation, it is important for the IRF to understand whether it is to charge for the professional component or if the non-employed provider is to bill.
Conditions of Participation	Classification of IRF - 75% Rule	None	Facility does not meet required threshold for CMS-13 qualifying discharges as a percentage of all discharges	Medicare Claims Processing Manual, Section 140.1.4
			Inaccurate assignment of impairment or qualifying diagnosis code	Medicare Claims Processing Manual, Section 140.1.4
		Orthotics and Prosthetics (O&P)	Substantial price concessions offered by a vendor for PPS-covered O&P items in exchange for referrals of items that a vendor may bill directly to Medicare	Medicare Claims Processing Manual (Pub. 100-04), sections 110.3.1, 110.3.2, 110.3.3 & 130.1
			Failing to pay an outside vendor for an O&P item that is necessary during the IP stay for which hospital is responsible	
		Ambulance/ Transportation	Substantial price concessions offered by a vendor for PPS-covered transportation services in exchange for referrals of services that a vendor may bill directly to Medicare	Medicare Claims Processing Manual (Pub. 100-04), section 10.4.
			Failing to pay an outside vendor for transportation that is necessary during the IP stay for which hospital is responsible	

KEY

CMG = Case mix group
COTA = Certified occupational therapy assistant
CPT = Current Procedural Terminology
FIM = Functional Independence Measure
HIPPS = Health Insurance Prospective Payment System
ICD-9 = International Classification of Diseases 9th Edition
IGC = Impairment Group Code
IP = Inpatient
MD = Medical doctor
O&P = Orthotic and prosthetic
OPT = Outpatient
OT = Occupational therapy
PAI = Patient assessment instrument
PRO = Peer review organization
PT = Physical therapy
PTA/ATC = Physical therapy assistant/Certified athletic trainer
PoC = Plan of Care
PPS-covered = Prospective Payment System-covered
PT or ST (PoC) = Physical Therapy or Speech Therapy (Plan of Care)
SW = Social worker

(which may include charity requirements), credit balances, Environmental Protection Agency laws, controlled substances, clinical research, wage-and-hour laws, discrimination laws, records management, HIPAA Privacy and Security, Occupational Safety and Health Agency laws, third-party payors contracts, etc.

Evaluation of control activities

Once the risks are identified, compliance personnel should work again with management and line-level staff to determine what controls exist for each of the risks. This may be accomplished by getting a general idea of the controls and their effectiveness or by formally documenting the controls. This formal control determination and documentation may be an extremely difficult part of the process, but if done thoroughly, it will allow the later validation or testing to run more smoothly. It is important to keep in mind where your organization is, with respect to its level of implementation of an enterprise risk

Continued on page 29

see page 34

The following is an example of a remediation plan for an ORF.

High Priority Remediation Area: Unlicensed Personnel Assessment: Current Process/Potential Controls:

1.) Position responsibilities and degree of supervision that must be provided are outlined in the policies regarding student programs, rehabilitation technicians, physical therapy assistants, occupational therapy assistants, and use of non-licensed clinical staff. All policies are included in the updated ORF Policy and Procedure Manual distributed to the field by February 1 of each year via e-mail (PDF document) and are also posted on the company Intranet. All clinic staff are required to read the complete policy manual and sign an acknowledgement form which is kept on site at each ORF in the staff's Human Resources file.

2.) Per the Responsibilities of the Program Evaluation Committee Policy, an overall therapy program evaluation is to occur quarterly. The Committee is responsible for reviewing the results of chart audits on each clinician in the facility for compliance with appropriate medical documentation standards. In addition, the Committee will review statistics related to delivery of therapy services in the facility. Data will be trended as appropriate for use in performance improvement plans as well as submitted to the Compliance Committee for exception reporting.

3.) Chart audits are conducted monthly to verify that clinical and patient demographic data supporting patient charges and billing requirements are present in the patient medical chart. Insurance information entered into the billing system determines what claim form fields are populated with clinician licenses, if required, and prevents claim from being billed if fields are not completed.

Table 2

Care Setting: Outpatient Rehabilitation Facilities (ORFs)				
Category	Sub-Category	Sub-Sub Category	Risk	Why is this a risk?
Billing integrity	Services performed within proper scope	None	Inappropriately billing for services performed by unlicensed personnel (aides or students)	Medicare Benefit Policy Manual (Pub. 100-02), chapter 15
			PTA/ATC (licensed personnel) treats patient when payor does not allow treatment	42 CFR 484.4 and Medicare Benefit Policy Manual- section 230.1.C
	Coding	Outpatient - CPT	Incorrect modifier usage (Specifically the review of the use of the KX modifier)	Medicare Claims Processing Manual, chapter 5- Part B Outpatient Rehabilitation and CORF/OPT Services
	Individual vs. group therapy	None	Billing Medicare for individual therapy when group therapy was performed	Medicare Benefit Policy Manual (Pub. 100-02), chapter 15
	Medical necessity	None	Treatment cannot be medically supported	Medicare Claims Processing Manual, chapter 5 Part B Outpatient Rehabilitation and CORF/OPT Services (throughout the manual)
	Plan of Care (POC)	None	Services performed fail to conform to POC	Medicare Benefit Policy Manual (Pub. 100-02), chapters 1 & 15
			Physician signature not received timely on initial POC	
			POC does not meet technical standards for payment (e.g., goals, etc.)	
			Re-evaluation billed without appropriate documentation regarding medical necessity	
			POC extension not developed and signed by physician in a timely manner	

management (ERM) model and/or adoption of a Sarbanes-Oxley Act (SOX)/Committee of Sponsoring Organizations of the Treadway Commission (COSO) fraud risk-assessment framework, to determine if a new framework needs to be developed, or if an established model can be modified to include the compliance elements. To prevent duplicate work within the organization, it is imperative to search thoroughly (i.e. really get to know the organization) when looking for control information. Controls can be developed by reviewing such data as: events metrics, insurance and lawsuit claims, external reviews, and technology risk assessments.

Controls can be classified as preventive (e.g., education, training, approvals, pre-billing edits) or detective (e.g., surveillance audits, outlier analyses).

Documentation of controls is not documentation of a process, but rather the documentation of "proof" that the process is working (that "proof" is the control). An example of the difference between process and control would be the training for new coders. The process may be that new coders are trained via an online education course within 30 days of hire. The control may be that the human resources manager runs weekly exception reports (i.e., hired >21 days previously and not yet trained) from the system and follows up with the coders and their supervisor.

Documentation of the controls can take many forms and can be as simple as adding to the line items of risks in a spreadsheet. At the time of your documentation efforts, if you are able to obtain validation that the controls are working as designed (you are ahead of the game!), you should add that validation to the documentation.

An example of a detective control for the IRF Interrupted Stay risk is shown below.

Continued on page 31

Case-level payment adjustments	Interrupted stays	Improperly billing for two separate and distinct stays when a Medicare patient is discharged and re-admitted within 3 days	Detective Control: Finance manager generates and analyzes the claims data semiannually, using the previous 6 months data to identify claims with potential errors (i.e., two admission dates within 30 days for same patient) for an interrupted stay. Billing Office Manager reviews each patient file to confirm accurate billing. A written report of the summary of findings is presented to the Compliance Committee on a semiannual basis.

Table 3

Comprehensive Outpatient Rehabilitation Facilities (CORFs)				
Category	Sub-Category	Sub-Sub Category	Risk	Why is this a risk?
Billing integrity	Services performed within proper scope	None	Inappropriately billing for services performed by unlicensed personnel (aides or students)	Medicare Benefit Policy Manual (Pub. 100-02), chapter 15
			PTA/ATC/COTA (licensed personnel) treats patient when payor does not allow treatment	42 CFR 484.4 and Medicare Benefit Policy Manual- sections 230.1.C., 230.2.C & 230.3.C
	Coding	Outpatient - CPT	Incorrect modifier usage (Specifically the review of the use of the KX modifier)	Medicare Claims Processing Manual, chapter 5- Part B Outpatient Rehabilitation and CORF/OPT Services
	Individual vs. group therapy	None	Billing Medicare for individual therapy when group therapy was performed	Medicare Benefit Policy Manual (Pub. 100-02), chapter 15
	Medical necessity	None	Treatment cannot be medically supported	Medicare Benefit Policy Manual – chapter 12 Comprehensive Outpatient Rehabilitation Facility, section 20.1 and Medicare Claims Processing Manual, chapter 5- Part B Outpatient Rehabilitation and CORF/OPT Services (throughout the manual)
	Plan of Care (PT or ST)	None	Services performed fail to conform to POC	Medicare Benefit Policy Manual (Pub. 100-02), chapters 1 & 15
			Physician signature not received timely on initial POC	
			POC does not meet technical standards for payment (e.g. goals, etc.)	
			Re-evaluation billed without appropriate documentation regarding medical necessity	
			POC extension not developed and signed by physician in a timely manner	
	Duplicate billing	None	Contracted party (i.e. PT, OT, ST, SW) bills CMS for payment in addition to facility billing for payment for same service	42 CFR 485
Conditions of Participation		Physician Requirements	Facility does not have a contracted medical director	42 CFR 485
			Facility does not have an on-call physician to provide	
		Social Workers	Lack of contracted or employed social worker (or other comparable personnel) for vocational or social adjustment services	
		Therapist Requirements	Facility does not contract with or employ all required therapies- Physical, Occupational and Speech	

Ranking the risks

Once the determination has been made as to whether controls (or even perceived controls) are in place for the risks, a ranking process must occur to determine the risks that need immediate attention. Representatives from Compliance, Legal, Audit, and Operations (the more the merrier!) should evaluate the risks, either independently or as a group, to determine the level of importance of each risk. It may be helpful to think of "importance" as having two axes; how well a risk is managed on one axis and the probability or presumption that the risk will occur on the other. The level of importance encompasses such factors as whether controls are in place and what would happen if controls failed or have not been put in place (i.e., how well the risks are managed). The presumption evaluation looks at the nature of the business conducted ("inherent" risk) and/or "residual" risk (i.e., operational/strategic risk – "the way we do business" risk). Those risks with a certain importance rank then become the focus of the next year's remediation plans.

Remediation plans

The risks have been ranked and now it is time to remediate any

Continued on page 34

 ...continued from page 31

risks of greater concern (i.e., those with higher levels of importance). Depending on the risk and the controls that were previously documented, remediation activities can include controls development, validation of the controls activities, or monitoring activities. A brief description of these activities includes:

1. **Controls Documentation/Development** The process of determining the controls that are in place and/or building/developing controls for a defined risk.
2. **Validation Activities** Those activities conducted by either division/field personnel or an independent party to validate that defined controls are in place for a specific risk (i.e., Operations or Compliance Audit conducts audits and results are reported to the Compliance Committee). If a control has been developed and documented by internal personnel, then the validation of that control should be conducted by someone independent of the people involved in the process and the person who developed and documented the control. Controls themselves are not generally a validation activity unless they are specifically testing another control.
3. **Monitoring Activities–** Those activities that personnel conduct to monitor the controls and/or the processes associated with the controls for a defined risk (e.g., Compliance Office review of operations self assessments and/or review of outlier analyses results and the presentation of those results to the Compliance Committee). In many instances, this is making sure that reports or other activity that is defined in the controls is taking place as documented.

See page 28 for an example of a remediation plan for an ORF.

Remediation/Development of Controls:

Remediation Actions:

Action Item	Target Completion Date	Actual Completion Date	Final Control(s)	Assigned Accountability
Controls to be identified as part of the Compliance/ SOX controls project			See attached SOX Compliance Controls spreadsheet	Jane Doe, Sue Doe, John Doe
Action plan to follow up on Claims Processing Assessment Audits			See attached audit template	Jane Doe, Jim Doe

Validation of Newly Determined Controls:

Control #1: Quarterly review of all system payor edits performed by the regional business office (RBO) to prevent bills from being sent to the payor if a required clinician provider number is not included in the billing information.

Validation Activities:

Control Validation Activities/Methodology	Target Date	Actual Completion Date	Q4 Update	Assigned Accountability
Verification that review is completed quarterly			RBOs will be responsible for conducting the review, and the VP of Bus Office Ops will verify that the review is completed for all RBOs	Jane Doe,

Control #2: Field audits to be completed annually by Regional Clinical Coordinators for all locations. The auditor checks the personnel file of at least three employees and includes a check for the signed job description.

Validation Activities:

Control Validation Activities/Methodology	Target Date	Actual Completion Date	Q3 Update	Q4 Update	Assigned Accountability
VP of Clinical Operations runs an annual report of field audits completed. Also monitors results and follow up through Regional Clinical Coordinators.			2007 field audits are in progress and ongoing.	YTD report and audits completed.	Jane Doe,
Annual report of field audit results of signed job descriptions and copy of state practice acts on file – presented at end of year Compliance meeting.				To be reported at Jan 2008 Compliance meeting.	Sue Doe,

Findings:

Validation Findings	Division Response Next Steps/Comments	Assigned Accountability
The annual report of field audit results of signed job descriptions is present/on file in personnel files. Report to be presented at the Compliance meeting on [date]. Results:[Number of] "yes" answers out of the [total number of] audits, which is a [%] compliance rate.	Continue field audits and assign corrective action plans as needed	Jane Doe,
The annual report of the field audit results for copies of the State Practice Acts on site for each credentialed discipline presented at the Compliance meeting on [date]. Results: [Number of] "yes" answers out of [the total number of] audits, which is a [%] compliance rate.	Continue field audits and assign corrective action plans as needed	Jane Doe,

Control #3: Clinical System Report–allows for the review of accounts with evaluations and re-evaluations with a signature other than a Physical or Occupational Therapist

Validation Activities:

Control Validation Activities/Methodology	Target Date	Actual Completion Date	Q4 Update	Assigned Accountability
Quarterly clinical system report run by patient account number for evaluations and re-evaluations for all patients where the medical record contains a signature other than a Physical or Occupational Therapist.			To be reported at Compliance meeting middle month of each quarter.	Bobby Doe

Ongoing Monitoring:

Control	Monitoring Activity	Frequency of Monitoring	Assigned Accountability
Clinical System Report	Quarterly clinical system report run by patient account number for evaluations and re-evaluations for all patients where the medical record contains a signature other than a Physical or Occupational Therapist.	To be reported quarterly at the Compliance meeting.	John Doe
Field audits - Audits completed annually by Regional Clinical Coordinators for all locations. The auditor checks the personnel file of at least three employees and includes a check for the signed job description.	VP of Clinical Operations runs an annual report of field audits completed. Also monitors results and follow up through Regional Clinical Coordinators.	To be reported annually at the end-of-year Compliance meeting.	Jane Doe, Sue Doe
	Annual report of field audit results of signed job descriptions and copy of state practice acts on file.		
Quarterly review of all system payor edits performed by the RBO to prevent bills from being sent to the payor if a required clinician provider number is not included in the billing information.	RBOs will be responsible for conducting the review, and the VP of Bus Office Ops will verify that the review is completed for all RBOs	To be reported quarterly at the Compliance meeting.	Jane Doe

What next? We do it all again!

To prepare for the next year, the entire compliance risk pool (i.e., all documented risks) should be reviewed again by your organization to confirm that each of the risks is still a valid regulatory risk. Items that were determined to no longer be a risk due to regulatory, industry or operational changes can be deleted, and any new risks can be added. You must identify the risks, evaluate the status of controls, remediate any weaknesses, and repeat! ■

Continued on page 36

 ...continued from page 36

Home Health and Hospice risk assessment

By Lisa M. Silveria RN, BSN

Risk assessments are a vital aspect of any compliance work plan. Risk is essentially present or at least opportunistic in every facet of health care, potentially on a daily basis. You can either choose to bury your head in the sand or become proactive and develop and implement a system-wide risk assessment.

At Catholic Healthcare West, we regularly complete a risk assessment from a system-wide perspective. It addresses the mission, reputation, legal, and financial implications to the organization along with the vulnerability components of likelihood of occurrence and detectability. The assessment is then evaluated against the controls in place. This serves as a foundation for moving the compliance work plan forward, and gaining the resources and support necessary to bring all components and high-risk areas into compliance, if necessary.

In Home Health Care (HHC) and Hospice, we are looking at each aspect and then apply the following factors:

- **Exposure to loss and materiality** – review expenses, accounts receivable, billing practices, budgeting, financial reporting practices/guidance, cost reporting, and credit balance reporting; review audit trails established and in place;
- **Business environment risk** – consider economic conditions of service area, needs, competition, marketing; explore the impact of new regulatory changes and implications to product line;
- **Prior years audits/reviews** – review all prior DHS (Department of Health Services), CMS and JCAHO surveys completed within last 3-4 years; look for compliance and sustainability with corrective action plans; assess for trends and patterns and effectiveness of operations (most issues found here relate to clinical, documentation, coding, and operational practices);
- **Control environment risk** – assess current controls and mechanisms in place to support agency mission and practice; verify oversight processes and reporting tools are in place to hold agency and leadership accountable; review policies and procedures, job duties and segregation, operational systems and controls;
- **Management/governance concerns** – solicit input, as part of a large integrated healthcare system, from areas such as Risk, Legal, Finance, Revenue Cycle, Care Management and others to identify exposure and potential risk areas; assess system and governance awareness through reports, communications, and even orientation.

The HHC and Hospice risk assessment is part of the operational review performed when a new agency or healthcare system is acquired, changes in leadership occur, and as requested by any vested party or as a result of a periodic audit/review. The scope and depth of the assessment can vary upon need and findings from routine reviews or activity currently in place.

Specifics within each key category

HHC and Hospice have both Medicare Conditions of Participation (CoP) and State Department of Health Services Title 22 regulations specific to areas noted below. In addressing these areas, we assess not only current practice and compliance, but also operational vulnerabilities and potential focus areas.

I. Patient choice, including tracking and trending

- Assess and monitor satisfaction of referral base
- Assess for kickback issues/practices and policies in place to assure compliance with laws; assess for practices of free or reduced fee services directly or indirectly
- Review polices and procedures for admission and discharge criteria
- Review practices in place for referrals not accepted and arrangements made for appropriate care level

II. Policies and procedures in place - clinical assessments and internal referral practice and criteria

- Review determination of Medicare eligibility for services and documentation expectations
- Assess mechanisms in place to obtain and track physician signatures
- Assess care coordination practices and communications
- Review documentation expectations/timelines and clinical record review practices
- Determine agency reviews/monitors in place to track and trend therapy practices, diagnosis, and care path development

III. Utilization management (UM) and Quality - chart review practices and processes

- Measure and compare to national benchmark practices
- Monitoring and trending of visit utilization by discipline and also by employee
- Review contract management and evaluation

- Review care delivery to patients in other settings on service, risk assessment, care coordination, and communications
- Conduct interdisciplinary team (IDT) meetings and case conferences

IV. Internal reviews/auditing program – formal program at a minimum to include:

- Timeliness of claims submission
- Charge description master (CDM) current – internal processes to update as needed; match to charges and service delivery
- Fiscal intermediary (FI) or CMS review processes and findings
- Cost report practices and polices

V. Processes in place to monitor and support Compliance– questions to address to all levels of staff:

- Integrity Plan
- Governing Board integration and participation
- Policy and Procedures for administrative, operational, clinical, human resources and staff awareness and education
- HR practices, hiring, orientation, disciplinary, firing, background checks, annual review, competency assessment and management
- Complaint management and trending

Summary

Integrated health care systems are becoming more reliant on risk assessments and expertise for conducting risk assessments for all their service lines. This allows the organization to globally evaluate the practices currently in place with a broader-stroke overview assessment, potentially identifying specific areas of non-compliance, working proactively and effectively toward corrective action steps, and monitoring for success.

It is essential to assess all internal and external components of the service line, rather than performing a risk assessment based upon a "hunch" or with a narrow focus. That way, you can conduct a more consistent, thorough, and comprehensive risk assessment that inevitably produces a solid work plan and corrective action strategy. ■

 ...continued from page 37

Risk assessment for skilled nursing facilities: Quality of care

By Deborah Rubbens, JD, LLM

Approximately 3 million elderly and disabled Americans receive care in our nation's nearly 16,500 Medicare- and Medicaid-certified nursing homes. Quality care for nursing home residents is a high priority for the current Administration, the Department of Health and Human Services (HHS), and the Centers for Medicare and Medicaid Services (CMS). Consequently, nursing facilities are closely monitored by the HHS Office of Inspector General (OIG), the Department of Justice (DoJ) and CMS.

The complexity of rules and regulations governing skilled nursing facilities (SNF) and the competitiveness of today's health care environment require that SNFs have an "early warning system" to detect potential risks. According to experts, "Like a weather forecasting system, organizations should continuously scan the enterprise's environment for potential warning signs and constantly update management on whether any particular risk is likely to occur, what the probability of its occurrence is, and how it could impact the organization if it does occur."[1]

Unrecognized or unmanaged risks, especially quality of care risks, can be lethal to the success of any health care provider. Much emphasis has been placed on quality care delivery as evidenced by extensive media coverage, numerous enforcement actions, and increased regulations. SNFs are thus advised to formulate and implement effective internal controls to ensure compliance with applicable state and federal statutes, rules, and regulations.

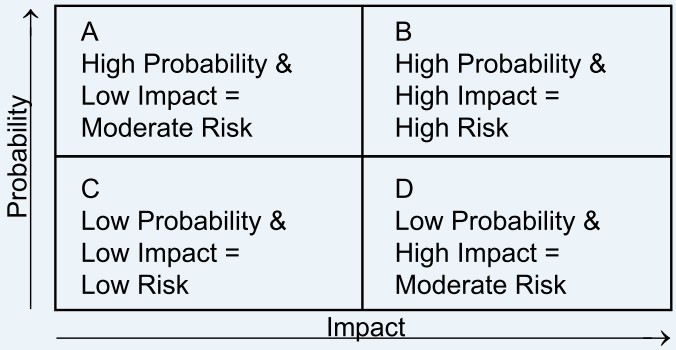
Because every nursing facility is unique, each one must determine for itself the areas where it is most vulnerable. Although the OIG Compliance Program Guidance for Nursing Facilities[2] (OIG Guidance) is a useful resource when identifying risk areas, the OIG also recommends that all nursing facilities evaluate their own compliance policies and procedures by conducting a baseline risk assessment as well as periodic reevaluations.

This article presents a simple, five-step framework that SNFs can use in conducting periodic risk assessments.

Framework for thinking about risks

Risk assessment is a continuous, dynamic process of gathering, analyzing, and updating information. Because risk assessment is such an important part of every compliance program, a simple framework is helpful in thinking about risks and their potential consequences.

In essence, a risk is a chance of injury, damage, or loss. Risk assessment involves the measurement of two factors: (1) the probability that the risk will occur, and (2) the magnitude or severity of the consequences if the risk occurs. The following table illustrates the relationship between probability and impact.



A risk that is highly probable and has potentially severe consequences would be considered a high risk (Box B), while a risk with low probability and modest consequences would be considered a low risk (Box C). Those risks that are most likely to occur and that have the greatest potential negative impact on the nursing facility should be managed through proper planning and control measures.

Identifying and prioritizing risk areas

The goal of a risk assessment is to identify, analyze, and minimize relevant risks associated with achieving the organization's objectives. The three main objectives of nursing homes are:

- Quality of care
- Effectiveness and efficiency of operations
- Compliance with applicable laws and regulations

The five key action steps in an effective risk assessment are:.

1. **Identify the risk areas:** Stay current with risk areas identified by the OIG, CMS, Medicare fiscal intermediaries and carriers, Medicaid State agencies, and other regulatory and law enforcement agencies.
2. **Evaluate risks and create policies and procedures:** Conduct an internal evaluation of the risks identified. Establish policies to avoid or reduce the level of risk, and then institute procedures to ensure that the policies are complied with.
3. **Educate and communicate:** Establish a mechanism to communicate effectively with the managers and staff of the departments affected.
4. **Rank risks:** Ask nursing facility department managers to identify and prioritize risk areas for their respective units.Rank risks according to importance and likelihood of liability exposure.
5. **Review and update:** Annually review the list of risk areas and include areas of greatest risk in the annual audit work plan.

Step 1: Identify risk areas. The first step in developing and implementing an efficient risk assessment is to know the environment in which you are operating. Each SNF should know well the risk areas presented in the nursing home industry.

All facilities should stay up to date with risk areas identified by the OIG, CMS, and other regulatory and law enforcement agencies that may issue rules, regulations, and reports on areas where SNFs are vulnerable.

To assist nursing facilities in conducting a risk assessment, the OIG has identified potential risk areas that the SNF can use as a starting point. Providers should also review the OIG's annual Work Plan to identify the particular vulnerabilities and risk areas on which the OIG will focus during the following fiscal year. The OIG's semiannual report identifies program vulnerabilities and risk areas that the OIG targeted during the preceding six months, and Special Fraud Alerts highlight immediate areas of concern.

The five broad SNF risk areas are:

- Quality of care
- Resident rights
- Billing and cost reporting
- Employee screening
- Kickbacks, inducements and self-referrals

Specific SNF risk areas monitored by the OIG for fiscal year 2007 include:[3]

- Rehabilitation and infusion therapy services
- SNF involvement in consecutive inpatient stays
- SNF payments for services on the day of discharge
- Consolidated billing
- Imaging and laboratory services in nursing homes
- Medicare Part D implementation
- SNF no-pay bills
- Inappropriate psychotherapy services

Quality of care is especially important in the nursing home industry. On March 16, 2007, the Inspector General testified that the OIG considers quality of care in nursing facilities one of its top three Medicare risk areas. With the expected growth and vulnerability of the long-term care population, the assurance of quality care warrants significant attention. CMS defines quality concerns as those in which the care given "results in a significant or potentially significant adverse effect on the patient."[4]

Since 1998, the Government Accountability Office (GAO) has reported on the unacceptably high proportion of nursing homes that provide poor care on a regular basis. The OIG has been working for several years on programmatic and legislative changes to improve quality in nursing facilities. CMS has also undertaken a number of enforcement initiatives to encourage nursing home compliance with federal quality standards. Nevertheless, concerns continue regarding quality care in nursing facilities.

Some of the special areas of concern to the OIG, CMS, and DOJ include:[5]

- Under- and over-utilization of psychotherapy services
- Impact of Medicare Part D on dual eligible residents
- Inappropriate or insufficient treatment and services to address residents' clinical conditions, including pressure ulcers, dehydration, malnutrition, urinary incontinence, and mental or psychological problems
- Absence of assessment of each resident's functional capability
- Inadequate staffing levels or insufficiently trained staff
- Failure to properly prescribe, administer, and monitor prescription drug usage
- Failure to provide appropriate treatment and assistance to maintain daily-living activities such as bathing, dressing, grooming, eating, toileting, and speaking
- Failure to prevent or treat pressure sores
- Failure to provide an ongoing activities program to meet the individual needs of all residents
- Failure to report incidents of mistreatment, neglect, or abuse to the administrator of the facility and other officials as required by law

Step 2: Evaluate risks and create policies and procedures. Once risk areas have been identified, each nursing home should evaluate the risks internally. It is necessary to verify the existence or likelihood of the risks and to assess their impact.

While an internal risk assessment is usually conducted under the lead of the compliance officer, the compliance committee or an ad hoc subgroup, the process should also involve upper management, department managers, and employees. Every employee–not just those charged with governance and management–is responsible for prevention and detection of fraud and errors.

Risk exposures can be identified and evaluated in many ways. Generally, a combination of interviews and reviews of written information will lead to the strongest analysis. Documentation to review may include the facility's strategic plan, organizational chart, internal and external audit reports, and policies and procedures.

Consider the development of a preliminary list of risks based on risk areas identified by the OIG and CMS, the compliance office, or a

Continued on page 43

hotline, where one exists. Once a list is established, the compliance officer or committee should contact relevant department managers to verify and add to the preliminary list of risks.

In-person interviews are recommended with senior management and the managers of departments where the greatest risks are likely to occur, such as the billing and coding or quality assurance functions. When face-to-face meetings are impossible, a risk questionnaire with a few questions from each risk category should be e-mailed.

During the interviews, managers should be asked to identify risks in their respective areas and then to discuss their policies and procedures for addressing each risk area. Many states require nursing facilities to have policies and procedures to prevent fraud, waste, and abuse in their institutions. Policies and procedures should be evaluated and updated regularly, given the ever-changing regulatory environment.

For quality of care, each facility should measure its performance against the standards set forth in federal regulations (42 CFR §483.25), CMS' requirements to qualify for participation in the Medicare and Medicaid programs, and state licensure requirements. Each SNF should develop and implement quality-of-care and care delivery protocols.

In addition, the OIG advises to "implement a system that reviews each resident's outcomes and improves on those outcomes through analysis and modification of the delivery of care."[6] One way to accomplish this is by developing and implementing a plan of care or plan of treatment signed by the treating nurse or physician for all residents. Such a plan can include all pertinent diagnoses, including a resident's mental status, prognosis, rehabilitation potential, functional limitations, nutritional requirements, and treatment.

Step 3: Educate and communicate. The compliance officer or committee should establish a mechanism to inform and educate affected departments or offices in a timely manner. While each SNF must decide how to best ensure that information is communicated quickly and accurately, the following approaches, or variations thereof, should be considered:

- The compliance officer, committee, or risk manager can host a risk assessment meeting to explain the risk assessment process and reach out to attendants for information. Introductory remarks from the CEO or COO demonstrate the nursing facility's commitment to the process.
- The CEO could send a letter to department managers to introduce the risk assessment, explain its importance, and request their participation.
- The compliance officer could send a letter or e-mail with the preliminary list of risks attached and ask for feedback.
- Risk information can be uploaded in the compliance section of the facility's Intranet.
- Articles on risks, their identification, control, and prevention can be published in the nursing home's newsletter.

Step 4: Rank risks. The next step in the risk assessment process is to prioritize the organization's response to the risks identified. The ranking should focus on the effectiveness of nursing facilities in meeting the needs of their patients and the quality of the services provided. Risks should be ranked according to importance and likelihood of liability exposure.

While all risk areas identified within an organization are inherently important, resource restraints require prioritization of risks. Cost-benefit analysis is a primary method of risk ranking. Questions to ask include:

- Has the OIG identified this area as high risk?
- Has the OIG audited this area in your region within the past two years?
- Has the nursing home been assessed overpayments for this procedure/risk area?

For quality of care, the questions include:

- Have any deficiencies been found in annual State or Federal Surveys?
- Has concern about this area been reported to management, the compliance officer, or the hotline?
- How would this look in the media?

Input should also be sought from department managers, who should, in turn, involve their employees in the risk prioritizations process.

Step 5: Review and update. The final step in the process is the annual review of identified risk areas and implementation of the policies and procedures targeting those risk areas. Strategies for dealing with the most serious risk areas should be incorporated into the annual work plan.

Because quality of care is such a high risk area for the nursing industry, nursing facilities should regularly evaluate the efficiency of their protocols that govern quality of care and care delivery by re-analyzing residents' health and level of care received. In this way, nursing facilities can better serve the public good and protect themselves from liability. ■

1 Kenneth E. Spence, Brian W. Kozik, Thomas P. Conaghan, and Leilani Kicklighter, Guide to Risk Assessments: Identify and Control Your Top Problem Areas, HC Pro, Inc., 2004, 5.
2 Office of the Inspector General, Compliance Program Guidance for Nursing Facilities, Federal Register, Volume 65, Number 52, Thursday, March 16, 2000. (hereinafter OIG Guidance)
3 Office of Inspector General, Work Plan Fiscal Year 2007, 7-8.
4 OIG Guidance.
5 42 CFR §483; Testimony of HHS Inspector General Daniel R. Levinson before the House Committee on Ways and Means, Subcommittee on Health and Oversight, March 8, 2007; OIG Guidance.
6 OIG Guidance.