

A STEP-BY-STEP GUIDE TO DEVELOPING A COMPREHENSIVE RISK ASSESSMENT & INCORPORATING IT INTO YOUR COMPLIANCE WORK PLAN

1. Understand the Organization (a/k/a “Establish Context”)

To put together a complete risk assessment, consideration must be given to all factors that affect the organization’s ability to carry out its mission and objectives. Examples of questions to ask to help establish context include:

- Who are we?
- What services do we provide and where?
- What licenses and certifications are needed for these services?
- What agencies oversee us?
- Who do we serve?
- How are we paid for services?
- How do patients choose us?
- Why do patients choose us?
- Who refers patients to us?
- Who do we refer patients to?
- Who are our other partners?
- What services do they offer?

Definitely do this exercise with your Compliance Committee and your senior leadership team. It could be as one large brainstorming exercise, or you could divide the group into smaller groups. Ultimately, you’re going to take this information and build a really good list of the people and things influencing the organization and the risks it faces. Before finalizing, distribute to your Compliance Committee for further review to ensure its complete.

2. Identify Risks.

- Take your organization’s specific list and use it to help identify specific risks. To help you start the process, consider defining broad risk categories first and then within each category, identify more specific risks. Examples of risk categories, include:

- Billing and Coding
- Quality of Care/Patient Safety
- Employees, Contractors & Vendors
- Inducements, Kickbacks & Referrals
- Privacy and Security
- High Risk Areas

- For “high risk areas” think of any service line or department within your organization where you may frequently encounter compliance issues, or it has been subject to prior

enforcement actions. Add to the high risk area any new services or service line you've recently added.

- Consider current areas of focus of federal and state regulators and enforcement agencies based on their published work plans, public statements, and recent enforcement activities. Add any that are relevant to your organization.
- Survey department leaders and your management team to request input on risk areas. Incorporate their responses.
- Distribute the identified risks to all members of the Compliance Committee for review and discussion. Make any additional refinements needed before finalizing the identified risks.

3. Analyze and Evaluate

- For each identified risk area, determine whether the cause is controllable or uncontrollable and whether the source of the risk is internal or external. In some cases, parts of a risk may be controllable and others uncontrollable. Some may be both internal and external. This will aid you later in determining risk mitigation strategies.
- Next, for each identified risk assign a number between 1 and 5 based on the perceived level of risk it presents to the organization and likelihood that risk will occur.
- Add those two numbers together; the resulting number is your "risk factor".
- Consider having each Compliance Committee member do this exercise separately and then have a meeting to go through and identify the rankings and develop consensus on the final risk factor assignments.

4. Determine Risk Mitigation Strategies (a/k/a "Develop Alternatives")

Once you have a comprehensive list of identified risks each with an identified risk factor or a mix of both, it's time to strategize ways to mitigate or remove the risk entirely.

- For each identified risk, identify strategies or measures to remove or mitigate the risk, including the types of resources that will be needed and whether internal or external resources will be required. To do this more efficiently, divide the list among your Compliance Committee members by assigning members to specific categories or identified risks based on their areas of expertise. Each Committee member should work to identify risk removal and mitigation strategies for each identified risk assigned to him/her. Committee members should consider working with, or getting feedback from, the applicable department leader(s).

- At the end of this exercise, distribute the full list of identified risks and risk mitigation strategies to the entire Committee for review.
- Meet again as a Committee and together for each identified risk based on the list of identified mitigation strategies, assign a number from 1 (low) through 5 (high) based on the level of resources (time, money, etc.) needed to implement the risk mitigation strategy. If some risks have multiple potential strategies not dependent on each other, separate them into separate lines and assign a resource level to each. This will be the “resource level” assigned to each identified risk.

5. Incorporate Into Your Compliance Work Plan (a/k/a “Respond to Risks”)

Now that you have a comprehensive list of risks with a risk level and resource level assigned to each and an understanding of which ones are internal, external, controllable and uncontrollable, it’s time to incorporate these risks and the risk removal and mitigation strategies into your compliance work plan.

Your compliance work plan is an evolving document which will span multiple years. A good rule of thumb is to “turnover” your work plan every three to five years, depending on the size and complexity of your organization.

To prioritize risks:

- For each risk, you should have a “risk factor” and a “resource level”. Subtract from the risk factor, the resource level assigned to the risk and list this in a separate column as “adjusted priority”
- Begin to prioritize, by pulling out and listing any risks with a risk factor of 9 or 10. These are high risk items.
- To further prioritize the high risk items, pull out any of the risks on this list that have an adjusted priority of 7 or higher. These will be your “highest priority” items. Rank them in order of their risk factor and adjusted priority assignment. For example, a risk with a risk factor of 10 and an adjusted priority of 9 would be listed at the top of the priority list and will have higher priority than a risk with a risk factor of 9 and an adjusted priority of 8. Since their risk mitigation measures have been identified as taking less resources, these should be easier to address and addressing one or more of them first can build some early momentum for your work plan. To help visualize this better you can also add the risk factor and adjusted priority numbers together and the higher the number, the higher the risk ranks in the priority list.
- Next, list as “high priority” items, any of the risk factors with a 9 or 10 that aren’t listed in the highest priority items (i.e., their adjusted priority is less than 7). Rank these in order of risk factor, followed by adjustment priority. For example, risk factors of 10 will be ranked first and those with risk factors of 9 will be further prioritized and ranked

based on their adjusted priority number (the higher the adjusted priority, the higher the ranking within risks with the same risk factor). These will be your high priority items.

- Move down your list, next assigning any risks with risk factors of 7 or 8 as “medium priority”. Follow the same process as for “high priority” rankings.
- After identifying “medium priority” items, assign any risks with risk factors of 4 through 6 as “average priority”. Follow the same process for ranking as above by listing those with the highest risk factors first and within those rankings ranking by adjusted priority.
- Finally, identify “low priority” items, assign any risks with risk factors of 2 through 3 as “low priority”. Follow the same process as ranking as above by listing those with the highest risk factors first and within those rankings, ranking by adjusted priority.

You should now have a prioritized list of risks and risk mitigation strategies for implementation which can guide your work plan. The priority list is intended to be flexible. You aren’t required to start at the top and work your way methodically down the list. Rather, you should develop your schedule and where each risk item fits within your work plan’s timeline based on what makes sense for your organization. For example, if the top five risks on your priority list all involve the exact same department, it may not be realistic to address all five in the same year. Feel free to sprinkle in average or low risk priorities, especially if they are identified as having very low resource levels and have a higher likelihood score.

You’ll want to build on this risk assessment throughout the year, making sure to identify the month and year when a risk item has been fully addressed. This will be helpful in the future when your work plan inevitably “turns over” so you can see how long its been since an item has been reviewed.

6. Monitor & Review

Make the work plan and risk assessment part of your standing Compliance Committee agenda and develop tools to document and share information on the work plan’s implementation.

Conduct an annual review of the risk assessment to determine whether any risks need to be added or removed and whether risk mitigation strategies have changed or need to be changed.

- At least three months prior to the start of the next work plan year, assign each member of the Compliance Committee the task of reviewing their assigned risk areas to determine whether the risk assessment needs to be updated. For example, if the service line that pertains to a risk was discontinued, the risk can be removed. Or, if a risk mitigation strategy involved an outside vendor you no longer work with, reassign the mitigation strategy. The Compliance Committee should seek input from senior leadership and applicable department leaders.

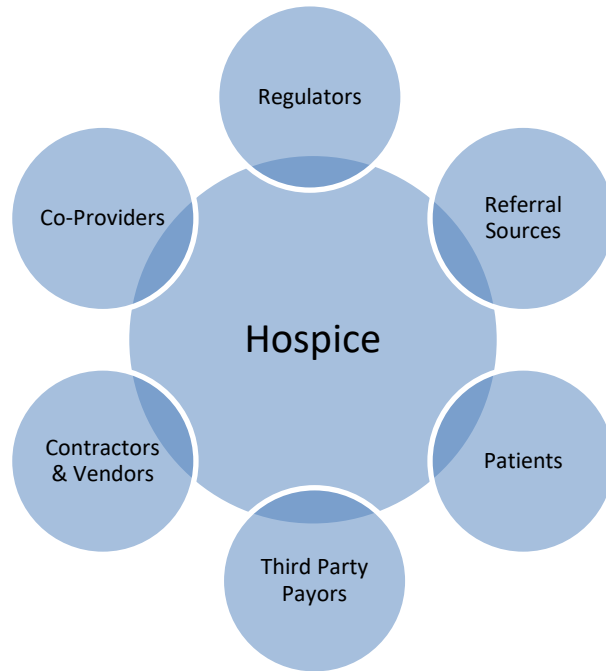
- Ask the Compliance Committee, senior leadership team and department heads to review the risk assessment to determine if any additional risks should be added in light of new events, enforcement activities, service line changes, etc. Any new risks assigned should be assigned a priority assignment (highest, high, medium, average or low) based on the above ranking process.
- Update the risk assessment based on the feedback, which may include updating the priority assignment of risk areas.
- Before the start of the next work plan year, determine the risk areas the work plan will prioritize for the year based on their priority rankings and what can realistically be accomplished.
- Repeat the process every year through the life expectancy of your work plan.
- When you reach the end of your work plan’s life expectancy, start the work plan process over from step one. You may find you’re listing the same risks but likely over the past three to five years there has been changes in the perceived severity and likelihood of the risk factor and the context of your organization may be different. For example, you may work with different vendors or different third party payers. Starting the risk assessment process from step 1 every three to five years can ensure you give full consideration to how the environment may have changed.
- If after the period of time you’ve identified for the life cycle of your work plan there are any risk areas you weren’t able to get to, if these are still risks identified in your subsequent work plan, make sure to prioritize them in the subsequent work plan to make sure they aren’t repeatedly “left behind” or “ignored”. Address these in the first year or two of the new work plan.

To help you visualize this process better, below is a Sample Risk Assessment for a fictitious hospice provider. This is provided for illustrative purposes. It should not be viewed as inclusive of all the various risks hospice providers face nor should you give any deference to the priority designation. It is provided solely so you can visualize the process better.

This Guide is intended for educational and informational purposes only. This document is not intended to be legal advice. Legal advice must be tailored to the specific circumstances and users are responsible for obtaining such advice from their own counsel. Nothing provided on this site should be used as a substitute for the advice of legal counsel.

Sample Hospice Risk Assessment

Step One: Understand the Organization/Establish Context



Regulators	Referral Sources	Patients	Third Party Payors	Contractors & Vendors	Co-Providers
<ul style="list-style-type: none"> • HHS • CMS • OCR • State Licensure • Accred. Org • State Medicaid • IRS 	<ul style="list-style-type: none"> • Physicians • Hospitals • SNFs/NFs • IL/AL • HHAs 	<ul style="list-style-type: none"> • Terminally ill • LTC resident • Inpatient • Homebound • Insured • Uninsured • Families 	<ul style="list-style-type: none"> • Medicare • Medicaid • TRICARE • Private Insurer 	<ul style="list-style-type: none"> • Medical Director • Therapy • Pharmacy • DME • Supplies • Staffing agency • EHR/IT Vendor 	<ul style="list-style-type: none"> • Attending physician • Hospital • NF/AL • Pharmacy

Steps Two Through Four: Identify Risks/Analyze & Evaluate/Develop Mitigation Strategies

Billing & Coding

A	B	C	D	E	F	G	H	I
Risk	Risk Level (1-5)	Risk Likelihood (1-5)	Risk Factor (B+C)	Risk Type	Risk Mitigation Strategies	Mitigation Resources	Resource Level (1-5)	Adjusted Priority (D-H)
Physician Certification for Hospice Services	5	5	10	Internal, controllable	<ul style="list-style-type: none"> • Audit, identify problems • Revise processes • Train • Audit again 	Internal w/support from consultant and counsel if necessary	2	8
Criteria for GIP Medicare billing	5	5	10	Internal, controllable	<ul style="list-style-type: none"> • Audit, identify problems • Revise processes • Train • Audit again 	External Audit Firm	4	6
Appropriate patient election form	5	4	9	Internal, controllable	Review and revise patient consent	Internal, with proposed consent reviewed by legal counsel	1	8

Quality of Care/Patient Safety

A	B	C	D	E	F	G	H	I
Risk	Risk Level (1-5)	Risk Likelihood (1-5)	Risk Factor (B+C)	Risk Type	Risk Mitigation Strategies	Mitigation Resources	Resource Level (1-5)	Adjusted Priority (D-H)
Medication Errors	5	3	8	Internal, controllable	<ul style="list-style-type: none"> • Audit, identify problems • Revise processes • Train • Audit again 	Internal	4	4
Drug Diversion	4	3	7	Internal/external, controllable, uncontrollable	<ul style="list-style-type: none"> • Implement strong processes to safeguard prescription medications, and avoid diversion by staff, family, etc. • Routine monitoring 	Internal	3	4

Employees, Contractors, Vendors

A	B	C	D	E	F	G	H	I
Risk	Risk Level (1-5)	Risk Likelihood (1-5)	Risk Factor (B+C)	Risk Type	Risk Mitigation Strategies	Mitigation Resources	Resource Level (1-5)	Adjusted Priority (D-H)
Unlicensed staff/contractors	5	2	7	Internal/external, controllable	<ul style="list-style-type: none"> • Build screening and validation processes • Train • Implement • Monitor 	Internal	2	5
Lack of Valid Business Associate Agreements	1	2	3	Internal, controllable	<ul style="list-style-type: none"> • Identify all business associates requiring BAA; • Determine if BAA exists; • Implement BAA for any missing • If any missing, perform breach assessment • Report any breaches 	Internal, may need assistance of counsel	3	0

Inducements, Kickbacks and Referrals

A	B	C	D	E	F	G	H	I
Risk	Risk Level (1-5)	Risk Likelihood (1-5)	Risk Factor (B+C)	Risk Type	Risk Mitigation Strategies	Mitigation Resources	Resource Level (1-5)	Adjusted Priority (D-H)
Medical Director Compensation	5	3	8	Internal, controllable	<ul style="list-style-type: none"> • Determine FMV compensation • Stark/AKS compliant agreement • Time tracking • Review annually 	Internal/External, (legal counsel and valuation expert)	2	6
Patient Incentives	3	3	6	Internal, controllable	<ul style="list-style-type: none"> • Review patient incentives being provided • Review policies • Determine if incentives fit within exceptions • Revise policies as needed • Provide training • Audit 	Internal with assistance from counsel as needed	4	2

Step Five: Incorporate Into Your Compliance Workplan

A	B	C	D	E	F	G
Priority Status	Risk	Risk Factor	Adjusted Priority	Total Score (C+D0)	Lead Department(s)	Work Plan Year
Highest Priority						
1	Physician Certification for Hospice Services	10	8	18	Care Team & Billing/Coding	2024
2.	Appropriate patient election form	9	8	17	Care Team & Billing/Coding	2024
High Priority						
3.	Criteria for GIP Medicare billing	10	6	16	Care Team & Billing/Coding	2025
Medium Priority						
4.	Medial Director Compensation	8	6	14	Executive/Finance	2024
5.	Medication Errors	8	4	12	Care Team	2025
6.	Unlicensed Staff/Contractors	7	5	12	HR	2026
7.	Drug Diversion	7	4	11	Care Team	2026
Average Priority						
8.	Patient Incentives	6	2	8	Care Team/Finance	2026
Low Priority						
9.	Lack of Business Associate Agreement	3	0	3	Executive	2025