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RISK ASSESSMENT OBLIGATIONS FOR MEDICARE ADVANTAGE AND PART D ORGANIZATIONS

by Regan A. Pennypacker

We assess risk all the time. What happens if we don't pay the electric bill? How close can we get to an angry dog? What if we said everything that was on our minds?

These seemingly easy choices we make each day are informed by our personal past experiences, knowledge of the experiences of others, and a weighing of benefits and risks based on this information. It could be said that assessing risk is a means of survival, because it helps drive the choices we make in each situation in the game of life. Each choice made, determined by our risk assessments, determines how far we get in the game.

Using that analogy, it should be clear that we have the basic tools to conduct a risk assessment hardwired in our brains. These tools come free of charge, and it is up to each person to decide how they use them. It is better to eliminate the possibility of making a poor choice rather than cleaning up the mess of making such a choice. That said, many industries mandate risk assessments to be conducted as part of their normal operations.

Federal agency requirement

Over the past two decades, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) developed a series of documents outlining compliance program requirements aimed at numerous entities supporting the healthcare and delivery system. After soliciting recommendations for formal guidance and after releasing a draft version, the OIG released finalized voluntary Compliance Program Guidance on November 15, 1999, for the Medicare + Choice (now Medicare Advantage, or MA) Organizations in an effort to promote "a high level of ethical and lawful conduct throughout the entire healthcare industry."[1]

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To conduct a risk assessment is to identify, track, and prioritize weaknesses and vulnerabilities within a particular organization, project, or other activity.

The Centers for Medicare & Medicaid Services (CMS) took the voluntary guidance and implemented requirements. Among other compliance program elements, CMS requires organizations such as those offering MA and/or Part D benefits to establish and implement an effective system for routine monitoring and identification of compliance risks.[2,3] Sub-regulatory guidance requires policies and procedures to conduct a formal baseline assessment of major compliance and fraud, waste, and abuse risk areas, such as through a risk assessment. The assessment has to take all Medicare business operational areas into account. Each area must be assessed for the types and levels of risks the area presents to the Medicare program and to the organization.

How should we define "risk assessment"? Dictionaries define the two words independently, and many industry descriptions are available. To conduct a risk assessment is to identify, track, and prioritize weaknesses and vulnerabilities within a particular organization, project, or other activity.

Answering the question "why" do risk assessments should be simple. To identify risks and analyze potential effects and damage is to proactively inform decision-makers regarding next steps. Done correctly, the process should include the assessment of the likelihood of adverse effects as well as the prioritization of next steps in planning auditing and monitoring activities.

Responding to the question "how" to do them can be more of a challenge. The agency does not specifically outline how an organization must conduct the assessment. However, suggestions are made by CMS regarding the factors for considering risks, such as size of the department, complexity of the activities conducted, and past compliance issues. Additional factors can and should be included, based on an organization's past experience and the knowledge of the experience of other organizations. Armed with a spectrum of factors, an organization may calculate risk scores using a wider lens:

- **Beneficiary impact** – How do the operational area's activities impact the health, wellness, and finances of Medicare beneficiaries?
- **Experience of the staff** – Has an operational area experienced recent or significant turnover? Has a change in management or other restructuring occurred in the last 12 months?
- **Division responsibilities** – Does the operational area work on the Medicare line of business only, or do they work on other lines subject to different regulations, such as Federal Employees Health Benefit Program, Marketplace plans, and/or Medicaid?
- **Vendor support** – Is an operational function shared with or supported by a vendor? Is the function performed entirely by a vendor?
- **Enrollment growth** – Has recent enrollment growth affected an area's ability to perform their function?
- **Agency audit protocol** – Is the operational area a focus in the most recently published CMS Program Audit Protocol?

New initiatives must be evaluated

CMS outlines areas of particular concern in the Compliance Program Guidelines published on January 11, 2013.[4] However, because changes have occurred in laws, regulations, and CMS requirements, organizations must not focus on the chapter guidance alone when building the baseline risk assessment. Risks will evolve as both the industry and the focus of the agency evolve. Staying well-informed on industry trends and enforcement actions is an important factor in maintaining a risk assessment.

In addition to the typical factors an organization may consider on a regular basis, new initiatives and other dynamic changes may impact operations, change risk priorities, and therefore require assessment. For example:

- Is the business considering an acquisition or a merger?
- Are there recent regulatory changes or requirements?
- What strategic initiatives are being considered?
- Is leadership considering conducting some work offshore?

To cite one of the above as an example, there have been many mergers in the past few years within the healthcare industry, and the payer industry has not been immune. As a recent example, Aetna and CVS Health completed

their merger on November 28, 2018. Such a transaction merits both organizations to complete a thorough risk assessment to determine the effects to operations, membership, and the resulting organization. The OIG recommended MA organizations conduct a comprehensive, self-administered risk analysis or contract for an independent risk analysis by experienced healthcare compliance professionals.[5] For something such as a merger, an independent lens may be warranted.

When completing such an assessment, it is possible that a number of high risks will be identified, and time may not allow all high risks to be addressed. Marti Arvin recently wrote in the October 2018 *Compliance Today* magazine about the risk assessment process and risk prioritization. If resources are not available to address all high-risk items, she says, "It is important that the governing body is clear on the potential consequences of not addressing each risk or providing support to obtain the resources."[6]

As noted above, an ad hoc risk analysis for something as significant as a merger could result in a number of risks being classified as high. However, even those organizations not considering mergers or acquisitions need to connect the proverbial dots between identifying risks and conducting proper auditing and monitoring activities. A compliance program audit or self-assessment should include a review of risk assessment tools, results, and the resulting auditing and monitoring work plans of MA and Part D organizations. These documents should tell a chronological story respectively: First, we conducted an assessment; then, the resulting low, medium, and high risks were identified; third, here is what we did to address them.

Leaving no stone unturned

Interviews and surveys often help inform a baseline risk assessment and promote ongoing evaluation efforts. Conversations with stakeholders can yield eye-opening revelations. Theories and assumptions on existing processes could be quickly de-bunked when speaking with those who know them best. Analytical surveys should be tailored to the organization's structure, benefit offerings, membership, and provider network. Existing organizations may customize surveys based on prior history of the organizations' noncompliance. New organizations entering the market should leverage well-documented industry pitfalls and common failures in assessing their own risks.

If stakeholder feedback warrants a change to the baseline risk assessment's results, updates should be made, because it represents the most up-to-date picture of where the organization stands. If concerns are raised during interviews regarding internal controls and the risk results are not adjusted accordingly, the feedback serves little purpose. Once risk results are adjusted, an evaluation of auditing and monitoring activities should take place to determine if oversight activities should increase.

The results of a risk assessment must inform an auditing and monitoring plan.[7] Although some audits or monitoring efforts are ad hoc, many activities should be in place as a result of the risk assessment. For example, if a department's activities are high risk, it should warrant regularly scheduled monitoring and perhaps an audit to formally test against a set of measures. If a vendor's activities are low risk, they might not appear on the annual audit work plan, but they should still be monitored on a regular basis.

Audits and enforcement actions

On an annual basis, CMS releases a report of the previous year's audit results and enforcement activities. CMS cited the failure to establish and implement a formal risk assessment and an effective system for routine monitoring and auditing of identified compliance risks as a common condition identified in the 2017 audits.[8] The agency noted an improvement in each set of program audit area scores with the exception of Compliance Program Effectiveness.[9]

If a vendor's activities are low risk, they might not appear on the annual audit work plan, but they should still be monitored on a regular basis.

MA and Part D organizations play a key role in today's healthcare system. Stakeholders should be aware that failure to establish policies and procedures to conduct a formal baseline assessment of their major compliance and fraud, waste, and abuse risk areas could result in enforcement actions.

According to CMS's most recently finalized Civil Money Penalty

Methodology, the agency may apply an aggravating factor to this type of condition, because the violation has been published among the top common conditions in an annual audit report.[10] CMS will apply the common conditions published in the annual report two years before the contract year being audited. For example, for 2019 program audits, CMS will apply the common conditions contained in the 2017 annual report. That said, potential penalties should not be the driving factor to implement procedures for assessing risk. The motivation should come from the desire to run a compliant and ethical organization, resulting in meeting or exceeding standards set by CMS. CT

Endnotes

1. Publication of the OIG's Compliance Program Guidance: Federal Register, Vol. 64 No. 219. November 15, 1999. https://bit.ly/1OaEYI3
2. 42 CFR §§ 422.503(b)(4)(vi)(F) General provisions for Medicare Advantage Organizations. https://bit.ly/2A2MkNy
3. 42 CFR 423.504(b)(4)(vi)(F) General provisions for Part D. https://bit.ly/2EEoprx
4. Centers for Medicare & Medicaid Services, *Managed Care Manual* Chapter 21 and *Prescription Drug Benefit Manual* Chapter 9, *Compliance Program Guidelines,* Section 50.6.3. https://go.cms.gov/2sf79Ub
5. Ibid, Ref #1
6. Marti Arvin, "Effective auditing and monitoring for your compliance program" *Compliance Today,* October 2018, pp. 28-33.
7. Ibid, Ref #3
8. CMS, *2017 Part C and Part D Program Audit and Enforcement Report,* May 8, 2018. https://go.cms.gov/2Bu4cRp
9. Ibid, Ref #5, p 14.
10. CMS, *Civil Money Penalty Methodology,* December 15, 2016. https://go.cms.gov/1OWdxyk

Takeaways

- Organizations should have an established risk assessment process.
- Customizing and refining risk factors adds additional integrity to an organization's process.
- New initiatives, such as mergers, offshoring, or adding a new plan should be assessed for risk.
- Interviews and surveys can support and inform changes to baseline risk assessments.
- Failure to conduct a risk assessment may be considered an aggravating factor in calculating civil money penalties.

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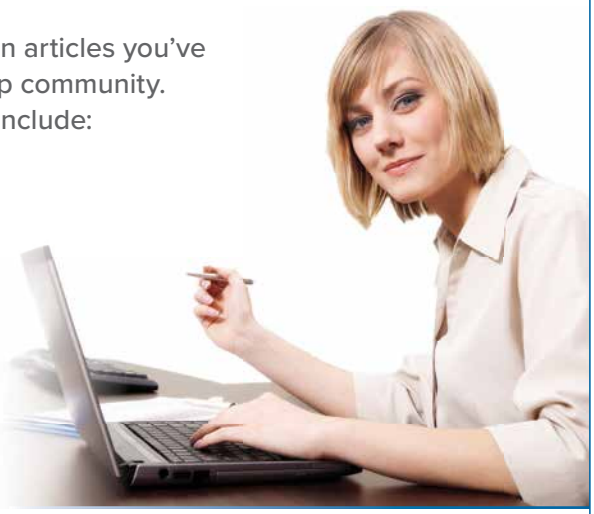

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