Best Practices: Training Programs to Combat Fraud, Waste and Abuse
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By Ellen Leinfuss, SVP, Life Science, UL EduNeering

Background:

“Our findings indicate that Medical Advantage (MA) organizations lack a common understanding of key fraud and abuse program terms and raise questions about whether all MA organizations are implementing their programs to detect and address potential fraud and abuse effectively.” That statement in the Health Care Compliance Association’s February 2012 report, Medicare Advantage Organizations’ Identification of Potential Fraud and Abuse, put the Center for Medicare and Medicaid (CMS) and all MA organizations in the hot seat.

MAs and Prescription Drug Plans (PDPs) serve about 64 percent of eligible Medicare beneficiaries. Every year, several hundred billion dollars in Medicare claims are paid by the US government creating seemingly unending opportunities for Fraud, Waste and Abuse (FWA). And, according to a 2012 government report, programs are at more risk for FWA than the Medicare and Medicaid programs.

Fraud, Waste and Abuse – Compliance Effectiveness

FWA problems are more than “compliance issues.” Every company, regardless of industry, knows of the impact to their bottom line due to lost customers, resources, efficiencies and reputation. Health Care companies are especially vulnerable to additional risks ranging from criminal and civil prosecutions, facility shutdowns, patient distrust and bans on participation in federal programs including Medicare.

FWA restrictions and regulations are unlikely to ease going forward, particularly with the Affordable Care Act (ACA) set to significantly increase the number of recipients. To combat FWA, regulations based on the CMS’ Compliance Program Effectiveness Audits have been amended to address the most persistent and serious challenges, including:

- Reporting Relationships, Governance and Oversight: Among several organization problem areas identified by the CMS were a lack of “C-level” senior management and Board involvement, inadequate allocation of resources (including funding and a dedicated compliance program focused on Medicare operations), and flawed organizational structure involving the compliance officer and senior management.

- Internal Compliance System Controls: Inadequate or absent process controls include a failure to ensure that those conducting business (including external entities) receive
comprehensive, up-to-date standards of conduct and compliance policies and procedures. Typically, companies have a corresponding failure to implement adequate mechanisms for ensuring adherence to the above. Of special concern to the CMS was the absence of compliance and FWA risk assessments, internal monitoring and/or auditing, and a failure to adequately implement systems for tracking and ensuring prompt response to detected noncompliance and FWA issues. The CMS specifically noted problems with the oversight of external First tier, Downstream and Related entities (FDRs): insufficient monitoring, oversight and auditing; and a failure to provide and ensure implementation of standards of conduct and compliance policies and procedures by external FDRs.

- **Fraud, Waste and Abuse Measures:** Surprisingly, the CMS identified an absence of a fundamental element of compliance: that training and risks are identified, assessed and remediated. In particular, the CMS found a lack of specific mechanisms targeted to FWA (such as provider types or operations), a lack of data analysis for identifying potential FWA risks and vulnerabilities and a failure to target FWA training to individual job duties and risks.

- **Poor Oversight of Third Party Entities:** Health plans routinely outsource major functions to third parties (for example, selling through brokers, dispensing through PBMs) without implementing an adequate monitoring, oversight and auditing program. One key challenge is identification of the individuals who work in the third party companies; delegating responsibility for policy training and education to the principals of those companies and simply assuming compliance by the organization’s employees is no longer sufficient to demonstrate or deliver effective FWA compliance.

The CMS’ findings affirmed many of the deficiencies noted in other reports by government agencies including the OIG and GAO. To assist the Health Care community achieve and demonstrate compliance program effectiveness, the CMS has released a “Compliance Program Effectiveness Self-Assessment Tool.” The checklist, which is based on the seven basic elements of a CMS-mandated compliance program, is designed to help evaluate compliance program design, identify program strengths and weaknesses and aid in the development and improvement of key components of an effective program.

### ELEMENTS I-III: EFFECTIVE TRAINING AND COMMUNICATION

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<thead>
<tr>
<th>Description</th>
<th>Yes</th>
<th>No</th>
<th>Documentation</th>
<th>Responsible Party or Department</th>
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<td>8. Do you establish, implement and provide training and education, addressing compliance for:</td>
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<td>A Employees involved in your Medicare line of business?</td>
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<td>B Chief executive and senior administrators or managers?</td>
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9. Do you ensure that First Tier, Downstream and Related entities (FDRs) receive compliance training?

10. Do you establish, implement and provide training and education, addressing FWA for:

| A Employees involved in your Medicare line of business? |     |    |               |                                 |
| B Chief executive and senior administrators or managers? |     |    |               |                                 |
| C Governing body? |     |    |               |                                 |

11. Do you either provide FWA training directly to non-deemed FDRs, or provide training materials to non-deemed FDRs?

12. Does the training and education occur at least annually for:

| A Employees involved in your Medicare line of business? |     |    |               |                                 |
| B Chief executive and senior administrators or managers? |     |    |               |                                 |
| C Governing body? |     |    |               |                                 |
| D FDRs? |     |    |               |                                 |

13. Is the training and education a part of the orientation for:

| A Employees involved in your Medicare line of business? |     |    |               |                                 |
| B Chief executive and senior administrators or managers? |     |    |               |                                 |
| C Governing body? |     |    |               |                                 |
| D FDRs? |     |    |               |                                 |

14. Do you measure the effectiveness of training (pre- and post-training testing, etc.)?

Excerpt from the checklist related to training.
Practical Steps to “Effectiveness”

Through UL EduNeering’s work with dozens of MAs and PDPs, we have developed practical, straightforward recommendations in four key areas to achieve, maintain and demonstrate effective compliance. They integrate current CMS guidance, recent audit trends and analysis of emerging trends in the CMS’ approach to compliance:

1. **Codes, Policies and Procedures:** Written Codes of Conduct, Policies and Procedures to prevent and detect FWA are fundamental to compliance. Effective compliance requires that the materials are also distributed, understood by relevant parties and integrated into behaviors.

   **Steps to Take:** By using a Learning Management System (LMS), it’s easy enough to show that Codes, Policies and Procedures have been distributed or even that employees (and possibly related entities) have been provided with training. While those efforts might fulfill the basics of compliance, they don’t meet the standard of effective compliance or efficient management and corporate integrity.

   To ensure that written materials are understandable, we recommend using surveys to your employees and key third parties to assess the following: Do they understand what the policies mean and how to apply them? Do policies and procedures apply to their areas of responsibility? Do the procedures enable them to comply AND identify noncompliance by other individuals?

   If the Codes, Policies and Procedures don’t meet the “understandability” test, write new ones. Use metrics to identify who is accessing the Codes, Policies and Procedures. If individual locations, operations and job functions are represented at a higher-than-average level, target additional training in those identified areas.

2. **Use of Risk Assessments:** The potential for FWA varies based on a range of factors including geography, population or demographics, provider type, operational activities, type of product, difficulty of understanding policy or procedure.

   **Steps to Take:** Risk can be assessed by using survey tools within the LMS. Based on answers to questions, individuals are placed into groups that determine the risk posed and the training or action required. For example, an email to the Chief Compliance Officer could be automatically sent in response to someone declaring a conflict of interest (COI). A web-based course could then be delivered to any individual with a role in which COIs more readily occur (such as procurement or sales/marketing), and a general “read and understand” policy to all others.

A second risk-based approach is to array policies along
a simplified matrix (probability versus severity) to align training to each policy. For example, simple policies and/or ones that are less severe on the risk scale, might only require distribution via “read and understand,” while policies that are more critical or frequent might lend themselves to the addition of assessments or refresher training. Finally, policies or individuals that might pose a greater risk to achieving compliance might require one-on-one training by a supervisor.

3. Third Party Entities: The CMS, OIG and the Department of Justice (DOJ) have been particularly pointed in their attention on the compliance of first-tier, downstream and related entities. Although most sponsors require their suppliers and providers to certify compliance with FWA requirements, certification does not equal effective compliance. It’s worth remembering that a third party’s noncompliance almost inevitably splashes back on the MA or PDP.

Steps to Take: Formal audits of third party suppliers are invaluable, along with good recordkeeping by the sponsor to ensure that any identified issue has been addressed and corrective action taken. Equally valuable are “informal” audits of suppliers’ behaviors. Beneficiary complaints, a spike in customer assistance calls and repeated coding or billing mistakes can all point to potential FWA problems. For the MA or PDP, it is essential to show that suppliers are consistently monitored, that metrics are employed to quickly identify anomalies, that responsive corrective actions are taken in a timely manner, and that systemic adjustments are made to prevent similar issues in the future.

In recent audits, government agencies including the CMS point to the need for MA and PDP organizations to move beyond self-certification by third parties by taking on responsibility for third party training on plans, company policies and anti-FWA behavior. The use by MAs and PDPs of self-registration tools within the LMS facilitates the enrollment of third parties, addressing inherent administrative and rapid turnover challenges. A program designed for those entities, including Medicare Basics, Beneficiary Protection, Marketing, Enrollment/Disenrollment and Compliance Requirements will demonstrate commitment to FWA education and achieve CMS training requirements.
FWA problems are more than “compliance issues.” Every company, regardless of industry, knows of the impact to their bottom line due to lost customers, resources, efficiencies and reputation. Health Care companies are especially vulnerable to additional risks ranging from criminal and civil prosecutions, facility shutdowns, patient distrust, and bans on participation in federal programs including Medicare.

4. **Training, Knowledge and Behavior**: Training must be accurately targeted, developed, distributed and tested. There is no real surprise to that statement, but many Health Care organizations have failed to fulfill the intent of those compliance requirements. Training must be targeted to job role and risk area; it must drive knowledge through engagement and relevancy, confirmed through testing; it must be distributed across the organization, including third party entities; it must be documented in formats that are easily accessible for review and audit; and it must enable generation of metrics to measure, adjust and demonstrate effectiveness.

**Steps to Take**: No matter how good the training is, effectiveness is defined by the behavior of learners. Testing is one gauge. Periodic surveys and questionnaires to employees and third party providers provide additional opportunities to assess effectiveness. Metrics generated by training distribution and testing results also provide important opportunities for program fine-tuning. All those tools, however, are based on consistent monitoring and correlation of behaviors with risks.

A best practice we employ is the development of a ROLES-based training approach. Individuals are organized into groups based on job role and responsibility, enabling training to be organized into curricula. The LMS is then automated to push out policies, training and assessment based on each role. Individuals receive the exact tools they need to achieve effectiveness, no more and no less.
Driving Effective Compliance: Agility and Change

Business isn’t static; regulatory compliance can’t afford to be, particularly with CMS signaling its intent to take a core proactive approach to assessing effective compliance. The US Congress, OIG, GAO and the White House are all demanding greater accountability for MAs and PDPs – and greater scrutiny and enforcement by the CMS.

The intensified scrutiny and enforcement pressure on the CMS is pushing MAs and PDPs to show a similar sensibility toward compliance as active instead of passive and proactive rather than reactive. This emerging sensibility requires Health Care organizations to continually assess risk, measure results, quickly identify potential or actual FWA, conduct thorough root cause analyses, and rapidly initiate corrective actions that prevent such events from occurring again.
About UL EduNeering

UL EduNeering is a business line within UL Life & Health’s Business Unit. UL is a global independent safety science company offering expertise across five key strategic businesses: Life & Health, Product Safety, Environment, Verification Services and Enterprise Services.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA’s Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA’s virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council and the Duke Clinical Research Institute.