

***THE CHANGING PHARMACEUTICAL SALES LANDSCAPE:
RECOMMENDATIONS FOR ACHIEVING COMPLIANCE
AND SALES EXCELLENCE***

BY: WENDY HECKELMAN, PH.D.

**WLH CONSULTING, INC.
WWW.WLHCONSULTING.COM
954-385-0770**

INTRODUCTION

Pharmaceutical sales force leaders currently face a variety of challenges. There is ongoing competition from other companies, increased competition from generic drugs, and a changing healthcare environment. There have also been reductions in the number of sales representatives at many pharmaceutical companies and rumors of their eventual replacement by peer to peer selling¹.

Sales leaders have also found it difficult to comply with the growing regulations and restrictions on sales force representatives. This is demonstrated by the large settlements levied against them in recent years. Since all pharmaceutical companies offer training to sales representatives but compliance violations have occurred despite this training, the type of training, rather than the amount of training, may be responsible. Training recommendations are provided to prevent future compliance violations, but proactive responses are also recommended to prevent further regulations and restrictions for pharmaceutical sales representatives.

SALES FORCE COMPLIANCE REQUIREMENTS

Pharmaceutical sales forces need to track and comply with a growing number of regulations and access restrictions. Laws and policies now exist at the federal, state, and local levels regarding pharmaceutical representative access and interactions with healthcare professionals.

At the federal level, sales representatives must comply with policies on their conduct issued by the FDA² and the OIG³. Additional legislation is also likely if the actions of the United States Senate Committee on Finance are any indication. The Committee's leaders, Senators Grassley and Baucus, have been vocal opponents of the pharmaceutical industry's sales and marketing practices. They have already launched initiatives ranging from the questioning of Drug Company pricing for Medicaid recipients, to limiting the involvement of pharmaceutical marketing personnel in medical education grant provision.⁴

At the state level, laws are being passed that are even more restrictive than existing federal laws regarding pharmaceutical representatives' conduct. For example, the District of Columbia's SafeRx Amendment Act of 2008⁵ requires that representatives be licensed by the District to sell pharmaceutical products. Many believe that DC is only the first to pass this kind of state law.

Voluntary guidance documents also exist at the national level. These are issued by organizations such as the Accreditation Council for Continuing Medical Education (ACCME) and the Pharmaceutical Research and Manufacturers of America (PhRMA). The ACCME Standards for Commercial Support⁶ contain restrictions on the involvement of pharmaceutical sales representatives in medical education content, design, or funding decisions. The 2008 PhRMA Code on Interactions with Healthcare Providers⁷ contains requirements and

¹ Agro, B. The New Sales Force. March 1, 2009. www.PharmExec.com

² Guidance for Industry: Industry-Supported Scientific and Educational Activities. HHS – FDA. November, 1997. <http://www.fda.gov/CbER/gdlns/sciedact.pdf>

³ OIG Compliance Program Guidance for Pharmaceutical Manufacturers. HHS – OIG. April 18, 2003. <http://www.oig.hhs.gov/authorities/docs/03/050503FRCGPPharmac.pdf>

⁴ Baucus, M. & Grassley, C. E. (2007). Committee Staff Report to the Chairman and Ranking Member - Use of Educational Grants by Pharmaceutical Manufacturers. Senate Finance Committee. <http://finance.senate.gov/press/Bpress/2007press/prb042507a.pdf>

⁵ 2008. D.C. Safe Rx Amendment Act of 2008. http://hpla.doh.dc.gov/hpla/frames.asp?doc=/hpla/lib/hpla/pharmacy/saferx_act.pdf

⁶ 2004, 2006, 2007. ACCME Standards for Commercial Support. http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf

⁷ 2008. PhRMA Code on Interactions with Healthcare Providers. <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>



accountability for pharmaceutical companies and representatives for compliance training and assessment as well as action following compliance failures. While there are no fines levied for not complying with these guidelines, they create an industry standard and it can be damaging to a company's corporate reputation not to comply.

At the local level, a growing number of healthcare institutions and Academic Medical Centers (AMCs) have also created their own policies regarding pharmaceutical representative access and interactions with healthcare professionals⁸. Some of these simply provide visitors' policies, such as advanced registration requirements; however, others place heavy restrictions on representatives' access to healthcare providers and behavior.

When pharmaceutical representatives fail to comply with these laws and policies there can be severe consequences. Federal compliance violations can result in large fines and Corporate Integrity Agreements (CIAs) that include ongoing scrutiny and instructions for internal changes. Violating healthcare institutions' policies can result in loss of access to the facility and providers. Both damage pharmaceutical companies' corporate reputations and erode public trust.

COMPLIANCE CHALLENGES

Complying with these requirements has been a significant challenge for pharmaceutical companies as demonstrated by the amount of government fines and the number of CIAs levied against them. From 2007 to date, 12 fines have been levied for a total of \$3.8 billion dollars and 10 pharmaceutical companies have had CIAs imposed on them⁹. If current trends continue and there are additional regulations and restrictions on representatives, pharmaceutical companies will face more fines and CIAs unless they make changes.

RESPONDING TO COMPLIANCE CHALLENGES

In order to prevent future compliance violations, pharmaceutical sales leaders need to determine why the violations are occurring and take appropriate steps to fix the problems. Preventing future violations is a minimum standard. To rebuild public trust, prevent further restrictions, and maintain access to healthcare providers, the solutions should also be proactive. Recommendations for proactivity include compliance with the voluntary industry guidelines issued by PhRMA and demonstrating the value of representative interactions with healthcare professionals by understanding and addressing the needs of healthcare providers.

PREVENTING COMPLIANCE VIOLATIONS

According to the Compliance and Ethics Leadership Council at the Corporate Executive Leadership Board, there are two groups of individuals responsible for the compliance violations at pharmaceutical companies. Sales representatives in the field are responsible for the majority, but a significant proportion of violations are due to improper management or executive conduct¹⁰. Therefore, appropriate solutions are needed to change sales representatives' behavior and leaders' behavior, or changes are needed to the corporate culture regarding compliance in the organization that enables upper level violations.

⁸ Rep access continues to decline. Pharmaceutical Representative. March 12, 2009. <http://pharmrep.findpharma.com/pharmrep/Featured+News/Rep-access-continues-to-decline/ArticleStandard/Article/detail/586743?contextCategoryId=9813>

⁹ Office of the Inspector General. Corporate Integrity Agreements Document List. http://oig.hhs.gov/fraud/cia/cia_list.asp

¹⁰ Compliance and Ethics Leadership Council (2006). Key Findings of Compliance Failure Analysis. Corporate Executive Board. www.celc.exexecutiveboard.com

COMPLIANCE BEHAVIOR IN THE FIELD

Sales representatives do not commit compliance violations in the field because they lack knowledge about compliance. All pharmaceutical firms offer extensive training for sales representatives. This includes knowledge of compliance requirements, in response to the 2003 Compliance Program Guidance for Pharmaceutical Manufacturers issued by the Office of the Inspector General (OIG). If representatives have compliance knowledge, yet there are continued compliance violations, then they are not applying their compliance knowledge in the field. This indicates that the problem is not with the amount of compliance training, but with the type of compliance training.

Research on adult learning has shown that a different kind of training is required to change behavior versus change knowledge because behavior is influenced by more than just what we know.¹¹ In order to change behavior, you also have to teach behavioral skills, provide practice opportunities, feedback, and reinforcement to ensure the skills are retained after training and applied in the field.¹² For example, regularly scheduled behavioral assessments after training by a supervisor can provide the necessary ingredients since they provide opportunities for feedback, practice, and continued reinforcement.

Therefore, to address compliance behavior violations of sales representatives in the field, compliance training should be behaviorally based. To create sustained compliant behavioral change, it should be followed by a behavioral assessment or monitoring of field behaviors.

COMPLIANCE BEHAVIOR IN THE ORGANIZATION

Behavior based training should also be used to address upper level compliance violations. However, because violations are occurring at different levels of the organization, changes to the organizational culture that is supporting these violations are also needed. Involving the entire sales organization in behavior change efforts will be more effective at changing organizational culture than individual training sessions. For example, sales executives could be involved in management training and assessment, and management could be involved in the training and assessment of representatives. This would not only help ensure consistent understanding of compliance throughout an organization, it would also help to provide modeling and reinforcement to support sustained behavioral change.¹³

MAKING PROACTIVE EFFORTS TO PREVENT FURTHER REGULATIONS AND RESTRICTIONS

Changing the behavior and organizational culture responsible for the compliance violations will reduce future violations and fines; however, this may not be sufficient to stop further regulatory scrutiny and restrictions of sales practices. For the scrutiny and restrictions to stop, the pharmaceutical industry needs to combat the perception that all information from pharmaceutical sources is "tainted" by commercial bias. In order for sales representatives to retain access to healthcare providers, the industry must create the alternate perception that representatives can provide valuable information and services, in a compliant manner. This requires compliance with existing regulations and adherence to industry attempts to self-regulate, such as the PhRMA Code, as a minimum standard. In addition, sales representatives must be able to meet healthcare providers' evolving needs.

¹¹ Gagne, & Driscoll (1988). Essentials of Learning for Instruction.

¹² Ajzen, I. (1991). The Theory of Planned Behavior; Bandura, A. (1977). Social Learning Theory; Baldwin, T.T. & Ford, J.K. (1988). Transfer of Training.

¹³ Bandura, A. (1977). Social Learning Theory; Baldwin, T.T. & Ford, J.K. (1988). Transfer of Training.

PHRMA CODE COMPLIANCE

The PhRMA Code on Interactions with Healthcare Professionals is a set of voluntary standards published by an industry association. It is an attempt to self-police and thereby ward off further external restrictions. New additions to the Code in the 2008 update include compliance training, assessment requirements, and required actions following compliance violations.

The Code states that companies "should assess their representatives periodically to ensure that they comply with relevant company policies and standards of conduct." Companies should also, "take appropriate action when representatives fail to comply." The Code also contains recommendations for the Chief Executive Officer and Chief Compliance Office of a company to certify compliance with the PhRMA Code.

An added incentive for following the PhRMA Code guidelines is consistency with the recommendations to change behavior provided above. For example, in order to assess representatives for compliance with policies and standards, you would need to assess representatives' behavior in the field, which would also help reinforce behavioral training. "Taking appropriate action" for compliance failures is also akin to providing training feedback. Finally, involving the highest levels of management is an important component in creating an organizational culture of compliance.

PROVIDING VALUE TO HEALTHCARE PROVIDERS

Sales representatives can only change negative public perceptions about their value if they can provide valuable information to healthcare providers, in a compliant manner. This requires awareness of healthcare professionals' needs and the ability to respond to those needs. Therefore, pharmaceutical representative training should also include knowledge on the changing landscape for pharmaceutical sales and the adaptive skills to meet the evolving needs of healthcare professionals.

The changing landscape for pharmaceutical sales refers to the new challenges that sales organizations face and is important for understanding healthcare providers' needs. These challenges include growing competition from generic drugs and a need to cater to a growing variety of healthcare provider types, including pharmacists, payors, and other outside stakeholders.

Training that addresses healthcare providers' evolving needs should include understanding of the shifting demographics of healthcare professionals, the growing number of healthcare provider types, and the growing role of payors in healthcare provision¹⁴. Representatives should also be able to address growing requirements for evidence-based information about diseases and treatments. If sales representatives are aware of healthcare providers' information needs and can help meet those needs in a compliant fashion, they can combat negative perceptions and provide value to both healthcare providers and their employers.

CONCLUSION

Although pharmaceutical companies currently offer compliance training designed to meet existing regulations, there are continued compliance violations and fines that damage both their bottom line and their corporate reputations. To improve, companies need to offer compliance training that is designed to change behavior and create a culture of compliance by including all levels of the sales organization in compliance training efforts. Traditional knowledge based compliance programs need to be changed to behavior based

¹⁴ Robinson, R. (June 2008). Redefining the Salesforce Landscape to Navigate New Territories. PharmaVOICE. p. 30-34.

training that teaches desired behavioral skills, and includes practice and feedback to reinforce learning. Assessing the behavior of sales representatives in the field following training is also important for complying with the PhRMA Code and ensuring the transfer of behavioral skills to the field.

In addition to training improvements, pharmaceutical companies should also take proactive actions to prevent further restrictions and combat negative perceptions. These efforts should include following the 2008 PhRMA Code guidelines and training sales representatives to respond to healthcare providers' needs in a compliant fashion.

If representatives can help healthcare providers meet their growing information needs, they can challenge the negative public perceptions about their value, prevent further restrictions, and maintain access to healthcare providers. This also helps pharmaceutical companies position themselves as proactive industry leaders in compliant behavior.

RECOMMENDATIONS FOR ACHIEVING COMPLIANT SALES EXCELLENCE

1. Design compliance training to create changes in behavior: teach behavioral skills, provide opportunities for practice and feedback, and reinforce successful application.
2. Include the entire sales organization in compliance training to create a culture of compliance. Sales leaders must endorse and perform the behaviors they wish representatives to follow.
3. Assess representatives' behavior in the field to comply with the PhRMA Code, provide training feedback, and measure training application in the field.
4. Educate representatives on the changing landscape for pharmaceutical sales, including the growing variety of healthcare provider types, so they can meet the needs of all healthcare providers. Ensure representatives can discuss products, symptoms, and diseases in evidence-based medical terms.