

DEFINING, QUANTIFYING AND MEASURING EFFECTIVENESS

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One of the greatest challenges confronting health care corporate compliance officers is the ability to demonstrate to a third party (e.g., management, board, government) in a quantifiable way that the compliance program that is in place at their health care organization is “effective.” While the government has been quite prolific in promulgating corporate compliance program guidelines for various segments of the health care industry, those guidelines merely provide the “process” that the government recommends including in the policies and procedures which comprise the health care organization’s corporate compliance program. These government guidelines do not provide guidance to date on how to quantify at a later time that such activities, in fact, are taking place.

Instead, what people currently are relying upon are crude benchmarks of certain easily identified activity measures to demonstrate that the compliance program is “working.” For example, one of the crudest measures people often look to is the number of telephone calls received to the hotline. Yet, suppose that the compliance program is very proactive in its training and the corporate culture is such that people do feel comfortable calling management directly with even the most sensitive potential noncompliant behavior issue. Is that organization’s compliance program “ineffective” because it received no telephone calls on its hotline during a predefined time period? Must there be a certain number of calls for there to be “effectiveness?”

Another crude quantifiable measurement example that the government often looks to is the amount of overpayments that the health care organization has returned on its own initiative as a result of self-monitoring. While in the initial years of the compliance program a focus on this measurement may prove helpful in demonstrating that compliance activities are making a difference, over time it is expected that there should be less mistakes that need correcting and more questioning at the front end. As a health care organization grows in revenue, is it necessarily the case that its overpayment amounts need to increase or is it legitimate for them to decrease? Nor are “overpayments” relevant to all types of health care organizations. Pharmaceutical manufacturers need to find counterparts to “overpayments”. See, in particular, the OIG’s measurements in the most recent pharmaceutical company CIAs.

On the other hand, compliance officers should not consider themselves or their corporate compliance programs to be guarantors of compliant behavior. Having employees who conduct criminal misbehavior does not necessarily mean that the compliance program is “inadequate” or “ineffective.” Rather, the lesson learned from the Caremark Delaware Chancery decision (Sept. 25, 1996) is that what is required from a corporate director to avoid personal liability in such

circumstances is a good faith exercise in the monitoring responsibilities and no one consciously permitting a known violation to occur. The duty owed by the directors of a corporation is to attempt in good faith to assure that an adequate corporate information and reporting system exists. Duties owed by compliance officers and from their compliance programs should be no different.

Consequently, it is the responsibility of the compliance officer to create at the inception of the compliance program not only the relevant policies and procedures that should be followed but also the quantifiable outcome benchmarks that he or she intends to rely upon to demonstrate that such policies and procedures are “happening.” Quantifiable outcome benchmarks are the way to get “credit” for the processes that are put in place. In other words, “effectiveness” requires two distinct elements to consider -- process measures and quantifiable outcome benchmark measures. While some might consider the absence of government guidelines for these “quantifiable outcome benchmarks” to be a negative, I consider that fact to be a positive because it gives every organization the flexibility to decide these benchmarks based upon its own capabilities and resources.

With these introductory comments in mind, let us consider each of the seven sentencing guidelines. The power point materials that follow include not only the description of the sentencing guideline, but also how the Department of Health and Human Services’ Office of the Inspector General (“OIG”) currently interprets this guideline in more detail in the various issuances promulgated to date. The purpose of this paper is to provide examples of how these guidelines should include not only the more obvious “process” requirements but also the potential “quantifiable outcome benchmarks.” It is helpful to set up these data tracking processes at the front end and to automate them as much as possible. These benchmarks may prove to be relevant for demonstrating “effectiveness” to a third party in the future.

Guideline One - Standards and Procedures

The “process” includes the need for written policies and procedures. The “quantifiable outcome benchmark” requires testing tools (e.g., questionnaires, round tables, interviews documented) to see if the employees understand the code of conduct after launch, to see if the right “high risk areas” have been identified in the written policies, e.g., for providers to see if claims submissions operational policies are sufficient, for managed care organizations to see if the ACR certification, accretion/deletion submissions operational policies are sufficient.

Guideline Two - Responsible Oversight Personnel

The “process” includes the need to establish a compliance council/committee. A “quantifiable outcome benchmark” could be the data collected to show that the council or committee is doing meaningful work, such as tracking attendance (both qualitatively and quantitatively - are the important people there frequently). You also may wish to track the committee’s substantive recommendations.

Guideline Three - Compliant Work Force

The “process” includes the criminal, OIG and other background checks etc. A possible “quantifiable outcome benchmark” could include tracking the number of prospective applicants that were turned away during a particular time period.

Guideline Four - Training Programs

The “process” includes the training materials and scheduling and how training policies dictate that such training is a condition of employment. A possible “quantifiable outcome benchmark” could be tracking what happens to those employees who do not attend, e.g., sanctions implemented, extra training for supervisors. Another possible “quantifiable outcome benchmark” is the comprehension checks after the training takes place, e.g., multiple choice type questions and the tracking of any retraining that may be required for those who do not do well on the comprehension checks. Remember, for teaching effectiveness, we learned the following general facts: (1) for the best emotional commitment for achieving a change in behavior after the teaching the optimal size of the group should be between 6-8; (2) a person’s attention span for learning only lasts 20 minutes with only 5-7 minutes of that time period for heavy learning; and (3) you can trigger another 20 minute time period by changing your teaching format, e.g., oral to written, speech to question and answer dialogue.

Guideline Five - Monitoring and Auditing Systems

The “process” includes the policies and procedures you intend to follow for monitoring and auditing the organization’s activities, especially its high risk areas. A possible “quantifiable outcome benchmark” could be the use of samples to confirm accuracy with operational requirements. Another one could be the amount of costs involved for the compliance program in general and for this particular aspect of the program to show the amount of resources dedicated to these activities in comparison to the organization’s total government receivables. However, this benchmark would require the tracking of compliance program costs at the front end. That likely would need the cooperation of the Finance and IS department of your organization.

For the reporting systems, obviously the maintenance of a hotline reflects the “process” required. For the “quantifiable outcome benchmarks”, consider tracking the calls by title and geographic area. If there are no calls or if there are only infrequent calls, then consider canvassing employees periodically to remind them and to test them about their awareness of the compliance hotline. Also test whether the phone number works on a regular basis to confirm it is operational. Document all of these type of tracking activities because if it is not documented, then, as far as the government is concerned, it did not happen.

Guideline Six - Disciplinary Actions

The “process” refers to the written policies for disciplining non-compliant personnel. A possible “quantifiable outcome benchmark” could be the tracking of the disciplinary actions that did take place and ways in which it can be demonstrated by infraction and title of the person that such actions have been applied consistently. This type of tracking would require consistent and complete communications between the compliance officer and the human resources department.

Guideline Seven - Corrective Actions

The “process” includes the policies adopted to assure that the potential noncompliance issues are not only found but also are acted upon timely. A potential “quantifiable outcome benchmark” could be tracking the promptness of the corrective action by collecting the data from other arms of the organization to show that corrective actions have taken place. Once again such tracking will require coordination with other departments of the organization.

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In closing, I challenge the audience to consider other “quantifiable outcome benchmarks”. Remember that “effectiveness” is more like an ideal or goal that we wish to achieve. “Effectiveness” requires “process” and “quantifiable outcome benchmarks.” “Effectiveness” also requires “effective documentation.” What will your health care organization’s “effectiveness checklist” look like? Good luck!