

## New Evidence in the World of Litigating Health Care Compliance Cases: The Compliance Effectiveness Study

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# NEW EVIDENCE IN THE WORLD OF LITIGATING HEALTH CARE COMPLIANCE CASES: THE COMPLIANCE EFFECTIVENESS STUDY

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Historically, litigating health care compliance issues and violations has been an incredibly frustrating proposition for health care providers. Health care providers spend tremendous resources, financial and human capital, developing and implementing compliance programs that are intended to prevent and identify compliance issues before they lead to matters warranting a government investigation. Yet despite these efforts, the number of administrative actions and prosecutions across the United States for compliance violations continue to increase. Further, whether a given act is deemed to be non-compliant, or perhaps fraud, often depends on which government regulator is making that assessment. Conduct in one jurisdictional venue may be deemed worthy of some type of enforcement action, while in another jurisdiction the same conduct does not trigger such a response. How a health care provider, especially one that operates in multiple jurisdictions is to have any confidence that their compliance efforts are effective is unclear.

In this author's opinion, at the core of this conflict and frustration for health care providers is the fact that what is required for an effective compliance program and what constitutes an "effective" compliance program that entitles the provider to the leniency and "rewards" set forth in the United States Sentencing Guidelines has been very ill defined. Thus making clear the need for a better understanding about what types of compliance program policies, procedures and processes do in fact decrease the likelihood of compliance related violations in a health care organization.

The Compliance Effectiveness Study was undertaken for the sole purpose of increasing our understanding about the relationships between the seven elements set forth in the Sentencing Guidelines and certain effectiveness measures. One consequence of this work is that it provides both the industry and government with an objective and empirically based platform to discuss and negotiate compliant versus non-compliant conduct, in contrast to the subjective environment in which they discussions have historically occurred.

## I. HEALTH CARE COMPLIANCE ENVIRONMENT

In recent years, policymakers have become increasingly concerned with ensuring that healthcare organizations comply with all federal and state regulations, licensure and accreditation standards, and standards required by federal, state, and private health insurers. In large part, this concern stems from estimates that a substantial portion of the nation's healthcare resources is being lost to fraud and abuse.

In the early 1990s, in response to estimates that at least ten percent (10%) of all health care dollars spent each year were being lost to fraud, the government instituted a two pronged approach to protecting federally-insured health care programs against fraud and abuse. First, the government significantly increased both the investigation and prosecution resources dedicated to the health care industry. Second, the government increased the importance and role of corporate compliance programs in health care institutions.

Corporate compliance programs were intended to be the mechanism by which industry professionals would be encouraged to take responsibility for health care fraud detection and prevention. Relying on the fact that the Federal Sentencing Guidelines and United States Department of Health and Human Services' ("HHS") declared the existence of an effective corporate compliance program to be a mitigating factor in criminal and administrative agency proceedings, the government expected this incentive to encourage health care organizations to "voluntarily" police themselves.

The incentive and goal were clear. However, the absence of specifically defined standards made achieving this goal difficult. Unfortunately, little guidance regarding what constitutes and how to establish an "effective" corporate compliance program existed. Thus, through the 1990s, the health care industry was faced with trying to meet a standard that to date had not been well defined.

In June 1999, a research team in collaboration with faculty from the University of California, Los Angeles' School of Public Health, Department of Health Services embarked on the first empirical study that would examine what, if any relationships existed between a seven-element corporate compliance program, as prescribed by the Federal Sentencing Guidelines and effective compliance.<sup>1</sup> Employing standard research methodology and design, the research team set out to explore two research questions: the impact that the seven elements have on effective compliance; and the relationship among the seven elements themselves.

The purpose of this article is to briefly review the design, methodology and findings of the Compliance Effectiveness Study.

## II. COMPLIANCE EFFECTIVENESS STUDY OVERVIEW

The Compliance Effectiveness Study (the "Study") is an evaluation study that was designed to identify, develop and increase current understanding about the relationship between corporate compliance programs and effective compliance. This study represents the first time that a study has examined these issues as they relate to corporate compliance programs generally and health care corporate compliance programs specifically.

The specific aims of the Compliance Effectiveness Study were:

1. To explore the relationship between the Federal Sentencing Guideline seven-element compliance program ("seven elements") and effective compliance; and
2. To explore the relationship among the seven elements themselves and industry compliance practices.

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<sup>1</sup> This Study has been generously funded by PricewaterhouseCoopers, L.L.P.

To achieve these objectives, the Compliance Effectiveness Study research team conducted a comparable, empiric, research based evaluation involving a comprehensive literature review, an expert panel process, and empirical analysis of data collected from 30 general acute care hospitals randomly selected from throughout the United States (subject hospitals).

The first task was to define the outcome measures for effective compliance. In order to identify practices in the industry and analyze the relationship between these practices and measurable outcomes, the Study examined those specific outcomes looked to by the government and healthcare community when evaluating the effectiveness of a compliance program. Overwhelming industry evidence revealed that employee awareness of compliance program issues, inpatient coding/billing accuracy, and outpatient coding/billing accuracy were the primary outcomes of interest.

The Study focused on the detailed compositions of the compliance programs that were in place in the subject hospitals as the foundation for examining whether a relationship existed between compliance program practices and the three measures of effectiveness used in the Study, employee awareness, inpatient coding accuracy and outpatient coding accuracy. Through this process, the Study identified the following:

- Baseline practices of effective compliance that represent best practices; and
- Significant relationships between certain of the seven elements and employee awareness, inpatient coding/billing accuracy, and outpatient coding/billing accuracy.

### III. COMPLIANCE EFFECTIVENESS STUDY RESEARCH DESIGN AND METHODOLOGY

In general, the Study was comprised of four stages: a literature review, an expert panel process, data collection, and statistical analysis.

#### A. Literature Review Methodology

The first stage of the Study, literature review was initiated in June 1999, and was undertaken to define the scope of what had been written to date on the subject of corporate compliance and compliance program effectiveness. The literature reviewed was derived from all industries that had a history of implementing compliance programs, including the banking, insurance and defense contracting industries. This process identified a total of 18,381 articles that addressed compliance programs and compliance effectiveness not only in health care, but also the environmental, banking, defense and insurance industries.

Two types of documents were evaluated: key compliance documents such as the Federal Sentencing Guidelines, HHS, OIG Model Compliance Guidance for Hospitals, Treadway Commission's COSO Report, the Defense Industry Initiative on Ethics and Conduct and relevant U.S. Government Accounting Office reports ("original source articles"); and compliance articles contained in research and public databases, such as Medline, Dow Jones Interactive and Lexis Nexus ("database articles").

An intensive screening process was used to assess the contribution that each of the articles made to the Study. Each article was evaluated specifically for its content related to either the seven compliance program elements, other potential compliance or effectiveness elements not identified in the Federal Sentencing Guidelines, the effectiveness of compliance programs, and content relating to the how the seven elements and effective compliance

could be measured. Of the more than 18,000 articles identified, 275 provided unique and valuable information regarding one or more of these areas of interest.

Once the final set of articles was established, the compliance principles contained therein were abstracted and compiled into a series of “indicators” that reflected unique and distinct compliance-related practices and concepts. Each indicator mapped to one of the seven elements.

## **B. Expert Panel Methodology**

To address the absence of peer reviewed corporate compliance and effectiveness literature, the Study employed an expert panel methodology to assist with developing a final set of indicators. The expert panel methodology used was a modified Delphi panel technique developed by the RAND Corporation, which has been widely and successfully used to develop evidence-based standards for rating the quality of medical care in managed care plans and for rating quality of care associated with particular clinical conditions.

The Study utilized a two-panel methodology. The first panel was comprised of a group of health care corporate compliance experts from PricewaterhouseCoopers, who each had a minimum of five years experience with designing, implementing and assessing health care corporate compliance programs (“In-house experts”). The second panel was comprised of a group of eighteen nationally known experts in health care compliance (“Industry experts”). These experts were selected from different geographic areas, were affiliated with health care organizations of different type and size, and possessed varying levels of professional training and compliance expertise. For the most part, industry experts held one of two positions in their affiliated organization, corporate compliance officer or in-house counsel.

First the expert panel reviewed the compliance program indicators derived from the literature review, and evaluated whether each indicator was an important and valid indicator of compliance programs, based on a review of the literature and their experience, opinion and judgment. For purposes of the expert panel process, importance and validity were defined as follows:

- Validity - adherence to the indicator should be indicative of a higher quality compliance program when compared to a lack of adherence to the indicator.
- Importance - The degree or magnitude of value that the indicator contributes to the compliance program’s effectiveness. Note that it is possible to have indicators that make a definite but very small contribution to a compliance program’s effectiveness. Such indicators can be perfectly valid, but nevertheless are relatively unimportant.

Each panelist was also encouraged to comment on the literature review and to provide suggestions for additions, deletions, and/or revisions to the compliance indicators.

Additionally, the expert panel also reviewed effectiveness outcomes in the course of this process. The expert panelists cited many potential definitions for and ways to measure effective compliance. In accordance with the Study research protocol, three of the effectiveness measures identified were used to define effectiveness in the Study. The expert panelist input led the research team to select the three Study effectiveness outcomes:

- Inpatient Coding and Claim Accuracy
- Outpatient Coding and Claim Accuracy
- Employee Awareness of Compliance

These effectiveness outcomes were selected primarily based on the expert panelists' input to the process and the fact that they represented the way in which effectiveness has been measured in the industry to date. The government has certainly looked to inpatient and outpatient coding accuracy as measures of effectiveness and in large part, the industry has adopted the knowledge or awareness of compliance issues as an effectiveness measure.

#### IV. DATA COLLECTION METHODOLOGY

With these three effectiveness measures and the final set of compliance indicators, or compliance practices, defined, the research team sought to identify whether a relationship existed between compliance program practices and the three effectiveness measures. To further this goal, the research team examined the detailed makeup of the compliance programs of 30 randomly selected acute care hospitals, subject hospitals.

General acute care hospitals were chosen as the target population for data collection because they have been implementing corporate compliance programs in one form or another since the early 1990's, longer than any other group of health care providers. This widespread implementation provided an excellent study population for investigating corporate compliance program effectiveness. Therefore, the study subjects were selected from all general acute care facilities that appeared in the 1999 American Hospital Association Directory with the exclusion of specialty hospitals (e.g., psychiatric hospitals, and rehabilitation hospitals) and government facilities.

The sampling process was stratified based on an organization bed size: 50-99 beds (small); 100-249 (medium); and 250 or more (large).<sup>2</sup> Based on anecdotal evidence that suggested hospitals with less than 50 beds are unlikely to have the type of seven-element compliance program being investigated in the Study, general acute care hospitals of less than 50 beds were excluded. The final Study subject sample was as follows:

- 8 small (50-99 beds) or 27% of sample
- 13 medium (100-249) or 43% of sample
- 9 large (250 or more) or 30% of sample

Three study instruments were developed to collect data at each hospital:

- a compliance program component questionnaire to collect data regarding the seven elements (Indicator Questionnaire);
- an employee awareness questionnaire to collect data on employee awareness (Employee Awareness Questionnaire); and
- a coding and claims database to collect data on inpatient and outpatient coding and billing accuracy (Billing/Coding Accuracy Database).

The Indicator Questionnaire contained questions that examined the components of the subject hospitals' compliance program, in particular the seven elements, as they related to the compliance structure and processes identified during the expert panel process. The

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<sup>2</sup> It was intended that the Study sample would also be stratified on the basis of tax status, e.g. for profit and not-for-profit. However after sixty-six invitations to for-profit organizations were declined, the study universe was redefined to include only not-for-profits.

questionnaire was administered during face-to-face interviews of up to seven members of a subject hospital’s senior management, including:

- |                               |                             |
|-------------------------------|-----------------------------|
| Member of the Board           | Director of Human Resources |
| Chief Executive Officer (CEO) | Audit Manager               |
| General Counsel               | Various Department Heads    |
| Compliance Officer            |                             |

The Employee Awareness Questionnaire was self-administered to 25 employees and 25 physicians within each organization’s administrative and clinical departments. Each respondent was randomly selected. Further, the respondents were instructed to complete the questionnaire and mail it directly to the research office using the postage paid business reply envelopes provided during the on-site visit with the questionnaires.

The Employee Awareness Questionnaires addressed two aspects of compliance, an employee’s substantive understanding of compliance issues and knowledge of their organization’s compliance program components.

The Billing/Coding Accuracy Database was used to conduct a retrospective coding and billing accuracy review at each of the subject organizations for the following two visit types:

- Medicare/Medicaid Inpatient visits; and
- Medicare/Medicare Outpatient visits, including ambulatory surgery, emergency department, outpatient ancillary, observation, and clinic visits

The purpose of these reviews was to determine the extent to which the claims reviewed were accurate. To assess coding/billing accuracy, the certified coders working for the research team evaluated technical coding appropriateness, completeness of documentation to support code selection, UB-92 coding related elements, and compliance with Centers for Medicare and Medicaid Services (CMS) Current Coding Initiatives. All reviews were completed in accordance with applicable *Physician’s Current Procedural Terminology* (“CPT-4”) and *International Classification of Diseases, 9<sup>th</sup> Revision Clinical Modification* (“ICD-9-CM”) diagnosis codes, and in accordance with the 2001 American Medical Association CPT-4 and ICD-9-CM coding manuals, AHA Coding Clinic, and AHIMA Ethical Coding guidelines.

The claim sample for each organization included 100 inpatient and 100 outpatient claims, and the results were recorded and analyzed in a proprietary study database. The outcome measure sought was simply a binary determination that a given claim/record “is” or “is not” accurate.

For all aspects of the Study, an extensive data confidentiality protocol was employed and maintained.

## V. COMPLIANCE EFFECTIVENESS STUDY RESULTS

Although the Compliance Effectiveness Study has been completed, as is common with empiric research, Study findings will continue to unfold over the next several months. From the initial study findings it appears that the several interesting and useful contributions to the area of effective compliance have been made.

As the first study to examine the relationships between a seven-element compliance program and effective compliance, the study findings not only provide insight about the ultimate research question but also provide insight to practical research issues that will undoubtedly be confronted by future researchers who study this subject. To this end, there were 9 major findings in this study.

First, no for-profit organizations elected to participate in the study. Second, in at least 30% of the subject organizations, it was reported that at least one aspect of their compliance program was applied differently to physicians versus non-physician employees.

Third, of the 6,000 randomly selected medical records sought for the billing accuracy review, subjects were only able to produce sufficiently complete records for the review to be conducted in 93.6% of the inpatient cases and 68.8% of the outpatient cases. The medical records sought included, but were not limited to such items as the medical chart, billing claim form, supporting documentation.

Fourth, the percentage mean score on the Indicator Questionnaire, which assessed performance on the seven elements, was 53.42% correct responses in contrast to the 100% correct responses that would be required by a zero tolerance standard. Table 1 presents a summary performance scores for all seven elements.

Table 1: Indicator Questionnaire: Summary performance scores

|         | Total Raw Score | % Total Correct Responses |
|---------|-----------------|---------------------------|
| Mean    | 264.96          | 53.42%                    |
| Minimum | 186.5           | 37.60%                    |
| Maximum | 336.17          | 67.78%                    |
| Median  | 267             | 54.02%                    |

The distribution of mean percentage performance scores across the seven elements ranged from a low of 45.5% on Element 1, Policies and Procedures, to a high of 80.4% on Elements 7, Response and Prevention. Table 2 presents a summary performance scores for all seven elements.

Table 2: Indicator Questionnaire: Summary performance scores by element

| Element        | 1<br>Stand.<br>&<br>Policies | 2<br>Oversight<br>&<br>Response | 3<br>Education<br>&<br>Training | 4<br>Lines<br>of<br>Comm | 5<br>Audit<br>&<br>Monitor | 6<br>Enforce<br>&<br>Discipl | 7<br>Response<br>&<br>Prevention | Total  |
|----------------|------------------------------|---------------------------------|---------------------------------|--------------------------|----------------------------|------------------------------|----------------------------------|--------|
| Total Possible | 130                          | 45                              | 64                              | 64                       | 121                        | 60                           | 14                               | 498    |
| Mean           | 59.26                        | 32.58                           | 36.99                           | 32.76                    | 62.32                      | 30.66                        | 11.27                            | 265.83 |
| Mean %         | 45.5%                        | 72.4%                           | 57.8%                           | 51.1%                    | 51.5%                      | 51.0%                        | 80.4%                            | 53.3%  |
| Min            | 33.67                        | 26.25                           | 23.08                           | 14.08                    | 21.00                      | 21.67                        | 7.00                             | 187.17 |
| Max            | 73.08                        | 36.33                           | 56.33                           | 42.92                    | 104.17                     | 37.83                        | 13.00                            | 336.83 |
| Median         | 60.54                        | 33.25                           | 37.54                           | 34.21                    | 61.92                      | 30.75                        | 11.33                            | 268.58 |



Fifth, the mean percentage score on the Employee Awareness Questionnaire, which assessed employee and physician knowledge about compliance related matters, was 52.61% correct responses collectively for employees and physicians. As to employees, the mean correct response was 60.79%, while the mean correct responses for physicians only was 42.11%. Table 3 presents a summary performance scores for the Employee Awareness Questionnaire.

Table 3: Employee Awareness Questionnaire: Summary performance scores

|                | Total Raw Score | % Total Correct Responses |
|----------------|-----------------|---------------------------|
| <b>Mean</b>    | 12.10           | 52.61%                    |
| <b>Minimum</b> | 6.63            | 28.83%                    |
| <b>Maximum</b> | 17.29           | 75.18%                    |
| <b>Median</b>  | 11.53           | 50.13%                    |

Sixth, the mean percentage score on the Billing Accuracy Database was 57.42% correct responses for overall billing accuracy, again in contrast to the 100% correct that would be required by a zero tolerance standard. As to only inpatient billing accuracy, the mean percentage score was 54.60%, while the mean percentage score for outpatient billing was 60.23%. Table 4 presents a summary performance scores for the Employee Awareness Questionnaire.

Table 4: Billing Accuracy Database: Summary performance scores

|                | Total Raw Score | % Total Correct Responses |
|----------------|-----------------|---------------------------|
| <b>Mean</b>    | 114.30          | 57.15%                    |
| <b>Minimum</b> | 45.00           | 22.50%                    |
| <b>Maximum</b> | 167.00          | 83.50%                    |
| <b>Median</b>  | 123.00          | 61.50%                    |

Seventh, the two study covariates, organization size and implementation period were not found to be statistically significant.

Eighth, 10 pairs of independent variables in the study model were found to be moderately to highly correlated, indicating that the seven elements, as defined in the Study, may not be uniquely distinct concepts. Of particular note was the fact that Element 3, Education and Training was highly correlated with Element 1, Standards of Conduct and Policies and Procedures with a negative correlation coefficient of -0.764 and Element 5, Auditing and Monitoring, with a negative correlation coefficient of -0.822. Additionally, Element 4, Lines of Communication was highly correlated with Element 2, Oversight Responsibility with a positive correlation coefficient of 0.828 and Element 6, Response and Prevention, with a positive correlation coefficient of 0.974. Although there was limited data available for Elements 3 and 4, the identified relationships suggest that Element 4, Lines of Communication may be a reasonable proxy for Elements 2, Oversight Responsibility and 6, Response and Prevention and Element 3, Training and Education may be a reasonable proxy for Elements 1, Standards of Conduct and Policies and Procedures and 5, Auditing and Monitoring.

Additionally, the effectiveness outcome measure Employee Awareness was found to be correlated with Element 6, Enforcement and Discipline, Element 5, Auditing and

Monitoring, Element 4, Lines of Communication and Element 3, Training and Education. The effectiveness outcome measure Inpatient Billing Accuracy was found to be correlated with Element 7, Response and Prevention, Element 4, Lines of Communication and Element 3, Training and Education. Further, the effectiveness outcome measure Outpatient Billing Accuracy was found to be correlated with Element 5, Auditing and Monitoring, Element 4, Lines of Communication and Element 3, Training and Education.

Lastly, in the Inpatient Billing Accuracy regression model, Element 7, Response and Prevention was found to be statistically significant, while Element 5, Auditing and Monitoring was found to be statistically significant in the Outpatient Billing Accuracy regression model.

## VI. CONCLUSION

Compliance programs have become an integral, necessary and very expensive part of the health care regulatory process, and what makes a compliance program effective has to date been very poorly understood. This study was a starting point for identifying and understanding the relationships that are involved and the issues that must be addressed in order to assure that compliance programs achieve their goal of detecting and preventing healthcare fraud and abuse.

There is no question that there is still a tremendous amount of work to be done. However, the Study has established an empiric, research-based process for assessing effectiveness, identifying the first time baseline practices and effectiveness attributes. Without this “starting point” it would have been difficult, if not impossible, for the industry to advance to the next step in understanding and implementing effective compliance programs.

Only when health care providers and government regulators come to some common understanding and agreement about what constitutes an “effective” compliance program can the tremendous subjectivity and ambiguity currently in the equation be removed. For at the present time what constitutes non-compliant conduct worthy of administrative or enforcement action continues to be a moving target for most health care providers.

It is the hope of the Study’s research team that the Compliance Effectiveness Study findings will both provide the basis for objective and unbiased discussions between the health care industry and government regulators regarding a threshold measure for effective compliance, as well as empiric evidence that can substantiate a health care provider’s considerable efforts to be compliant.