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# COUNSEL'S CORNER: One Law Firm's Philosophy of Compliance for Physician Practices and Smaller Entities



By Alice G. Gosfield

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In the late 1980's, when the federal sentencing guidelines first mentioned the fact of having a compliance plan as a mitigating factor, some physician group practices asked us if they had to pay attention. Back then, the healthcare fraud and abuse world was entirely different. It seemed for our clients that compliance programs would not be worth the effort or expense since they weren't at much criminal risk.

Fast forward to February 2016 when the voluntary repayment rules for Medicare Parts A and B were published. (see Gosfield, "[The Oxymoronic Landscape of Voluntary Repayments](#)". "[Voluntary Repayments: The Physician Perspective](#)".) After that, no reasonable person could read the comments to the regulations and not conclude that compliance plans are an essential element of a physician practice operation, or for any other entity submitting claims to the public programs.

### OIG Compliance Guidance

When the Office of the Inspector General published its model compliance guidances for [billing agents](#) and then two years later for [small group practices](#), both of which were voluntary, we thought our clients—predominately physician practices and smaller entrepreneurial companies—would be stymied about how to begin to approach compliance plan development. They tended to have more limited resources. They couldn't figure out how to prioritize how to begin and where to focus. We firmly believed that we should not prepare or write a templated compliance plan. We believed the only compliance plan that would work would be one that was imbued not only with the sweat equity of the practice managers but also, above all, the physicians themselves. If they did not feel a personal stake in the content and implementation of a compliance program, then they would not have any hope of generating and maintaining a culture of compliance. We broke down the principles of compliance into three very simple rules for practice leaders to apply.

1. What makes us think we are doing this right?
2. If we are doing it wrong, what will it take to fix it, both in terms of repayments as well as in terms of education, changing processes, improving documentation, and potentially more.
3. How will we know it has stayed fixed?

#### Helpful Protocols

To help them back then, we published an online Fraud and Abuse Compliance Plan Development Protocol. We addressed how to prioritize the focus of the plan, what substantive topics typically would have to be addressed, and issues to consider in allocating resources. We included compliance related issues in physician employment contracts, including repayments as a result of post-payment audits. We also addressed antitrust law issues because, even though not part of fraud and abuse, we had too many clients who were confused about their antitrust exposure, especially in light of managed care contracting and risks associated with talking to other groups. We added some discussion of Stark and anti-kickback guidance as well. The document was not limited merely to billing compliance, although it combined elements from both the physician practice and billing agent compliance guidances.

When the HIPAA privacy rules came out, we applied the same approach, since HIPAA's compliance challenges are similar to those of fraud and abuse risk avoidance. The security rules only expanded the need for additional content, which we added to a HIPAA Compliance Plan Development Protocol ([table of contents](#)).

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#### Compliance Program Effectiveness

Then, earlier this year, when the OIG and representatives of the Health Care Compliance Association published their [Resource Guide](#) of more than 400 suggested measures of compliance program effectiveness the issue of whether the compliance program is working was highlighted as never before. In fact, caselaw supports the conclusion that entities may be held liable for the ineffectiveness of their programs. (United States v. MerckMedco Managed Care, L.L.C., [336 F.Supp.2d 430](#), 440-41 (E.D. Pa. 2004).) We think the mere publication of the Resource Guide has changed the "standard of care" in compliance, so to speak. We think its publication was a significant boon to the prospect of taking compliance seriously. We had to revise our protocol again to address some of the implications of measuring effectiveness, such as having an audit plan.

But, as with the earlier OIG compliance guidances, we found the 400 suggestions in the guide to be overwhelming, even to us. We believe this is because it was intended to be applicable on a pick and choose basis to any entity with a compliance program. So, with our constituency in mind, we created a smaller derivative 10-page document focused around what we thought they would be able to handle. We teased out the repetitive themes that include such items as:

- testing employees regarding substantive knowledge,
- conducting internal focus groups,
- surveying staff,
- verifying that elements of the plan have been implemented,
- reviewing documentation of activities undertaken,

- auditing files of compliance issues that have been confronted,
- reviewing the results of investigations and remedial actions that have been taken,
- evaluating whether legal counsel has been appropriately utilized, and
- using third parties to facilitate assessments (e.g., consultants, outside auditors).

The guide offered various techniques to deploy:

- Periodically review the plan and policies and procedures implementing it and update as rules, regulations and policies change.
- Maintain a compliance manual which assigns responsibility.
- Include relevant compliance responsibilities in job descriptions.
- Disseminate updated information to workforce and contractors.
- Provide continuing and ongoing education.
- Create an annual compliance audit plan.
- Maintain a sufficient compliance budget.

Similar principles and measures can be applied in the HIPAA and security context as well.

#### Philosophy of Compliance

So what is our philosophy of compliance today? We still believe the only plan that will work is the customized one the practice develops itself. We think starting small and developing skills is better than attempting a massive plan adoption based on something a specialty society or other source has published or an outside vendor has charged a considerable sum to produce. We have seen templated plans with blanks that have not been completed. We have seen plans which replicate the typographical errors in the source document from a specialty society. We believe these create liability under the "reckless disregard" standard if you actually have a plan you don't follow.

We think any plan must be written in the active voice ("The billing manager will review a sample of 50 EOBs every month and will report on the findings to the compliance officer") rather than what we see when we review other plans ("EOBs will be reviewed periodically"). It should assign clear responsibility. With regard to the voluntary repayment rules in particular, given the breadth of the credible evidence which can trigger the obligation to investigate further and if problems are found look back six years, who has the responsibility to take the many actions and make the many judgments those rules generate should be addressed in the plan; and we address what those issues and choices are in our revised protocol.

What is written in the plan must be done; so grandiosity and documenting intentions which remain unfulfilled either from a budgetary or operational perspective are dangerous paths. We think a formal audit plan, which need not be extensive, ought to be developed and the shareholders in the practice should be required to review the reports it generates and allocate appropriate resources to what is learned. We think appropriate use of attorney-client privilege is essential to all of this, particularly when errors occur, as they inevitably will. When and how counsel is brought in should be addressed.

Our clients who have taken our advice have been able to navigate the new territory without much trouble, so far. Ours is not the only approach to compliance, but we are more firmly convinced than ever, that both in HIPAA and especially the security arena, as well as in fraud and abuse liabilities, those who have not taken formal, significant steps at risk avoidance are in greater peril than ever.