

## The Evolving Nature of Ethics and Compliance in the Healthcare Industry

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For better or worse, in the American business environment ethics and best expectations gradually become supplanted by government regulations. Witness the defense industry scandals of the 1980's and the promulgation of the Federal Sentencing Guidelines in 1991. In the late 1990's, the Centers for Medicare and Medicaid (CMS) began issuing "voluntary compliance guidance" for different segments of the healthcare industry. But in the years since then, a spate of new regulatory activity has transformed compliance from a voluntary activity to one that is mandated. How healthcare organizations can anticipate and respond to the interplay between ethics and regulatory compliance is one focus of "Healthcare Regulatory Compliance," a UW Extension Outreach Certificate Program. Consider the example of quality in healthcare.

In Latin, it is "*primum non nocere*" but most of us are more familiar with the English translation: "First, do no harm." Since the days of the Greeks and Romans, this dictum, codified (to a degree) in physician oaths over the years, has sufficed to assure the

public that healthcare was focused on safety and quality—upholding ethical precepts of "doing good."

But in 1999, the Institute of Medicine (IOM) rocked the healthcare industry and the consumer's confidence with a landmark report titled "*To Err is Human: Building a Safer Health System.*" With the report's cataloging of "preventable" errors, the IOM undermined the moral high ground, previously entrusted to the healthcare industry under the "first, do no harm" standard. Ethical practice in healthcare now required one to attend to the delivery system's inherent flaws and diligently study outcomes to improve quality. Following the report, a variety of patient safety initiatives were proposed, and patient advocacy groups joined the movement to ensure that there would be no turning back. A follow up IOM report in 2001, "*Crossing the Quality Chasm*" laid a broad framework for how to improve healthcare quality.

However, in a 5-year follow up to the 1999 IOM report, authors, Leape and Berwick asked: "*Five Years After to Err is Human: What have We Learned?*" They concluded: "The groundwork for improving safety has been laid in these past five years, but progress is frustratingly slow." The authors called

for "public outrage, reformed reimbursement policies, and regulation" to address the shortfall in improving safety and quality.

Enter the federal government. In the five years following the Leape and Berwick progress report we have seen a flurry of regulatory and reimbursement initiatives in an effort to accelerate the pace of improvements.

- In 2003, the Medicare Modernization Act authorized CMS to begin demonstration projects related to pay for performance. For the first time, Medicare could consider quality in its reimbursement strategy, not just quantity.
- In 2003, JCAHO (now The Joint Commission) required hospitals to follow 11 safety practices; now that list numbers 20 National Patient Safety Goals.
- At academic institutions residency training hours were limited to reduce fatigue-related errors.
- In 2007, Medicare altered its voluntary hospital quality reporting program and began reducing payments to hospitals that did not participate.
- In 2007, as required by Con-

gress, Medicare introduced the Physician Quality Reporting Initiative (PQRI)—incentivizing physicians for reporting on specified quality measures.

- The Deficit Reduction Act of 2005 prodded Medicare to (in 2008) stop paying for “hospital acquired conditions.”

Medicare recently emphasized its intention to further meld quality and reimbursement initiatives. In a recently released “roadmap” related to value based purchasing (VBP), CMS writes:

“Development of quality measures is essential for all VBP programs because VBP aligns payment more directly to the quality and efficiency of care provided, by rewarding providers for their measured performance across the dimensions of quality.”

The transition from “voluntary” adherence to quality principles to the current, highly regulated quality environment illuminates how

society cedes its ethical aspirations to mandated compliance expectations. These are the kinds of topics we consider in the UW Program.

The course examines this push-pull between ethics and federal/state legislation, and addresses how organizations can position themselves to develop ethical cultures and anticipate the directions that ethics and regulatory compliance may take. Quality, safety, privacy, financial relationships, research, and other topics are all considered within this framework.

While it remains debatable whether it was ever enough to “do no harm” the government is clearly saying: those days are over. Healthcare organizations that adopted an ethical approach to “doing the right thing for patients” likely were addressing quality concerns all along, and no doubt found it easier to transition into the new, more regulated environment.

## **Bibliography/Sources**

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