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How are ethics and regulations connected in the hospital setting?

By William C. Moran

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If we are to understand how ethics and regulations are connected, we have to first have a common understanding of how we define each of them. According to Webster, "ethics" is the study of standards of conduct and moral judgment, and "regulations" are rules, ordinances or laws by which conduct is regulated. Thus, ethics gives us underlying principles by which we judge human behavior, and regulations carry out those principles by saying how a designated group of people should act. Ethics tells us what is right and what is wrong, and laws and regulations apply what is right and wrong for society.

The study of ethics and regulations, and the connection between the two, has been going on at least since the time of the Greek philosophers. One of those philosophers, Aristotle, wrote a treatise, Nicomachean Ethics, to help sort through what is good and what is bad. He followed with a treatise, Politics, to apply the good and the bad to societal issues by discussing legislation and regulations.

In this article, I will address three questions: What are the ethical principles behind the ten major hospital regulatory categories? Can ethics and regulations be at odds with each other? What will the future bring for ethics and regulations?

What are the ethical principles behind the ten major hospital regulatory categories?

In the hospital setting, there are ten major categories of regulations based on ethical principles. Some hospitals do not provide services in a few of these areas, but most hospitals would be governed by the vast majority of these regulations. These ten categories are:

- **Anti-kickback** regulations are premised on the ethic that public money (namely Medicare and Medicaid) will be used in the best interest of the patient, without regard to the financial interests of the physician and hospital.
- **Clinical research** regulations are based on ethical considerations for the human subject who is involved in that research, as well as the ethical considerations that exclude conflict of interest between the researcher and the pharmaceutical or medical device company that sponsors the research.
- **Emergency Medical Treatment and Active Labor Act (EMTALA)** regulations try to ensure that no one will be turned away from a hospital and sent somewhere else unless they first receive a medical exam and, if necessary, are stabilized prior to being transferred. The ethical premise here is to ensure the patient's safety before considering financial implications.
- **Health Insurance Portability and Accountability Act (HIPAA)** regulations address the privacy and security of patient information, based on the ethical principle that only certain people have a right to know the personal medical facts involved.
- **Quality of care** regulations deal with the evidence-based standards of good health care, including the quantity of services provided. The ethical underpinning here is that payment should be for generally accepted good performance by the clinicians involved.
- **Corporate governance and compliance** regulations address the structure and process used to ensure that regulatory issues are appropriately addressed. This follows the ethical principle that laws and regulations need to be properly enforced at the local level.
- **Cost reports** regulations address efforts including the collection of bad debts, failure to return credit balances, and miscalculating wage indices.
- **Claims development and submission** regulations cover all the individual claims submitted to receive reimbursement.
- **Laboratory services** regulations address the bundling of claims and assurance of medical necessity.
- **Physicians at Teaching Hospitals (PATH)** regulations deal with ensuring that services provided are not duplicately billed.

The last four categories have regulations that are based on the ethical principle that hospitals should accurately and honestly bill for services that are allowed by Medicare and Medicaid.

Can ethics and regulations be at odds with each other?

The short answer is Yes. Let me give you two examples, the first of which is the seminal case

for ethical consideration in human subject research. The Tuskegee experiment[1] is the most obvious example of the ethics of a situation being at odds with the regulations. As you probably know, the U.S. Public Health Service recruited 399 impoverished African-American sharecroppers who had syphilis for research related to the natural progression of the untreated disease. The study began in 1932. In 1947, penicillin became the standard treatment for syphilis, but the research continued until 1972. The control group continued to receive placebos, not penicillin. As Dr. John Heller, the head of the study stated, "The men's status did not warrant ethical debate. They were subjects, not patients; clinical material, not sick people." This was in 1972. Finally, a whistleblower within the Public Health Service went public, Congressional hearings were held, and the experiment was immediately stopped. The creation of Institutional Review Boards and other human subject mechanisms are partly a result of the Tuskegee experiment. In this case, all the Public Health Service regulations were followed, but the ethical underpinning was faulty.

One other example took place in 1998 on the sidewalk outside Ravenswood Hospital in Chicago. A man with a gunshot wound lay bleeding on the public sidewalk outside the hospital. The legal policy of the hospital stated that Emergency Room personnel could not leave the department. When the hospital was told about the man on the sidewalk, the hospital called 911. The ambulance took longer than usual. A police sergeant finally brought the man inside the hospital. The man subsequently died. Later, a jury awarded the man's family $12.5 million dollars. In this case, the legal policy did not allow for the situation that occurred. This prompts the question of whether ethical matters should be considered primarily by legal considerations or by other factors.

What will the future bring for ethics and regulations?

I suggest three trends: More transparency, more quality-of-care "Pay for Performance," and more questions about the end of life.

Transparency

There are currently two bills in the Congress, one in the Senate and the other in the House, that address transparency in money paid by pharmaceutical and medical device companies to hospitals and physicians. The "Sunshine Laws" would make these monetary contributions public by posting them on the Internet. By the way, this is something the Cleveland Clinic already does. And some states, such as Minnesota, Maine, and California, have passed laws that require this type of information. The other area of transparency will focus on consumer involvement, making more information available to consumers so they can make better decisions about their health needs and how and where they want to be treated.

Quality of care

The government's push for Pay for Performance would contribute both to better quality care and to cost savings. Pay for Performance will include an increasing numbers of items every year, and along with cutting fraud, waste, and abuse, will result in significant cost savings for taxpayers. How to decide and quantify quality of care and who will pay for it will be a major battleground between payers and providers.

End of life

Questions about care at the end of life will multiply, and ethicists will try to make reasoned decisions, in the midst of technological advances and family anxiety. A recent case in Belgium provides a good example. A man was in an auto accident 23 years ago and was thought to be in a coma all that time. A year ago, his physician decided to conduct a test of his brain by using a new CAT-scan. They found he was not in a coma, but was totally paralyzed. He had been able to hear people discuss his medical condition for some part of those 23 years. I am sure there will be other families who will want their loved ones to be re-tested. Decisions about when and under what circumstances loved ones should be tested and kept alive will occur more frequently.

Conclusion

As I mentioned in the beginning, the discussion of ethics and regulations has been occurring for centuries, and will continue to occur as long as people want to distinguish right from wrong. Let's keep the conversation flowing. ■

1 More information is available at http://www.cdc.gov/tuskegee/timeline.htm.