John I. Allen, Section Editor

Here Comes the Sun: Medical Professionalism and the Implications of the Sunshine Act for Gastroenterology Practice

Lauren D. Feld,[*] Jonathan Yeh,[‡] and Andrew D. Feld[§,‖]

*Icahn School of Medicine at Mount Sinai, New York, New York; [‡]University of Washington School of Law, Seattle; [§]Group Health Cooperative, Seattle; and [‖]Department of Gastroenterology, University of Washington, Seattle, Washington

Roadmap to the FUTURE of PRACTICE

The Affordable Care Act, passed in 2010, contained a number of regulations that directly affect physician practices, behavior, and relationships with others in the health care industry. One such provision is the "Physician Payment Sunshine Act," which is the subject of this month's Practice Management: The Road Ahead column. The authors have provided us with a detailed and enlightening review of how our relationships with pharmaceutical and medical device companies have become transparent and public. It will be important for you to understand this law and take the time to review your own data through CMS's Enterprise Portal (http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Physicians.html).

John I. Allen, MD, MBA, AGAF
Special Section Editor

Professionalism has long been a cornerstone of the practice of medicine, dating back to at least the fifth century BC and the origins of the Hippocratic Oath. The modern concept of medical professionalism has been traced back to the work of late 18th century English physician Thomas Percival, who is credited with having developed the first modern code of medical ethics. The American Medical Association's (AMA) Code of Medical Ethics, first issued in 1847 and recognized as the first national code of ethics propagated for any profession, borrowed extensively from Percival's *Medical Ethics*.[1]

In recent years, the concept of medical professionalism has continued to evolve. Although a single comprehensive and universally accepted definition of the term has been elusive, for many, medical professionalism has grown to be seen as something "[m]ore than the adherence to a set of medical ethics."[2] Rather, it is the "heart and soul of medicine," the daily expression of the "desire to help people and to help society as a whole by providing quality health care."[2] Thus, some attempts to develop a normative definition of professionalism in medicine focus on core physician behaviors, with the belief that "the concept of medical professionalism…must be grounded in what physicians actually do and how they act, individually and collectively."[3]

Whether defined in terms of a code of medical ethics, a set of core behaviors, or some loftier philosophical precepts, central to the idea of medical professionalism is the belief that the practice of medicine is a quintessentially public service. As noted in the Preamble to the Charter on Medical Professionalism, "[p]rofessionalism is the basis of medicine's contract with society" and "[e]ssential to this contract is public trust in physicians, which depends on the integrity of both individual physicians and the whole profession."[4]

Professionalism and the Business of Medicine

Although the practice of medicine may be considered by many to be a fundamentally public service profession, modern medicine is also undeniably big business. In the United States alone, health care expenditures in 2011 were estimated to have reached $2.7 trillion, or 17.9% of the total US gross domestic product, and currently are projected to reach $4.8 trillion by 2021.[5]

The potentially corrupting influence of commercial interests on the integrity of the medical profession has

Resources for Practical Application
To view additional online resources about this topic and to access our Coding Corner, visit www.cghjournal.org/content/practice_management.

Abbreviations used in this paper: **AMA, American Medical Association; CMS, Centers for Medicare and Medicaid Services; FHC, Fred Hutchinson Cancer Research Center.**

1542-3565/$36.00
http://dx.doi.org/10.1016/j.cgh.2014.07.022

long been recognized in the law. For example, the corporate practice of medicine doctrine generally prohibits business corporations in many states from practicing medicine or even employing a physician to provide professional medical services under the rationale that such relationships tend "to the commercialization and debasement of [the medical] profession,"[6] and is based on the premise that corporate involvement in medical practice undermines the physician–patient relationship and the physician's exercise of independent medical judgment in the sole interest of the patient.[7]

Most attempts to codify standard principles of medical professionalism include provisions addressing the conflicts of interest that are inherent in the financial interactions between physicians and companies involved in the medical industry, such as medical device and pharmaceutical manufacturers. For example, the AMA Code of Medical Ethics explicitly declares, "Under no circumstances may physicians place their own financial interests above the welfare of their patients" and contains a specific provision with a laundry list of rules governing gifts to physicians from industry.[8] Additional provisions specifically govern conflicts of interest in biomedical research and clinical trials, conflicts of interest for physicians who hold financial interests in imaging facilities, and financial incentives and the practice of medicine.[9]

Similarly, the Charter on Medical Professionalism, jointly developed by American and European internal medicine associations, establishes the "[c]ommitment to maintaining trust by managing conflicts of interest" as one of its 10 core professional responsibilities of physicians, stating the following: "Medical professionals and their organizations have many opportunities to compromise their professional responsibilities by pursuing private gain or personal advantage. Such compromises are especially threatening in the pursuit of personal or organizational interactions with for-profit industries, including medical equipment manufacturers, insurance companies, and pharmaceutical firms. Physicians have an obligation to recognize, disclose to the general public, and deal with conflicts of interest that arise in the course of their professional duties and activities."[10]

Physician professional organizations, medical educators, medical student groups, health care providers, and even major health care industry groups and individual companies all have issued guidelines intended to govern the financial interactions between physicians and the health care industry. Clearly, there is recognition of the need to reconcile the often-competing demands of medical professionalism with the enormous financial interests of health care providers and the health care industry.

Voluntary Disclosure of Financial Conflicts of Interest

Despite the clear recognition of the importance of health care without financial conflicts of interest, with the exception of a handful of statutes that prohibit certain egregious practices, such as the Anti-Kickback Statute, the False Claims Act, and the Stark law, compliance with the vast majority of existing regulations governing the disclosure and reconciliation of financial conflicts of interest arising from industry payments to physicians are voluntary in nature and carry little or no real penalty. For instance, although the AMA Code of Medical Ethics provides detailed guidelines for a broad array of financial practices, violation of the Code can result in, at worst, expulsion from the AMA.

Compliance with voluntary disclosure rules has been shown to be far less than universal. In 2009, researchers that analyzed physician payments reported (as part of a legal settlement) by "five companies that account for nearly 95% of the market for total hip and knee prostheses"[11] concluded that a total of 20.7% of directly related payments and 50.0% of indirectly related payments reported by the device manufacturers during the 2007 calendar year were not disclosed by physicians who were subject to conflict-of-interest disclosure regulations as authors of presentations, or as board members or committee members at the 2008 annual meeting of the American Academy of Orthopedic Surgeons. These payments were not insignificant: the 43 directly related payments that were not disclosed totaled $4,320,563, and the 16 indirectly related payments that were not disclosed totaled $7,772,105.

However, the consequences of the failure to reconcile financial conflicts of interest can potentially be severe for both patient safety and public trust. For example, in March 2001, the Seattle Times published a lengthy 5-part series examining 2 failed clinical trials at the Fred Hutchinson Cancer Research Center (FHC) in Seattle that occurred from the mid-1980s to the late 1990s and may have led to the deaths of a number of the patients enrolled in these trials.[12] Although there were potentially more serious issues involving informed consent and the appropriate disclosure of risks to patients, the articles suggested that the financial interests of the physicians at the FHC who ran the clinical trials—which were not disclosed to patients enrolled in the trials—might have compromised the integrity of the trials and called into question whether the physicians had been motivated to stubbornly continue failed trials at least in part because of the potential financial rewards that the physicians may have reaped had the trials been successful.[12]