Perspective: Self-Regulation: Who Needs It?

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Self-Regulation: Who Needs It?

By developing and enforcing a well-designed set of rules, e-health codes of ethics can direct attention to the best-quality sites.

by Mark E. Boulding

Two groups have developed new codes of ethics for health care Web sites in the past year. One group, Health Internet Ethics, or Hi-Ethics, represents a coalition of the most widely used Internet health sites and content providers. Its members met several times over a period of months to draft and revise their principles, which were released 8 May 2000. The other group, the eHealth Ethics Initiative, represents an ongoing project that was started when the nonprofit Internet Healthcare Coalition called an Ethics Summit meeting in January 2000. The meeting brought together representatives from industry, academe, government, medicine, law, and patient and consumer groups, who created a draft through a collaborative process that included a public comment period. The resulting eHealth Code of Ethics was released at a press conference on Capitol Hill 24 May 2000, with Sens. James Jeffords (R-VT) and Joseph Lieberman (D-CT) present. Both codes address common issues for health care Web sites, such as privacy of consumer health information, quality of content, disclosure of financial conflicts of interest, and delivery of health care services online.

Almost as soon as they were announced, the codes drew public comment on their limitations. Janlori Goldman, a noted privacy advocate, criticized the Hi-Ethics Code for not being specific enough in the area of enforcement and consumer recourse. Glen McGee, a bioethicist, complained that neither of the two new ethics codes applied to anyone who wanted to ignore them. He stated that “the most dangerous thing in Internet health care may be simple codes of ethics.” The emergence of critics did not surprise anyone involved in developing the codes. Because of the lengthy history in Washington of devising self-regulatory schemes as a tactical defense against new legislation, particularly by large Internet companies, a new self-regulatory code is often met with skepticism.

Given this history, the policy question raised by critics of the two new codes seems straightforward: Are they strong enough that we can safely forgo any new laws? My goal in this paper is to demonstrate that this question is not the one we should be asking. Self-regulation is in itself an important goal. While self-regulatory systems may help policymakers to understand complex new areas or take on some of the government’s burden of enforcing agreed standards of conduct, they cannot replace laws. Those who create them solely as a means for avoiding new legislation are likely to be disappointed. Likewise, those who criticize all self-regulation on the grounds that its main purpose is to allow a self-serving industry to avoid new legislation are missing the potential benefits of good self-regulation.

If the creators of a self-regulatory system understand its valid purposes and design the system with a view to understanding its limits, then the system is worth having, regard-

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less of whether any new laws are passed. Critics can comfort themselves with the thought that if the self-regulatory system is indeed just a shallow device intended only for the simplistic purpose of avoiding new laws, it is not likely to be effective. I begin with an overview of the two codes, followed by a discussion of the inability of self-regulation to substitute for law and a discussion of the aspects of “good” self-regulation.

Understanding The Codes

The two ethical codes that appeared in early 2000 have much in common not only with each other but with similar efforts to draft codes of conduct for health care online that have received less media attention. As a participant in the creation of both, I was pleased that two different sets of authors, using two very different processes, had identified and addressed the same set of critical issues. Both focus on three areas: privacy of consumer health care information, quality of information online, and delivery of health care services over the Internet.

■ Privacy. In the area of privacy, both codes call for special protections for consumer health information. They require those who follow the code to establish special security measures to avoid inadvertent disclosures to others. Where such disclosure is desirable (because it helps either the consumer or the disclosing entity), the codes require that consumers affirmatively agree (in the jargon of the Net, “opt in”) before allowing the disclosure. Current law does not clearly contain any such requirement of advance consent. In fact, some Web sites—usually in their privacy policies—grant themselves blanket permission to make any information supplied by a user available to their “strategic partners.”

■ Quality of content. In the area of quality of content, the codes address two main issues: the indirect influence of sponsorship on content, and blurring of the line between content and commerce as reflected in the implementation of a particular Web site. The former occurs when financial arrangements influence content that a site presents as editorially independent. The latter occurs when a Web site, as viewed by a user, makes it difficult to tell what content is intended to be editorial and what is sponsored content or advertising. The two codes call for general disclosures about who runs, or provides significant financial support for, health care Web sites, as well as specific disclosures in the case of content that is influenced by advertising or sponsorship. They also require health care Web sites to avoid a site design or layout that blurs the distinction between independent content and sponsored content or advertising.

■ Online delivery of services. Both codes also discuss the practice of medicine or other health care professions online. Because the delivery of professional health care services over the Internet is only just emerging as a business model, the two codes are much less directive in this area than in privacy or quality of content. They both state that there are existing rules that govern the conduct of health care professionals and that health Web sites must make it clear to consumers when they intend to deliver professional health care services online that would be governed by these rules (as opposed to giving generalized information about a particular disease).

Both codes require Web sites that deliver professional health care services online to clearly explain to users any limitations inherent in the medium. The eHealth code goes a little farther than the Hi-Ethics code in this regard, as it requires health care professionals working for a health care Web site to disclose their credentials and explicitly discuss specific limitations that affect their care of individual patients. The relatively flexible approach to professional health care online in both codes may reflect a realization that the governing bodies and associations of the health care professions are likely to come up with their own guidelines or rules for delivery of care over the Internet.

■ Compliance. When it comes to compliance, the codes follow a mixed model of disclosure and voluntary standards. In some
cases, they state that policies are required but not what the content of those policies must be. In other cases, they state affirmative obligations. In this sense, they are a blend of the classic disclosure-based Internet model of self-regulation and the health care model (which is more often based on standards). They also both imply the concept of a chain of trust, in that they require those who follow the codes to make sure that any others with whom they have relationships follow the applicable portions of the codes. For example, where personal information is shared with third parties, those third parties must agree to respect the provisions of the codes and privacy policies that apply to that information.

Also, the codes both contain an obligation to provide a mechanism for, and respond to, consumer feedback. Neither code directly addresses the issue of enforcement, although both sponsoring groups have announced efforts to follow through in the development of compliance mechanisms.

**Differences.** Although the two codes are similar in many respects, their scope and style differ. The eHealth code is intended to apply to almost any entity in the health care field that chooses to follow it. Much of its content is aspirational, rather than directive, and it has an academic flavor. The Hi-Ethics principles, in contrast, read almost as a practical implementation of the eHealth code. They are more directive, and the legal influence on their drafting is clear. By their terms, the Hi-Ethics principles apply only to members of the Hi-Ethics group, and in fact membership in that group is linked with compliance. The groups responsible for both codes, as well as others with similar codes, have reported that they are in discussions with each other with a view to clarifying the interrelationships between their codes.

**Self-Regulation Versus Law**

As noted above, one main criticism of both codes is that their authors intend them to minimize the call for new laws applying to health care Web sites and perhaps to prevent any new laws at all. In my view, however, even the best self-regulatory system cannot serve as an effective substitute for law.

**Who is involved.** First, consider that self-regulation only works for those who agree to be self-regulated. Looking at self-regulation as a way to police all of the bad actors in an industry is a mistake. Instead, we should view it as a way in which better companies seek to distinguish themselves and their offerings. The universe of Web sites selling homeopathic Viagra mixed with ginseng will not be signing on to either of the two current codes of ethics. That is not to say that a group of ginseng- and Viagra-selling Web sites could not put together their own code and agree among themselves to follow it. Self-regulation necessarily involves self-definition of a limited group with similar interests and goals.

Consider the often-cited gold standard for self-regulation, the Good Housekeeping Seal of Approval. Any company can submit its products for the Good Housekeeping seal, administered for the past century by the Good Housekeeping Institute.9 In fact, companies that do submit their products probably already have a pretty good idea that they will receive the seal. The seal’s guarantee only applies to companies that volunteer for the review process.10 By design, it does not reach a significant number of companies, including almost any company with substandard products. As this example shows, if we expect to regulate everyone involved in a particular activity, then laws are the only effective way to achieve our goal. A purely voluntary system of self-regulation will simply fail to pick up enough members of the group we wish to regulate. For this reason, we should not criticize self-regulation on the grounds that it does not effectively stop all harmful or decep-
tive activities on the outer boundaries of an industry. Good self-regulation is designed to reach the center, not the fringes.

■ **Need for both.** Second, because of this limited reach of self-regulatory systems, we should not even expect them to provide an effective means of avoiding new laws. If there are good policy reasons for not passing a new law in a specific area, then airing those policy reasons in a public setting will prove a better way to avoid the new law than will the creation of a new self-regulatory system. Returning to the Good Housekeeping seal, for example, it is hard to imagine anyone arguing that it allows us to consider repealing the past century’s worth of legislative and judicial protections for consumers who buy retail goods. We should apply the same reasoning prospectively and not argue that the Internet seal program of the moment obviates the need for new laws in its field of application. Of course, there may be cases where simplistic self-regulatory efforts by industry are used as one of several tactics to argue against new laws. However, these tactics (to the extent they succeed) represent a flaw in our legislative process more than a flaw in the idea of “good” self-regulation.

The work of the National Committee for Quality Assurance (NCQA) provides a current example of successful self-regulation that does not eliminate the need for laws. The NCQA is a nonprofit organization that provides a number of services to help employers and others assess the quality of managed care plans. These services include accreditation, objective measurements of quality, and public self-reporting. The NCQA’s efforts have had an observable positive effect on quality, both self-reported and reported by objective observers. Notwithstanding this success, policymakers are still considering additional governmental regulation of health plans to improve quality of care and protect consumers’ rights. Neither these reform proposals, nor the continued reports of problems at some health plans that drive them, indicate any failure by the NCQA. On the contrary, they represent a logical evolution in the self-regulatory process in which the higher standards set by the NCQA and followed by a small group are extended to an entire industry.

■ **Support of law.** Finally, many existing examples of successful self-regulatory systems have in common the support of law. The best argument one could devise for the separate goals of laws and self-regulation is to examine the historical partnership between the two, and the dependency of self-regulation on law. An example is the United Kingdom-based Prescription Medicines Code of Practice Authority (PMCPA), an independent body of the Association of the British Pharmaceutical Industry (ABPI). The PMCPA administers and enforces a self-regulatory Code of Practice for the advertising and promotion of prescription drugs. According to the ABPI, the Code of Practice itself is regularly revised in consultation with the British Medical Association, the Royal Pharmaceutical Society of Great Britain, and the Medicines Control Agency (the governmental body responsible for regulating prescription drugs in the United Kingdom). Today the PMCPA regulates many British pharmaceutical companies in the area of prescription drug advertising. The PMCPA does not, and cannot, prevent Web sites in the United States and elsewhere from sending unapproved prescription drugs or herbal medicines into the United Kingdom. However, it does serve to set a standard among its membership for advertising of prescription drugs to physicians. The self-regulatory system of the PMCPA exists in parallel with a governmental entity, the Medicines Control Agency, and the two work together to regulate all aspects of prescription drugs, including advertising and labeling activities.

If laws are necessary for the success of these self-regulatory systems, then we also should expect to find examples of unsuccessful self-regulatory systems in areas that lack the underpinning of laws. The United States does not have a general federal law on individual privacy, despite the existence of general...
regimes for the protection of privacy in the European Union and other countries. Efforts to create a self-regulatory system in the area of Internet privacy are perceived as failures, with many critics pointing to the absence of enforcement systems or laws as the reason for that perception. Recently, the chairman of the Federal Trade Commission (FTC), Robert Pitofsky, commenting on self-regulatory efforts in Internet privacy, said that “the most effective self-regulatory programs are those that have the rule of law to back them up.” Not only is self-regulation a poor substitute for law, but it also needs a framework of supporting laws to succeed.

Given policymakers’ continued concerns about online health care and privacy, the success of both of the recent codes of ethics may depend on how well their authors work toward creating compliance and enforcement mechanisms that coordinate with proposed new laws or regulations. Some current proposals for compliance recognize the key theme discussed above: The best self-regulation works hand in hand with law. For example, during the press conference at which the eHealth Code of Ethics was unveiled, Senator Lieberman announced that he was considering draft legislation that would require governmental review of industry-developed, self-regulatory standards. More recently, the FTC in a report to Congress examined the practice of covert online profiling of information about Web site users, which both ethical codes address. The FTC report states that “self-regulation cannot address recalcitrant and bad actors, new entrants to the market, and drop-outs from the self-regulatory program.” On that basis, the report proposes new legislation giving the FTC the explicit authority to promulgate mandatory standards in the online profiling area. The proposal also would allow the FTC to review self-regulatory standards and grant “safe-harbor” exemptions to organizations that comply with FTC-approved self-regulatory regimes.

Even absent new legislation such as that proposed by the FTC, the Hi-Ethics and eHealth codes may be able to integrate with existing laws. There are a number of examples of existing self-regulatory efforts that did not require the creation of new laws. In the PMCPA example, failure to follow voluntary self-regulatory standards results in a referral to the government for enforcement action. In that case, the referral occurs not because the failure to follow the standards is a violation of law (if so, the standards could hardly be called “voluntary”), but because the standards closely track underlying laws. In other cases, such as Web site privacy policies, the government may take action in the absence of an underlying substantive law, on the grounds that the breach of self-regulatory promises violates general consumer-protection laws.

Finally, many government regulations require adoption of policies or procedures without fully specifying their content, which provides an opportunity for self-regulatory groups to fill in the blanks. For example, the final regulations on electronic signatures and security under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 contain a generalized requirement that electronic signatures used by health care providers meet a standard, but they leave the actual selection and implementation of the standard to the provider. The two codes could design their enforcement component to follow any of these existing models.

Who Needs Self-Regulation?

If self-regulation works only in the limited ways I have described, what good is it? Does anyone really need it? The answer depends more on circumstances than on abstract principles. As a general matter, self-regulation should work well in areas where complexity...
or rapid change makes it difficult for consumers to understand potential dangers and for our legal system to react to actual harms. The provision of health care information and services and the protection of personal health information certainly meet these criteria. Where self-regulation does make sense, we can expect it to result in a number of benefits. Good self-regulatory systems should create a basis for improving trust, educate policymakers, and remove some of the burden of policing an industry sector from the government. In the area of health care Web sites, we should be able to derive all of these benefits from the self-regulatory system that we hope will emerge from the two recent codes of ethics.

Perhaps the most important goal of any self-regulatory system is building consumers’ trust in its participants. Self-regulation often arises in response to erosion of trust. This is certainly the case in the area of health care Web sites, which the media have faulted on both ethical and privacy grounds. The codes of ethics available for these sites today are efforts by a small group of responsible players to build consumer confidence and to establish a relationship of trust. Laws rarely achieve the goal of building trust, because they merely set a baseline for compliance. A successful self-regulatory system, however, can create an environment of trust by setting standards that only responsible organizations can meet. Participants in the self-regulatory system obtain the benefit of differentiating themselves from others whose conduct, while it may be legal, is not exemplary.

Serving as a first line of defense for problems that would otherwise cost public dollars to address is another benefit of a good self-regulatory system. The NCQA and the PMCPA both shift some of the burden of policing their respective fields away from the government. They do not replace laws, but in fact assist in the operation of law. Some self-regulatory systems, like those for the U.S. legal and medical professions, become so important to the government that they take on aspects of governmental police powers (for example, the ability to discipline members by levying fines or denying them the license to practice their profession).

Because most self-regulatory systems are developed by individuals or groups with a strong interest and expertise in the relevant field, they also have the potential to inform policymakers. Even though we should not expect a self-regulatory system to prevent new laws, we can expect it to help policymakers to develop well-reasoned ones. Unlike our legal system, good self-regulatory systems also have the potential to accommodate rapid changes. Because their drafters are so close to the leading edge, self-regulatory codes on the Internet can adapt to new developments quickly. For example, during the drafting of both the Hi-Ethics and the eHealth Ethics codes, the California HealthCare Foundation released a report exposing some serious privacy risks for health care Web sites. In their final form, both of the codes address these issues directly. The authors of the codes were able to adopt the language within three months of first learning of the problems.

These benefits of good self-regulatory systems strongly support the development of self-regulation for health care Web sites. To achieve the goal of improving the quality of health care through technology, we need to rebuild public trust, educate policymakers and consumers, accommodate rapid change, and support the existing legal framework (or any new framework that may develop).

Self-regulation is particularly appropriate for health care Web sites because of the complex information and services they provide, and because of the large number of Web sites offering questionable information or products. Incorrect information about health care choices can easily result in serious harm. Consumers typically do not have sufficient understanding of the scientific method to grasp how the anecdotal comments of an untrained author differ from the investigator’s report of a randomized, placebo-controlled, double-blinded clinical trial in a peer-reviewed publi-
cation, or how financial interests might affect the content of a news article. By putting in place and enforcing a well-designed set of rules, the codes of ethics can help consumers and health care professionals to direct their attention to high-quality sites. Over time, they even have the potential to teach users how to filter the good from the bad.

Since we do not have to choose between two mutually exclusive paths—the one being self-regulatory systems for health care Web sites and the other being new laws regulating those sites—where should we then focus our attention? What is the relevant policy debate? First, both the Hi-Ethics and eHealth codes face difficult implementation and enforcement issues at the same time as we are considering new laws. We must concentrate on ways that the two codes and new laws can support each other, rather than viewing them as competing efforts. Second, we must identify a concrete and limited set of issues for health care Web sites on which we have a realistic chance of achieving consensus. No self-regulatory system can please everyone. The existing examples of “good” self-regulation discussed above have their critics. However, these self-regulatory systems achieve their objective of enforcing a common standard among their members—a standard that is higher than would exist without their presence.

Meaningful change is more important than trying to create a perfect system. Particularly in the privacy area, we face a diversity of viewpoints that may make our task difficult. We should not allow disagreements in some areas to overshadow general agreement on ethical standards of conduct for health care online. Finally, we cannot lose sight of our shared objective: to use new technology to improve the quality of health care. By joining self-regulatory and legislative efforts for health care Web sites, we should be able to achieve this goal.

The author was personally involved in the drafting of both the Hi-Ethics code and Internet Healthcare Coalition eHealth code described in this paper and has an ongoing relationship with the organizations that developed those codes. His employer has a commercial interest in health care online and has provided funding and other support to both Hi-Ethics and the Internet Healthcare Coalition as well as other entities discussed here. He has financial interests in Medscape that could be affected by implementation or enforcement of the ethics codes, or by government regulation of his company. However, the views expressed in this paper are those of the author alone and do not necessarily represent those of his employer.

NOTES
8. For example, see B. Kane and D. Sands, “Guidelines for the Clinical Use of Electronic Mail with

9. More information about the Good Housekeeping Institute and its seal program can be found on the Good Housekeeping magazine Web site, <goodhousekeeping.women.com/gh>, or in any issue of the magazine.

10. The Good Housekeeping Web site states that “if a product bearing the Seal proves to be defective within two years of purchase, Good Housekeeping will replace the product or refund the purchase price.” <goodhousekeeping.women.com/gh/misc/institute/ghinstr2.htm> (30 August 2000).

11. Some major examples include the federal laws creating and empowering the Federal Trade Commission, the state laws enacting Article 2 of the Uniform Commercial Code, and the judicial development of the doctrine of strict products liability.


14. The NCQA, for its part, is calling for increased participation by hospitals and fee-for-service providers in its self-regulatory system. NCQA, *The State of Managed Care Quality*.


18. See, for example, the European Union’s Directive 95/46/EC on “the protection of individuals with regard to the processing of personal data and on the free movement of such data.”


21. Based on the author’s personal knowledge after attending the event.


23. See GeoCities, Inc., Docket no. C-3849, 1999 FTC LEXIS 17 (FTC, 5 February 1999). The GeoCities case was the first of several cases where the FTC successfully obtained consent decrees against Web sites that did not follow their own privacy policies.


25. A recent study of consumer opinion found that online health users trusted “portal” health care Web sites the least when it came to protecting their health information. Cyber Dialogue, *Ethics Survey Of Consumer Attitudes about Health Web Sites* (Oakland, California HealthCare Foundation, 2000), 10


27. Of course, any self-regulatory system also may have the effect of advancing the economic interests of members through differentiation, which may raise anticompetitive concerns. See McGee, “Economics and Net Medical Ethics.” However, this critique applies to both self-regulation and direct government regulation (for example, in the systems of mandatory regulation that apply to physicians or attorneys) and therefore should not serve as a criterion for choosing between the two.
