HHS Issues Final HIPAA Privacy Rule

by Hollis Hanover

On August 14, 2002, the U.S. Department of Health and Human Services (“HHS”) issued the much-anticipated final Standards for Privacy of Individually Identifiable Health Information (the “Privacy Rule” or the “final rule”) under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). The HIPAA Privacy Rule is aimed at protecting confidential health information from being disclosed by “covered entities,” which include health care providers, health plans, and health care clearinghouses. The Privacy Rule was originally published by HHS in December 2000 (“the original rule”) and most covered entities must comply with the rule’s terms by April 14, 2003. A more detailed summary of the final Privacy Rule will be provided in the near future. Additional information can be found at http://www.hhs.gov/ocr/hipaa/whatsnew.html.

The final rule largely adopts modifications proposed at the end of March 2002 (the “proposed modifications”) that were designed to strengthen the original rule’s privacy protections without hindering patients’ access to health care. Based on comments received after issuance of the original rule and the proposed modifications in March 2002, HHS revised several key areas of the Rule, including the following:

Consent and Notice of Privacy Practices
The most significant change from the original Privacy Rule is the removal of the consent requirements for disclosures of protected health information (“PHI”) connected with routine health care delivery purposes — any treatment, payment or health care operations (“TPO”). Covered entities will need to provide patients with a notice of the provider’s privacy practices and the patient’s privacy rights, and do their best to obtain a written acknowledgement from the patient of receipt of such notice. Obtaining formal consent is optional, but encouraged, under the final Privacy Rule. The final rule does not modify the content requirements for this notice, which under the original final rule require providers to describe in specific detail their planned uses and disclosures of health information. The preamble of the final rule provides for the use of a “layered notice” — a short, summary notice

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that is placed on top of a longer notice containing all the required elements of the notice. The privacy notice must be provided at the time of first service delivery, except in emergency treatment situations or where otherwise impractical, but providers are required to attempt to obtain the acknowledgement as soon as practicable thereafter. Other covered entities, such as health plans, would not be required to obtain this acknowledgement.

HHS has emphasized that covered entities may voluntarily obtain patient consents as "an integral part of the ethical and other practice standards for many health care professionals" and that entities have "complete discretion" in designing their consent process.

The final rule allows for certain disclosures by covered entities, to other covered entities for the treatment, payment, or certain operational purposes of the other covered entity, for treatment purposes to health care providers, regardless whether they are covered entities, without consent or authorization if (1) both the disclosing and the receiving entities have a relationship with the individual whose information is being exchanged; and (2) the PHI pertains to the recipients' relationship with the individual. If these two criteria are met, PHI may be disclosed for operational purposes of the covered entity, such as quality assessment, accreditation, licensing, credentialing, case management, training, or activities relating to improving health care or reducing health care costs, or for the purposes of detection or compliance with fraud and abuse laws.

Authorization

The final rule does not alter the original Privacy Rule's requirement that covered entities obtain patient authorization for uses of patient information beyond TPO, but it does permit the use of one form of disclosure, rather than the several different forms required by the original rule.

Minimum Necessary Rule

The original Privacy Rule required providers to adopt policies and procedures to safeguard and limit disclosure of the PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. While this requirement remains in effect, the final rule clarifies that a provider could discuss a patient's treatment with other professionals involved in the patient's care without fear of violating the rule if they are overheard. The final rule further clarifies that incidental uses or disclosures that are the byproduct of an otherwise permissible use or disclosure do not violate the regulations, if the provider otherwise meets the minimum necessary rule and takes "reasonable safeguards" to avoid being overheard. Therefore, processes or conduct such as a patient sign-in sheet in a doctor's office waiting room, keeping patient charts at their bedside, or doctor's conferring with others at a nurse's station can continue without fear of violating the rule.

Business Associates

Under the original and final Privacy Rule, third parties who may receive PHI from covered entities in the course of providing certain defined services for, or functions on behalf of, covered entities are defined as business associates. Covered entities are required to enter into a contractual agreement with business associates to safeguard the PHI shared with the business associate. The final rule allows most covered entities (except small health plans) to operate under existing contracts with business associates for up to one year beyond the April 14, 2003 compliance date of the Privacy Rule. This extension does not apply to oral contracts or other arrangements not reduced to writing and new written contracts entered into after April 14, 2003.

HHS also provides model language for business associate contracts to assist covered entities in compliance with the business associate provisions of the Privacy Rule. Importantly, these sample provisions are not necessarily sufficient to form a complete and binding contract. The parties to these agreements may wish to include other contractual provisions not required by HIPAA, such as indemnification and limitation of liability clauses, in order to allocate the risk associated with the use and disclosure of confidential patient health care information.

Medical Research

The final rule allows researchers to use a single combined form for both HIPAA and informed consent purposes, and modifies other provisions to more closely track (but still not supersede or preempt) the requirements of the so-called "Common Rule" and Food and Drug Administration regulations, both of which govern federally-funded research. As a result, the final rule, while reducing complexity, does not alter the basic requirement that those involved in medical research comply with multiple and overlapping sets of federal (as well as more stringent
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Accounting of Disclosures:
The final rule eliminates the requirement that a covered entity account for disclosures pursuant to a patient’s authorization (on the theory that the patient already knows about the disclosure if he or she has authorized it), incidental disclosures, or disclosures that are part of a limited data set. The Privacy Rule provides a simplified alternative approach for accounting for multiple research disclosures that includes providing a description of the research for which an individual’s PHI may have been disclosed and contact information.

Disclosures for Treatment, Payment, or Health Care Operations of Another Covered Entity: The final rule clarifies that covered entities are permitted to disclose PHI without consent or authorization for the treatment, payment and certain health care activities of another covered entity.

PHI: Exclusion for Employment Records: The final rule clarifies that employment records maintained by a covered entity in its capacity as an employer are excluded from the definition of PHI. If, however, an employee’s PHI is created, received or maintained by a covered entity in its capacity as health care provider and not as an employer (i.e., hospital employee is a hospital patient), then the patient’s information would be protected PHI under the rule.

Comment
By and large, the final Privacy Rule is less burdensome for health care providers than the original rule issued in December 2000. Now that the final rule has been issued, compliance with the HIPAA Privacy Rule needs to be a priority for all covered entities and business associates as the effective date of April 14, 2003 draws near. Navigating the seas of these comprehensive regulations safely will be essential for all providers in the coming months. ●
PhRMA Adopts New Voluntary Ethics Code on Interactions with Health Care Professionals

On April 18, 2002, the Pharmaceutical Research and Manufacturers of America ("PhRMA"), the research-based pharmaceutical industry’s association, adopted a voluntary Code on interactions with physicians and other health care professionals (the “PhRMA Code” or “Code”). Taking effect on July 1, 2002, the Code addresses interactions with respect to marketed products and related pre-launch activities. It does not address relationships with clinical investigators relating to pre-approval studies.

Pharmaceutical company officials have emphasized that their efforts reflect an attempt to establish a common set of rules that will inspire broad industry compliance. PhRMA is reported to remain interested in having the U.S. Department of Health and Human Services, Office of the Inspector General (“OIG”) issue a compliance guidance document for pharmaceutical sales and marketing to provide more details on acceptable and unacceptable interactions between physicians and drug companies.

While the Code is voluntary, Assistant U.S. Attorney for the Eastern District of Pennsylvania James G. Sheehan, has suggested that the government will look closely at whether companies have in good faith adopted the standards expressed in the Code. “To the extent people operate outside the lines, the more they’re exposed,” according to Sheehan. While the relationship between the Code and the federal antikickback statute is unclear, the industry hopes that the OIG will treat compliance with the new Code as a de facto safe harbor. At a minimum, compliance with the code may be evidence that a drug manufacturer lacked the intent to induce necessary to prove a violation of the antikickback law.

The new Code supersedes PhRMA’s existing Code of Pharmaceutical Marketing Practices, which had incorporated the American Medical Association ("AMA") 1990 Guidelines on Gifts to Physicians from Industry. The Code and the AMA Guidelines are largely consistent, although the new Code is more restrictive and specific than the older guidelines in a number of respects. For this reason, while the Code does not apply to them directly, physicians and other health care professionals would do well to acquaint themselves with its provisions.

What follows below is a brief overview of the PhRMA Code’s main provisions. Additional information concerning the Code is available at http://www.phrma.org.

Basic Principles
The PhRMA Code is founded on the basic principle that pharmaceutical company sales representatives provide valuable information to physicians and that companies need feedback and advice from physicians to improve products and promote enhanced patient care. Toward this end, the Code provides that “interactions should be focused on informing health care professionals about products, providing scientific and educational information, and supporting medical research and evaluation.”

The Code is also based on the principal that a “health care professional’s care of patients should be based, and should be perceived as being based, solely on each patient’s medical needs and the health care professional’s medical knowledge and experience.” As such, the Code provides that prescriptions should reflect independent decision making by the physician and that “no grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a health care professional in exchange for prescribing products or for a commitment to continue prescribing products.”

Finally, under the Code, nothing is to be “offered or provided in a manner or on conditions that would interfere with the independence of a health care professional’s prescribing practices.”

Covered Activities
The PhRMA Code addresses the following sales and marketing practices:

- Meals, Entertainment, Gifts & Recreation
- Consultants and Speaker Training Meetings
- Third-Party Educational or Professional Meetings
- Scholarships and Educational Funds

A. Meals, Entertainment, Gifts & Recreation
The provision of free meals, trips, gifts, and recreational activities to physicians has long been pointed to as a source of questionable influence on physician prescribing activities. The PhRMA Code addresses this issue in the context of informational presentations and the provision of educational and practice-related items.

With respect to informational presentations and discussions by industry representatives and others speaking on behalf of a company, meals may be offered, but not any entertainment or recreational events. If a meal is provided, the meal/event must:

- Be modest as judged by local standards;
- Be offered only occasionally;
- Occur in a venue and manner conducive to informational communication;
- Provide educational/scientific value; and
- Be eaten with a company representative present (i.e., no “dine & dash” programs permitted).

In addition to these guidelines, the Code provides that the inclusion of a health care professional’s spouse or other guests is not appropriate.

The PhRMA Code is stricter on the topic of meals than the AMA Guidelines in a number of respects. In particular, the AMA Guidelines are less specific with respect to the types of events within which physicians may participate (e.g., inexpensive boat rides and other forms of inexpensive entertainment are permitted). The AMA Guidelines also permit spouses to attend meals at otherwise permitted drug-company sponsored conferences, and do not specifically address the issue of “dine & dash” type events.

With respect to educational and practice-related (gift) items, such items may be offered to health care professionals if they are:

- Primarily for the benefit of patients;
- Are not of substantial value ($100 or less) (e.g., an anatomical model used in an examination room or stethoscope is okay);
- Are not intended for the personal benefit of the health care; professional (e.g., no DVD or CD players, flowers or sporting event tickets);
- Not offered in the form of cash or cash equivalents (for example gift certificates), except as provided as compensation for bona fide consulting services (see below);
- Not offered on more than an occasional basis, even if the individual item is otherwise appropriate; and
- Items of minimal value primarily associated with the health care professional’s practice (e.g., pens, notepads, and similar “reminder” items with company or product logos).

In addition, the Code permits the provision of marketing samples for patient use in accordance with the federal Prescription Drug Marketing Act. Literally read, the provision on product samples is more restrictive than the AMA Guidelines, which permit physicians to accept samples for personal or family use in particular circumstances. The Code is also more restrictive with respect to gifts, as the AMA Guidelines do not place limits on the frequency with which otherwise appropriate gifts may be accepted and do not expressly ban gifts offered for a physician’s personal benefit.

B. Consultants and Speaker Training Meetings

The PhRMA Code permits pharmaceutical companies to retain health care professionals as “bona fide consultants” if they provide legitimate services to the company. This includes, for example, the retention of a health care professional to serve on an advisory board or as a trainee at a corporate speaker-training meeting.

Companies are permitted under the Code to pay their bona fide consultants reasonable compensation for services rendered. The Code also permits companies to offer bona fide reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing these services. In addition, the Code allows companies to provide bona fide consultants modest entertainment or recreational activities. This is an exception to the Code’s general prohibition against providing entertainment or recreational activities to health care practitioners. (See Section A above).

Companies may not, however, pay for a consultant’s spouse to attend consultant meetings. This contrasts with the AMA Guidelines which permit companies to subsidize the cost of lodging or meals for a consultant’s spouse.

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necessary to achieve the identified purpose; 
• The retaining company maintains records concerning and makes appropriate use of the services provided by the consultants; and 
• The venue and circumstances of any consultant meeting are conducive to the consulting services, the consulting services are the primary focus of the meeting, and any social and entertainment events are clearly subordinate.

While not an exact match, it has been noted that these factors track closely with the antikickback statute’s safe harbor for personal services contracts.

C. Third Party Educational or Professional Meetings

The Code also addresses third-party educational or professional meetings such as continuing medical education (“CME”). Because these events can contribute to the improvement of patient care, the Code permits companies to provide financial support to these events provided that:

• The event is a conference or meeting held at an appropriate location, where the gathering (a) is primarily dedicated to promoting objective scientific and educational activities and discourse, and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented;
• Contributions are given to the sponsor of the conference (rather than individual health care professionals). These contributions can be used to lower registration fees and/or provide meals/receptions for all attendees; they should not be used to cover the costs of travel, lodging or other personal expenses of non-faculty health care professionals, or the costs of spouse attendance;
• Control over the conference content is left to the third party organizer;
• Any meals or receptions hosted directly by the company comply with the sponsoring organizations’ guidelines; such meals or receptions are modest in nature and conducive to discussion among faculty and attendees; and the amount of time spent at the company’s meals or receptions is clearly subordinate to the amount of time spent at the educational activities of the meeting.

As noted above, the Code generally prohibits companies from covering travel, lodging, or other personal expenses of non-faculty health care professionals whether such support is provided directly to a health care professional or indirectly through the third party conference sponsor. Funding to compensate health care professionals for their time in attending a meeting or conference is similarly prohibited.

D. Scholarship and Educational Funds

The PhRMA Code allows companies to offer financial assistance for scholarships and other educational funds to permit medical students, residents, fellows, and other health care professionals in training to attend “carefully selected educational conferences.” The Code generally
The Supreme Court recently ruled that an Illinois law that provided HMO beneficiaries with a right to independent medical review of certain benefit denials is not preempted by the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 et seq. Rush Prudential HMO, Inc. v. Moran, 2002 WL 1337696 (June 20, 2002). The decision resolves a split on this issue among the lower appellate courts and has the effect of upholding similar laws in 40 other states.

The plaintiff in this case was Debra Moran, a woman who received HMO insurance coverage with Rush Prudential HMO through her husband’s employer. Moran applied for and was denied coverage for unconventional shoulder surgery by an out-of-network provider. Rush would have paid for conventional surgery by an in-network provider, but indicated that the unconventional procedure was not medically necessary. Moran challenged the denial and sought an independent medical review as provided under Illinois law, § 4-10 of Illinois HMO Act, 215 Ill. Comp. Stat., ch. 125, § 4-10 et seq. (2000). Rush denied this request. Moran subsequently sued to compel compliance with the statute. She also had the surgery done and sued Rush for reimbursement.

After extensive litigation in both state and federal court, a state court ordered Rush to submit to review by an independent physician. The outside physician decided that the unconventional surgery was medically necessary. Rush refused to accept the independent reviewer's decision and denied Moran's claim again. Moran amended her state court complaint to claim that the surgery was medically necessary under the Illinois HMO Act. Rush successfully removed the case to federal court, where the district court ruled that all of Moran’s claims were completely preempted by ERISA. Moran appealed to the U.S. Court of Appeals for the Seventh Circuit. As reported in the Winter 2001 issue of Health Law Briefs, the Seventh Circuit agreed with the lower court that Moran’s request for reimbursement was preempted by ERISA, which provides a specific remedy for such claims. 230 F.3d 959 (2000). However, the appellate court ruled that independent medical review requirement was a law that regulates insurance and therefore was “saved” from preemption under ERISA. 29 U.S.C. §1144(b)(2)(A). This ruling was in direct conflict with a decision by the U.S. Court of Appeals for the Fifth Circuit, Corporate Health Insurance, Inc. v. Texas Dept. of Insurance, 215 F.3d 526 (2000). Rush filed a petition for certiorari with the Supreme Court, which took the case to resolve the split in the circuits.

The high court affirmed the Seventh Circuit’s decision. While ERISA broadly preempts “any and all State laws insofar as they may now or hereafter relate to any employee benefit plan...” 29 U.S.C. § 1144(a), the statute also contains a “savings clause” that states that “nothing in this subchapter shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities.” § 1144(b)(2)(A). This savings clause was included to conform with the McCarran-Ferguson Act, 15 U.S.C. § 1011 et seq, which mandates that the business of insurance be regulated under state law, and that no federal law can invalidate or interfere with such laws. The Court noted that the Illinois independent medical review statute clearly relates to employee benefits plans. The issue for decision was whether it was also a law that regulates insurance and thus protected by the McCarran-Ferguson Act.

The Court’s precedents for determining whether a law regulates insurance for purposes of the ERISA savings clause require the application of a common-sense inquiry under which “a law must not just have an impact on the insurance industry, but must be specifically directed toward that industry.” If the law passes this test, the Court then applies a three-factor analysis established for implementing the McCarran-Ferguson Act.

The Court first found that the Illinois law passed the common-sense inquiry, finding that HMOs are both insurers and health care providers. To the extent that they underwrite and spread risk, they are clearly in the business of insurance and subject to state regulation of such activities. The Court ruled that this conclusion was clearly supported by Congress’s treatment of HMOs as insurers in numerous contexts. The Court rejected Rush’s argument that HMOs ability to pass risk off to providers and reinsurers somehow takes the HMO out of the business of insurance. The HMO is still bound to provide health benefits to its participants even if providers and other third party insurers breach their obligations to the HMO.

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The Court then found that the Illinois independent medical review law passed the three-factor test under McCarran-Ferguson—i.e., the law targets practices or provisions that “ha[ve] the effect of transferring or spreading a policyholder’s risk;…[that are] an integral part of the policy relationship between the insurer and the insured; and [are] limited to entities within the insurance industry.” Union Labor Life Ins. Co. v. Pireno, 458 U.S. 119, 129, 102 S.Ct. 3002, 73 L.Ed.2d 647 (1982).” The court noted that a state law is not required to satisfy all three McCarran-Ferguson criteria to survive preemption and focused its inquiry on the second and third factors, which it determined were clearly satisfied by the Illinois law. The law is integral to the policy relationship because it affords the beneficiary with the authoritative right to independent review of the HMO’s medical obligations, according to the Court. The Court also found that the Illinois law was aimed at a “practice…limited to entities within the insurance industry.” After clarifying that HMO contracts are contracts for insurance (and not merely contracts for medical care), and that the Illinois law regulates the interpretation of HMO contracts, the Court found that the law does not apply to entities outside the insurance industry.

Lastly, the Court rejected Rush’s argument that, even if ERISA’s saving clause applied in this case, congressional intent for ERISA’s civil enforcement provisions to be the exclusive remedy for wrongful denial of benefits by ERISA health plans should still override the alternative remedy provided by the Illinois law. The Court found that the independent medical review required by Illinois law has the practical effect of providing a binding second opinion regarding medical necessity, but does not otherwise displace the normal ERISA remedies and causes of action. Rather, the independent review statute is more like a regulation of the insurance contract, similar to laws that mandate certain benefits or preclude denial of benefits solely because of untimeliness.

Based on all these factors, the Court found that the Illinois law was not preempted by ERISA.

Justice Thomas, joined by Chief Justice Rehnquist and Justices Scalia and Kennedy, dissented. The dissenters would have ruled that ERISA preempted the Illinois law because the independent medical review mandate was, in their view, the equivalent of an arbitration-type procedure that supplanted or supplemented the remedies provided by ERISA, in violation of congressional intent. Justice Thomas stated that this decision conflicts with Supreme Court precedents and eviscerates the uniformity of ERISA remedies Congress deemed integral to the “careful balancing of the need for prompt and fair claims settlement procedures against the public interest in encouraging the formation of employee benefit plans.”

Comment
The Court’s long-awaited decision in Rush v. Moran represents yet another chink in the ERISA preemption armor and provides a boost to state regulation of HMOs. Some 40 states have similar laws mandating independent medical review of claims denials. The court’s decision has the effect of upholding all of these laws. Independent medical review was also a common feature in all of the major patient protection bills recently considered by Congress. The Court’s decision continues the trend toward reading the ERISA preemption provision narrowly and the savings clause broadly so as to permit states to expand their efforts to even the playing field between patients and managed care organizations. But, at the same time, it further erodes the uniformity that ERISA was supposed to provide. While many states have similar laws, they differ from each other in important respects, forcing insurers to adjust to the inevitable inconsistencies that these laws present. On balance, therefore, the Court’s decision further demonstrates the need for consistent federal legislation that will protect patient rights without requiring insurers to bear the expense of complying with 50 different sets of rules.
Managed Care Class Actions Heat Up

by Edward J. Malone

Earlier this year, managed care organizations (MCO’s) and their subscribers faced off again over a new set of motions to dismiss filed by MCO’s in multi-district litigation pending in the United States District Court for the Southern District of Florida. On February 20, the district court issued a lengthy opinion that handed victories and defeats to both sides. See In re Managed Care Litigation, 185 F.Supp. 2d 1310 (S.D. Fla. 2002). The court dismissed all of the claims of certain plaintiffs, but allowed the racketeering and breach of fiduciary duty claims of other plaintiffs to proceed.

The gist of the lawsuit is that MCO’s have breached fiduciary duties owed to plan members by misapplying the definition of “medical necessity” set forth in their summary plan descriptions (SPDs). Rather than determining medical necessity in a manner consistent with the best interests of patient subscribers, the suit alleges, MCO’s have created incentives for physicians to provide the minimum possible level of care. The suit claims that plaintiffs are entitled to relief under federal Racketeer Influenced and Corrupt Organizations Act (RICO), the Employee Retirement Income Security Act (ERISA), and certain common law theories.

The court first considered whether plaintiffs’ RICO claims were barred by the McCarran-Ferguson Act, which allows states to regulate insurance companies that operate within their borders. Although the United States Supreme Court has previously held that because RICO actions advance state law policies prohibiting insurance fraud, they are not barred by McCarran-Ferguson, the Court has yet to apply this rule to states that do not provide for private insurance fraud lawsuits. Id. at 1320-22. The Court then held that the RICO claims of the remaining plaintiffs should be allowed to stand, rejecting defendants’ arguments that the plaintiffs had not adequately pleaded either that RICO enterprises exist or that the defendants “operate or manage” such enterprises. The court reasoned that at least in the Eleventh Circuit, each network of physicians, hospitals, pharmacies and other professionals through which the defendant MCO’s deliver health care to their subscribers, and which the defendants “openly celebrate,” could constitute an enterprise. Id. at 1323-24.

The court also found that the plaintiffs had adequately pleaded that the MCO’s “operate or manage” these enterprises because “[e]ach insurance company is poised at the apex of the network of its creation and facilitates the interaction between members of the enterprise on a daily basis” and because plaintiffs allege that each company “applies extortionate financial and contractual pressure on physicians…” Id. at 1324.

The plaintiffs were less successful in staving off the MCO’s attacks on their ERISA claims. First, the court considered plaintiffs’ claims that the plans breached their fiduciary duties by misrepresenting the “medical necessity” definition in the plan documents – the “medical necessity breach of fiduciary duty claims.” Although it questioned the extent to which the plans owe fiduciary obligations to current plan members to provide them with accurate information concerning the availability of future benefits under an ERISA plan, it

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assumed for the sake of argument that they do. But it held that the current subscribers’ claims for injunctive relief to stop the alleged ongoing violations of the plans’ fiduciary obligations should be dismissed because those plaintiffs had an adequate remedy under ERISA’s claims for benefits provision, 29 U.S.C. 1132(a)(1)(B)—i.e., the provision that allows plan participants to be reimbursed for the cost of the benefits sought.

The Court next considered plaintiffs’ allegations that current subscribers were entitled to restitution and remedial disclosures under section 1132(a) (3) for alleged misrepresentations and omissions in the SPDs. In these “SPD claims,” plaintiffs alleged that the SPDs misrepresented “medical necessity” and failed to disclose both the source of the plan’s financing and the identity of the organizations through which benefits would be provided. Once again, the court dismissed the claims because the plaintiffs had an adequate remedy under other ERISA provisions — section 1132(c), which provides specific remedies in situations where a plan administrator refuses to comply with a request for information from a plan participant or beneficiary, and possibly section 1132(a)(1)(B), which provides remedies for violations of an SPD. Although it had already dismissed the medical necessity claims, the court nevertheless considered whether the current subscriber plaintiffs’ failure to exhaust their administrative remedies before filing their medical necessity claims should be excused, and concluded that they should not. The plaintiffs argued that the exhaustion requirement should be waived because no administrative procedure capable of addressing their claims had been disclosed to them. The court responded that this was no excuse because the plaintiffs had never asked. The Court acknowledged that it had permitted the plaintiffs to pursue RICO claims based on similar facts and allegations, but noted that RICO and ERISA are different statutes based on different policies. The court reached no conclusion regarding whether the plaintiffs could be excused from exhausting administrative remedies in connection with their claims regarding the source of financing and SPD administration claims because “those claims are not clear attempts to circumvent the claim review process…” Id. at 1333.

The court then held that the breach of fiduciary duty claims of the plaintiffs who are no longer subscribers to defendants’ plans could state valid misrepresentation claims, so long as they were tailored to conform to the court’s interpretation of the duties ERISA imposes on fiduciaries to disclose information. Specifically, those claims had to amount to more than an allegation that defendants misled their subscribers by failing to give enough information about the cost suppression incentives to enable them to understand medical necessity. Id. at 1333-34.

Towards the end of its opinion, the court considered two other ERISA issues. First, it considered plaintiffs’ claims that the defendants had breached fiduciary duties under section 1104(a)(1)(A) of ERISA by allegedly contracting with providers to suppress information about the providers’ financial incentives to limit the cost of services they will provide or recommend to subscribers. Although the court had previously held that absent a specific inquiry, plans had no affirmative duty to disclose financial incentives, allegations that the plans had taken specific actions to suppress information could state a claim for breach of fiduciary duty under ERISA. Id. at 1334-35.

Second, the court dismissed plaintiffs’ allegations of a conspiracy among the managed care plans because section 1132(a) of ERISA provides sufficient relief for breaches of fiduciary duty, so there is “no justification for fashioning an independently-standing ERISA conspiracy claim against the Defendants.” Id. at 1335.

The upshot of the opinion is that while the court limited the tools available to plan subscribers to prosecute their claims that the MCO’s misled subscribers, the tools it left them with are still very powerful. It will likely be harder for plaintiffs to prove criminal activity under RICO than it would have been to establish breach of duties under ERISA, but if they succeed, the remedy—treble damages—will be harsh.
Florida had previously attempted to prohibit dentists in the state from advertising specialty practices and certifications that were not recognized by the State or by the American Dental Association (ADA). That law was found to be an unconstitutional ban on commercial speech in 1998. In response, the State amended the law so that dentists were permitted to advertise their non-approved specialties and certifications, as long as their ads disclosed that the specialties and certifications were not approved by the State or ADA.

Richard Borgner, a Florida dentist who specializes in “implant dentistry,” won his challenge to the original law in 1998, arguing successfully that the outright ban violated dentists’ First Amendment right to advertise. Borgner went on to challenge the new law on constitutional grounds, though not with the same degree of success. While he won in the lower court, which ruled the new law unconstitutional, the United States Court of Appeals for the 11th Circuit recently found the new law to be constitutional. Borgner v. Brooks, 284 F.3d 1204 (11th Cir. 2002).

Dr. Borgner advertised himself as a member, Fellow, and Diplomate of the American Academy of Implant Dentistry and the American Board of Oral Implantology/Implant Dentistry. Neither the State nor the ADA recognizes either of these organizations, nor does the ADA recognize the specialty of implant dentistry.

In order to decide whether the new law amounted to an unconstitutional ban on commercial speech, the court considered four related questions: (1) whether dentists’ advertisements are protected by the First Amendment, (2) whether the State has a substantial interest in protecting consumers, (3) whether the law advances the State’s interest, and (4) whether the law is more restrictive than it needs to be to serve that interest. The court found that the ads are examples of protected commercial speech. However, it also found that the State has a substantial interest in protecting consumers from potentially misleading advertisements, and that the new law reasonably advances that interest.

The court seems to have been most persuaded by the State’s introduction of the results of two consumer surveys. The survey results showed that a majority of consumers would be led to believe that credentials in ads such as Borgner’s were recognized by the State or by the ADA, a mistaken assumption that the law was designed to prevent.

One of the surveys found that nearly two-thirds of respondents believe that a dentist who advertises as being “certified by a board as a specialist in a particular area” has been certified by the State of Florida or the ADA. The survey also showed that nearly three-fifths of respondents believe that a dentist who advertises as being a “specialist in a particular area” or “having his or her practice limited to a certain area” has been certified by the State or the ADA. Based on the survey evidence, the court found that consumers rely heavily on State certification and ADA approval when evaluating both general and specialized dentists.

The court found that actual harm to the public would result if advertisements such as Borgner’s were not regulated. Finding that the law’s disclosure requirement did not go too far in regulating those ads, the court held the law to be constitutional.

The Borgner decision could have far-reaching effects on the advertising rights of health care professionals of all types. The ruling confirms that states have significant power to limit truthful provider advertising if it can be shown that consumers will nonetheless be misled. As a result, physicians, dentists, and other health care providers will need to exercise greater care in how they describe themselves in their advertisements and other marketing materials.
defines such conferences as "major, educational, scientific, or policy-making meetings of national, regional, or specialty medical associations." This section of the Code serves as a limited exception to the Code's prohibition against funding the personal expenses of individual health care professionals who seek to attend third-party educational or professional meetings (see Section C pg. 6). ●

Notes
1. The federal Anti-kickback statute, 42 U.S.C. Section 1320a-7b(b), prohibits the knowing and willful inducement of referrals or the purchase of products and services, under a federal health care program. Due to the complexity of the Anti-kickback law, OIG has developed a series of "safe harbors." Health care transactions that meet the requirements of a safe harbor will not be subjected to scrutiny by OIG. Other transactions that do not fall within a safe harbor are not necessarily unlawful, but may be subject to OIG scrutiny.
2. PhRMA Code, preamble.
3. PhRMA, Code, preamble.
5. Id.
7. See PhRMA Code, § 4.
8. See PhRMA Code, Question h.
9. See PhRMA Code, Question i.
10. See PhRMA Code § 3.

Newsletter Contact
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Rob Portman
Jenner & Block, LLC
601 Thirteenth Street, N.W., Suite 1200 S, Washington, D.C. 20005
Tel: 202 639-6880
E-mail: rportman@jenner.com

Offices
Chicago
One IBM Plaza
Chicago, Illinois 60611-7603
312 222-9350

Dallas
1717 Main Street
Suite 3150
Dallas, Texas 75201-4647
214 746-5700

Washington, D.C.
601 Thirteenth Street, N.W.
Suite 1200 South
Washington, D.C. 20005-3823
202 639-6000

www.jenner.com