UnitedHealth Group and Aetna Agree to Settlements of Out-of-Network Reimbursement Rates

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Readers may recall an article in a previous issue of the *Northern Ohio Physician* which discussed various enforcement activities and litigation directed toward providing relief for patients, physicians and other healthcare providers who have been frustrated by the low reimbursement levels paid by managed care plans for healthcare services performed on an out-of-network basis. Since that article was published, relief has arrived in the form of a flurry of settlement agreements.

During a three day period in mid-January, 2009, UnitedHealth Group Inc. (UnitedHealth) and Aetna entered into separate settlement agreements with New York's Attorney General Andrew Cuomo, putting to rest the Attorney General's investigation into their use of the Ingenix database to establish "usual, customary and reasonable" (UCR) reimbursement rates for out-of-network services, and UnitedHealth entered into a settlement agreement with the American Medical Association (AMA) and other plaintiffs to resolve a class action lawsuit filed in 2000.

New York Settlement

In February 2008, the New York Attorney General announced his intent to sue five UnitedHealth companies and investigate other prominent health insurance companies for defrauding consumers by underestimating the UCR charges, resulting in underpayments for out-of-network healthcare services and requiring patients to cover a higher share of the costs. On January 13, 2009, just eleven months later, the parties reached a settlement. The settlement provides that UnitedHealth will pay $50 million to finance the development of a new, independent database that will determine UCR reimbursement rates and will replace the Ingenix database formerly used by UnitedHealth and most other major health insurance companies. The settlement additionally requires the creation of an informational Web site that will educate healthcare consumers about market prices of medical services by displaying reimbursement rates and other healthcare-related information. Two days later, the Attorney General entered into a similar agreement with Aetna, which agreed to pay $20 million for the new database. On February 2, 2009, the Attorney General announced that Aetna also agreed to pay more than $5 million, plus interest and penalties, to reimburse out-of-network claims that were underpaid.

"We are committed to increasing the amount of useful information available in the healthcare marketplace so that people can make informed decisions, and this agreement is consistent with that approach and philosophy," said Thomas L. Strickland, executive vice president and chief legal officer of UnitedHealth.

Class Action Settlement

In 2000, the AMA and other private plaintiffs filed a class action lawsuit against various UnitedHealth companies as well as MetLife and American Airlines challenging the calculation of UCR by Ingenix as flawed. Nearly a decade later, the parties reached a settlement establishing a $350 million fund in which members of the plaintiff class will be eligible to receive compensation. This settlement is the largest monetary settlement of a class action lawsuit against a single healthcare insurer in the United States. While this agreement is a substantial accomplishment, the settlement agreement is nevertheless subject to court approval.

The Future of Reimbursement Rates for Out-Of-Network Care

These settlement agreements are huge milestones for healthcare providers, although the battle for appropriate out-of-network reimbursement is far from over. The success of these agreements is largely dependent on the creation of a practical alternative to the Ingenix database, court approval of the class action settlement agreement, and continuing diligence by all parties in implementing fair out-of-network reimbursement rates. ■

Physician Interaction With Pharmaceutical Companies: New Rules and Nationwide Trends

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Background

In the 1993 film *The Fugitive,* Harrison Ford plays the role of the handsome and eminently ethical surgeon Richard Kimble. Dr. Kimble is betrayed by a murderous plot engineered by a corrupt pharmaceutical company and a complicit physician. The pharmaceutical company has enticed Kimble's corrupt physician-colleague with lavish fishing trips and travel, leading to altered clinical study results designed to falsely promote a new and dangerous drug.

Wild and unrealistic as the Hollywood story line in *The Fugitive* is, it nonetheless symbolizes the extreme end of a growing public perception of "impropriety" in the relationship between healthcare professionals (HCPs) and pharmaceutical companies. These two groups are increasingly trying to address that perception of impropriety — in ways that will affect physicians immediately.

In reality, effective relationships between HCPs and pharmaceutical companies are essential to quality medical care. The HCPs provide necessary input to the companies regarding patient needs and clinical data, leading to the development of new and effective medications and devices. The pharmaceutical companies design and develop the products needed and then provide the HCPs with the most accurate, up-to-date information regarding the products. Patients benefit from this symbiotic relationship. However, over the past several years there has been growing public skepticism regarding the HCP-pharmaceutical company relationship. This negative perception has been fueled, in part, by the increasing cost of healthcare and certain high profile stories of alleged improprieties, including vast waves of lawsuits.

New trends — transparency and rebutting the appearance of impropriety

This "appearance of impropriety" has prompted new and revised guidelines and legislation intended to rebuild faith in the healthcare industry, eliminate the perceived and actual conflicts of interest and promote transparency in the relationships between HCPs and companies. This trend can be seen throughout the medical community — in the new PhRMA Code, in proposed federal laws, in new hospital guidelines and procedures, in medical society ethical standards, and in medical journals.

For example, one proposed federal bill, the Independent Drug Education and Outreach Act of 2008 (introduced July 31, 2008 by Sen. Herbert Kohl, D-WI and Sen. Richard Durbin, D-IL) seeks to eliminate pharmaceutical sales representative detailing altogether by establishing

a centralized, government operated program for distributing prescription drug information directly to HCPs.

A second piece of proposed federal legislation, the Physician Payments Sunshine Act of 2009 (introduced January 22, 2009 by Sen. Charles Grassley, R-IA and Sen. Herbert Kohl, D-WI) would require pharmaceutical companies to publicly disclose any payments to physicians (including gifts, honoraria, consulting fees and speaking fees) over a low threshold amount — perhaps $25. This information would presumably be posted to a public Web site. At least one large pharmaceutical company, Pfizer, announced in early 2009 that it will begin to voluntarily publicize such payment information.

The American Medical Association has weighed in with implementation of the Prescribing Data Restriction Program. This program gives HCPs the option of whether or not to allow pharmaceutical sales representatives to have access to their prescribing data. This "physician choice" option is also built into the new PhRMA Code.

Another example is apparent to any physician reading their weekly medical journals. Most medical journals and publications now specifically require that all medically related article authors disclose the existence of any pertinent financial interest or other relationship with industry — within the text of the article.

The revised PhRMA Code

One significant effort to correct this "appearance of impropriety" has come from the pharmaceutical companies themselves. In July 2008, the Pharmaceutical Research and Manufacturers of America (PhRMA) released the updated *Code on Interactions with Healthcare Professionals,* superseding and building upon the 2002 version. PhRMA is a trade organization representing companies that develop and market new medications, primarily pharmaceutical and biotechnology companies. A copy of the revised PhRMA Code can be found on the PhRMA Web site (www.phrma.org).

The revised PhRMA Code became effective on January 1, 2009. Nearly every major pharmaceutical manufacturer has voluntarily signed off on this new Code, including Abbott, Bayer HealthCare Pharmaceuticals, Bristol-Myers Squibb Company, GlaxoSmithKline, Johnson & Johnson, Eli Lilly and Company, Merck & Co., Inc., Pfizer, Inc. and Wyeth. The changes to the PhRMA Code revolve around the related themes of (1) ensuring that interactions with HCPs are focused on providing scientific/educational information and supporting medical research; and (2) eliminating any appearance of impropriety.

What's new in the January 1, 2009 PhRMA Code?

Changes have been made to almost every aspect of the PhRMA Code, including substantially tighter restrictions on meals, gifts, entertainment, continuing medical education sponsorship, consulting, speaker training programs, relations with HCPs who are members of formulary or practice guideline committees, and the availability of prescribing practice statistics to pharmaceutical sales representatives (aka detail representatives). A helpful set of "Questions and Answers" are appended to the new Code, providing examples of what is deemed permissible and not permissible in specific situations.

Gifts, meals, entertainment and travel

Under the revised PhRMA Code, there will generally be no more entertainment, *in-restaurant* meals, resort stays, travel, and promotional items like pens, pads and coffee mugs. Detail representatives may still provide occasional meals to medical offices, but the meals must be modest, they must be in-office or in-hospital, and they must be accompanied by a scientific and/or informational presentation. Meals with sales representatives cannot generally be offered *outside* of the office and cannot be part of any entertainment or recreational event. Free medication samples may still be provided to HCPs.

Detail representatives are also prohibited from giving away entertainment or recreational items (i.e., theater or sporting event tickets, sporting goods, vacations, etc.) to any HCP "who is not a salaried employee of the company," because such items do not involve the exchange of medical or scientific information. Thus, even if a physician is acting as a consultant or speaker for a company, no tickets are permitted. This is also true for personal items such as music CDs, DVDs, flowers, cash or gift certificates. In fact, detail representatives cannot distribute any noneducational items to HCPs or to their staff, regardless of value. The only gift items that detail representatives may offer are those designed primarily for the education of patients or HCPs and are less than $100 in value (i.e., an anatomical model). Any item that has independent value outside of the HCP's professional responsibilities would be considered inappropriate (i.e., a DVD player). Charitable contributions, such as a pharmaceutical company purchasing a foursome slot at a fundraising golf tournament, are also still permitted so long as the funds are paid to the charity rather than to individual HCPs. (See phRMA Code Q & A No. 22).

CME — educational courses and meetings

The revised PhRMA Code provides limitations on CMEs and third-party conferences, and states that a company "should separate its CME grant-making functions from its sales and marketing departments" and "develop objective criteria for making CME grant decisions…" Thus, unless a physician is on the faculty, a company cannot offer to pay the physician's cost of travel, lodging or personal expenses for attending the program. The same is true for subsidies. The company likewise cannot provide any advice or guidance to a CME provider or medical conference sponsor regarding a program's content or faculty, even if the sponsor requests such guidance.

Consulting arrangements and agreements

The revised PhRMA Code recognizes that consulting agreements between HCPs and pharmaceutical companies allow the companies to obtain information and advice from medical experts, including insight on "the marketplace, products, therapeutic areas and the needs of patients." However, the revised PhRMA Code establishes certain limitations on such consulting agreements, and if a physician's practice includes providing medical consultation to a company, the agreement will be affected. First, all such agreements must be based solely on the physician's medical expertise, reputation, knowledge. Also, a HCP-consultant may receive reasonable compensation and reimbursement for reasonable travel, lodging and meal expenses so long as a legitimate consulting agreement is in place. However, this compensation must be both reasonable and based on fair market value, and any meetings must be held at a venue conducive to the consulting services and activities — no resorts allowed.

Speaker programs and training meetings

Regarding company speaker programs and speaker training meetings, the revised PhRMA Code recognizes that HCPs participate in such company-sponsored programs to help educate others about the risks, benefits and appropriate uses of the company's products. Thus, HCPs may still participate in these programs, but again there are additional limitations under the revised PhRMA Code. First, if the HCP intends to speak at any company-sponsored programs, the HCP must be chosen purely on merit. Also, the HCP can receive reasonable compensation for time and expenses only if the HCP is given extensive training on the company's products and the HCP has a legitimate consulting agreement in place. However, the compensation is now limited. Each company, individually and independently, must cap the total amount of annual compensation paid to an individual HCP for all speaking arrangements. In addition, the materials used during a company-sponsored program must identify the company and disclose that the HCP is presenting on behalf of the company.

Formulary and practice guideline committee members

Interactions between companies and HCPs who serve on formulary or practice guideline committees are further regulated under the new PhRMA Code. Such HCPs can still simultaneously serve as a speaker or consultant for a company. However, the HCP must disclose to the committee the existence and nature of the relationship with the company. This obligation continues until two years after termination of the relationship with the company.

The new landscape — beyond PhRMA

The revised PhRMA Code is but one example of the active nationwide trend toward transparency and rooting out actual and/or perceived improprieties in the relationships between HCPs and industry. Similarly-themed codes and rules have been adopted and updated to incorporate these themes by a broad spectrum of entities in the medical field, from medical device manufacturers (through the Advanced Medical Technology Association), to the American Medical Association and specialty professional organizations, to hospitals and health systems nationwide, and of course to federal and state lawmaking bodies. Medical news headlines will undoubtedly be filled with additional rule changes, incorporating this trend, in the coming years. Ultimately, should these changes prove successful, Hollywood will have to look elsewhere for its story lines.

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