

# Client Advisory

Legal News ■ Spring 2006

on Walter & Haverfield's Technology,  
Bioscience and Health Care Industry Services Groups

## Technology, Bioscience and Health Care Developments

The Walter & Haverfield Health Care Industry Services Practice Group has morphed into the Technology, Bioscience and Health Care Industry Services Section! We believe that technology, especially biotechnology, life science and health care industry services are inter-connected and deserve to be in a practice group owing to the volume of the work for these types of clients performed by our firm. Why is this occurring?

First, many of our physician clients have developed intellectual property pertaining to medical devices that they either license to third parties to manufacture or they manufacture the products themselves. They may distribute the products themselves or enter into relationships with others to do the distribution.

Second, a number of our clients are consultants to manufacturers of medical products and pharmaceutical companies, which involves us in a variety of legal issues concerning new medical technology and the risk areas associated with that technology for physicians who serve as consultants. While this is not traditional health care legal work, it is closely related.

Third, our life science clients have become very active. Not only are they distributing life science products throughout the world, but they are developing new products with their own technology. These endeavors have allowed us to assist our clients in national and international markets.

Finally, Northeast Ohio has become a source for new technology, especially in the health care and life science industries. This development has compelled us to spend a greater amount of time in those industries to increase our client base and provide assistance to many entrepreneurial and start-up businesses in these fields.

Our Practice Group will, however, continue to provide updates and client advisories principally on health care regulatory matters because it is such an active industry, but we will also highlight our new developments in the biotechnology and life sciences field as well as letting you know of our accomplishments in all of these fields.



The past 15 months or so has been particularly eventful for the lawyers in the Technology, Bioscience and Health Care Industry Services Section. For the second year in a row, Bob Crump, the Chair of the Practice Group, has been named by Inside Business magazine as one of Northeast Ohio's Super Lawyers for his specialization in health care business transactions. He has also been so honored by the Law and Politics publication which is circulated throughout Ohio. Bob began 2005 by representing clients acquiring new businesses, one in Toledo, Ohio, and the other in Charlotte, North Carolina, and has since worked on many business transactions for clients in the biotechnology, life science and health care industries.



Chuck Schaefer, who is the Chair of the Walter & Haverfield Business Group and who also devotes a substantial amount of his time to representing clients in the health care industry, closed 2005 by representing the owners of Roscoe Medical in the sale of their business to an investment partnership based in Tennessee. His legal prowess in representing the owners of Roscoe was not lost on the buyers. We have been engaged following the acquisition to represent Roscoe on various health care and business matters.



Amy Leopard, who directs the Walter & Haverfield Health Care Compliance practice, was extremely active as usual during the last 15 months. Amy was named one of the best lawyers in the United States in health care by "The Best Lawyers in America," which is the oldest and probably best recognized listing of outstanding lawyers in the country. She spoke on the subject of medical equipment and supply contracting at the Fall 2005 Medtrade show in Atlanta and Medicare appeals at the Spring 2006 Medtrade in Las Vegas. She spoke on physician contracting at the American College of Legal Medicine's last annual meeting, and she has authored articles on obtaining Medicare coverage for telehealth services and the new Medicare appeal rules. The Cuyahoga County Commissioners recently appointed her to the Alcohol and Drug Addiction Services Board. Amy continues to serve as adjunct professor at the Case Western Reserve University Law School teaching an advanced health law transactions course.



The newest member of the business and regulatory part of our practice group is Cliff Mull. He joined Walter & Haverfield after his graduation from Case Western Reserve University Law School in January, where he also received a degree in bioethics, from the Case Western Reserve Medical School. The degree in bioethics focused on the ethical, cultural and policy dimensions of health care, technology and the life sciences. While attending law school, Cliff clerked with the Law Department of University Hospitals of Cleveland and at Athersys Inc. in the area of intellectual property. Cliff finished ninth in his law school class and was awarded membership in Order of the Coif, which is the law school equivalent to Phi Beta Kappa. Cliff recently wrote an article on hospital-physician gain sharing arrangements for Cleveland Physician.



The two principal litigators in our group are Michael Jordan and John Schiller. Mike Jordan, the Director of Health Care Litigation, handled several significant cases in the past 15 months. He had two major trials, both of which resulted in favorable outcomes for clients. The first involved the dissolution of an ophthalmology practice, with the Court awarding our client in excess of \$800,000 plus partial attorneys fees. The second involved a claim for disability benefits against an insurance carrier, and our client was awarded over \$1,000,000 plus attorney fees by the Court. Mike has participated in the Ohio State Legislator's discussion of proposals regarding malpractice reform and spoke at the 2006 American College of Legal Medicine's annual meeting in Las Vegas, Nevada, on malpractice coverage issues. He was also a featured speaker for the American Health Lawyers Association teleconference on Peer Review issues on January 24, 2006. Mike was an author for "The Biggest Legal Mistakes Physicians Make and How to Avoid Them" writing two chapters, one of them on handling of business litigation matters and the second discussing the sale of a physician practice. Mike serves as Chair of the American Health Lawyers Association Labor and Employment Practice Group and is the designated arbitrator in health care matters for the American Health Lawyers Association and the American Arbitration Association. He was named one of the best lawyers in American in the 2006 edition of "The Best Lawyers in America."

John Schiller is an experienced litigator who has substantial experience in representing health care clients in litigation matters, often before the Ohio Department of Insurance, the Ohio Legislature, and the United States Congress. In March, 2005, John won a \$1.8 million jury verdict in federal court in Akron, Ohio, representing a small business owner from Texas who had a contract to supply parts to the Eaton Corporation. The case involved the early termination of the contract for the parts by Eaton, and after a week-long jury trial, the jury awarded Walter & Haverfield's client all its economic damages including lost profits that it had suffered as a result of the improper termination of the contract. Proving that he is a well-rounded individual, John was the subject of an article in the August 1st edition of Crain's Cleveland Business because of his assistance in rekindling the career of Rock-n-Roll Hall of Famer, Solomon Burke, who has been called the "Best Soul Singer of all Time."



We have not provided an update on health care developments in a number of months, so we are going to use this Client Advisory to give you a brief summary of some of the more important rules that have come down recently.

### **Deficit Reduction and Medicare Payment Issues**

After the Centers for Medicare and Medicaid Services (CMS) published the final 2006 Medicare fee schedule rule, Congress passed the Deficit Reduction Act of 2006, which reduces Medicare spending by \$6 billion over 5 years. Although the law restored the hospital and physician payment amounts, Congress dealt the industry a blow by tinkering with various reimbursement issues affecting other industry segments, such as capping surgery center and non-hospital therapy services, codifying the multiple imaging procedure payment reductions, and limiting home oxygen and equipment rentals (e.g., hospital beds) to 36 months and 13 months respectively. In response, many professional societies are organizing grass roots support to convince Congress to reconsider these reductions and limit the applicability of restrictions going forward.

Congress continues to debate hospital-physician relationships and to address compliance issues. The DRA requires CMS to submit a strategic plan for dealing with physician ownership in specialty hospitals and to establish hospital-physician gainsharing demonstrations in at least six (6) sites. Finally, the new law requires mandatory compliance policies for health care entities that receive at least \$5M annually in Medicaid payments. Those providers will be required to have fraud and abuse policies, employee handbooks, and compliance training documented by January 1, 2007 in order to be eligible for Medicaid payments.

### **Stark II Restrictions on PET/Nuclear Medicine**

CMS has revised the list of services regulated by the Stark II physician self-referral law. The final rule adds nuclear medicine and PET to the list of designated health services regulated effective January 1, 2007. An exception under the new rule must be met for all financial arrangements between a referring physician (or an immediate family member) and an entity that bills Medicare for those services.

Physician ownership in an imaging center that bills for PET and nuclear medicine will be allowed only in rural areas or within unified group practices that meet the conditions to qualify for the in-office ancillary exception, requiring, among other things, that a group practice furnish the services in designated locations meeting physician supervision rules. CMS has allowed a one-year transition for divesting ownership interests to allow time for physician-owned entities not meeting an exception to find a suitable buyer.

Also, as a reminder for group practices, the Stark rule requires that methods for determining productivity bonuses for doctors in the group be established in advance. In other words, physician groups must decide how to allocate revenue and bonus physicians before the revenue is collected.

### **E-Prescribing and Electronic Health Records**

The U.S. Department of Health and Human Services (HHS) has proposed new rules on donated technology to referring physicians for electronic prescribing and electronic health record (EHR) software and training. The proposals would add exceptions to the Stark physician self-referral law and a safe harbor under the antikickback statute but are very restrictive in terms of the value of the technology covered. Donors are limited to hospitals, group practices, and Medicare Advantage and prescription drug plan sponsors. The donated technology cannot be equivalent to technology the physician already has and must be "used solely" for these purposes. The final rules for donated e-prescribing and EHR technology are expected to take some time to develop based on the extensive comments from the provider and technology communities.

## Home Medical Equipment Accreditation and Licensure

In anticipation of Medicare competitive bidding for home medical equipment (HME), CMS has proposed new quality standards for medical equipment, prosthetics, orthotics and supplies suppliers. Both HME suppliers and accreditation bodies have criticized the relevance and practicality of the proposed Medicare quality standards but accreditation appears inevitable. CMS continues to review options for implementing competitive bidding for HME as the industry launches a push to limit the scope of the competitive bidding project with H.R. 3559, the Hobson-Tanner bill.

In Ohio, HME facilities that sell or lease certain medical equipment directly to the public must now either be licensed or registered by the Ohio Respiratory Care Board, including the following categories:

- (1) Life-sustaining Equipment (prescription HME that medically sustains, restores, or supplants a vital bodily function, such as breathing);
- (2) Technologically Sophisticated Medical Equipment (prescription HME that requires individualized adjustment or regular maintenance by a condition or the effectiveness of the equipment).

Licensed facilities must (1) maintain a facility adequate to store, maintain, lease or sell HME; (2) train personnel or staff to ensure that HME is safely maintained, leased and sold; (3) maintain minimal product and professional liability coverage; (4) document and file all sales and leases of HME; and (5) meet federal, state, and local rules and regulations for the maintenance, storage and sale of HME. Alternatively, the facility may be accredited by a national accrediting body recognized by the Board, such as JCAHO, and then register with the Board.

## Medicare Appeals

The Medicare reform act made numerous changes to the Medicare appeals system including appeals to the Administrative Law Judge (ALJ) level. Effective January 1, 2006, ALJ appeals for a large part of the country are being heard by a new Medicare appeals court in Cleveland. Under the new rules, providers and suppliers must provide a full and early presentation of evidence at the qualified independent contractor (formerly fair hearing) level. This change means that providers appealing Medicare denials must identify and introduce all evidence necessary to make arguments that may later be asserted at the ALJ level, including documentation of services and expert affidavits.

Keeping up with regulations affecting health care practitioners and providers can be an arduous task. For questions regarding any of these changes, please contact a member of the Technology, Bioscience and Health Care Industry Services Section or your regular Walter & Haverfield attorney.

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The information in this newsletter is a summary of often complex legal issues and may not cover all the 'fine points' related to a specific situation or court jurisdiction. Accordingly, it is not intended to be legal advice, which should always be obtained in consultation with an attorney.

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