



November 2011

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The Katten Muchin Rosenman LLP Health Care Practice is pleased to present this newsletter to keep our clients and friends informed of developments in health care law and the implications for their business. Please feel free to share this newsletter with others who may be interested.

Illinois Trial Court Upholds Patient Safety Act Privilege Protection of Walgreens Patient Safety Work Product in Case of First Impression

In a case that has attracted national attention, the Illinois Department of Financial and Professional Regulation (IDFPR) sued Walgreens when it refused to turn over the medication error incident reports for three of its pharmacists. The basis for Walgreens' decision was that these documents were collected as part of the company's patient safety evaluation system and reported to The Patient Safety Research Foundation, its component patient safety organization (PSO), which was certified by the Agency for Healthcare Research and Quality (AHRQ) as permitted under the Patient Safety and Quality Improvement Act of 2005 (PSQIA). The trial court ruled in Walgreens' favor and dismissed the IDFPR's lawsuit holding that the incident reports were protected under the PSQIA and therefore not discoverable. The case is now on appeal to the Illinois Appellate Court, which is likely to be the first appellate court to interpret the provisions of the PSQIA.

The privilege and confidentiality protections afforded under the PSQIA are far broader than most state peer review confidentiality statutes; they apply in both state and, for the first time, federal proceedings. In addition, any licensed provider in the state, such as hospitals, physicians, nursing homes and pharmacies, can take advantage of these protections when establishing a patient safety evaluation system and collecting and reporting documents, data, evaluations and other protected patient safety activities to a PSO through a required contractual arrangement. There currently are 81 certified PSOs in the United States.

Michael Callahan, partner in the Health Care Practice, and Wells Hutchison, partner and co-chair of the Health Care Civil Litigation Practice, assisted Walgreens and its legal counsel in the development of its arguments and also prepared an amicus brief in support of Walgreens that included several PSOs from around the country. For a copy of the pleadings and briefs in this case, click [here](#). For a copy of PSO educational materials, click [here](#). If anyone has questions about participating in PSOs or about the protections afforded under the PSQIA, please contact [Michael Callahan](#).

Health Care Practice and Attorneys Recognized in *Chambers, Best Lawyers*

Katten's Health Care Practice was ranked among the best in Illinois and New York in the 2011 edition of *Chambers USA: America's Leading Lawyers for Business*. In addition, partners Michael R. Callahan, Laura Keidan Martin and Peter F. Nadel were recognized with the guide's highest individual rankings. The guide also recommended partners W. Kenneth Davis, Jr., D. Louis Glaser, Steven Olson and Joseph Willey.

Michael Callahan, D. Louis Glaser, Laura Keidan Martin and Peter F. Nadel also were selected for inclusion in the 2012 edition of *The Best Lawyers in America*.

Health Care Litigator

Katten's Health Care Civil Litigation Practice recently launched a new publication, the *Health Care Litigator*, which examines recent litigation relating to the delivery of and payment for medical services.

In the inaugural issue:

- Seventh Circuit Appeal in Case Against Medical Center Could Impact the Ability to Bring Suits Under the False Claims Act
- Putative Class Action Seeks Ruling That Illinois Health Care Providers Must Accept Insurance Payments in Lieu of Asserting a Lien Against a Patient's Tort Recovery

- Illinois Appellate Court Relies on the Rule of Non-Review to Uphold the Dismissal of Tort Claims by Physicians Whose Preliminary Applications for Privileges Were Rejected

View the complete newsletter [here](#).

CMS Issues Final ACO Regulations

After receiving more than 1,300 public comments on its Proposed Rule for Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program, CMS published its [Final ACO Rule](#) in the Federal Register on November 2. In addition, the FTC and DOJ filed their [Final Statement of ACO Antitrust Enforcement Policy](#) and CMS issued an [Interim Final Rule](#) with a 60-day comment period describing five separate fraud and abuse waivers applied to Stark, the Anti-Kickback Statute and the Civil Monetary Penalty laws. Finally, the IRS also issued [Fact Sheet 2011-11](#) confirming [Notice 2011-20](#) from April 18, 2011, on its expectations regarding ACOs participating in the Shared Savings Program.

As stated by CMS in the Final ACO Rule, the overall intent of CMS, the IRS, FTC and DOJ in modifying their respective rules and statements (collectively, the Final Rules) was to incorporate greater flexibility in terms of eligibility requirements, ACO governance and legal structure, the antitrust review process, and the timing for shared savings evaluations and repayment of losses. These standards also have reduced and simplified the quality performance standards, increased financial incentives to participate in an ACO, eliminated the downside risk and first-dollar sharing in the Track 1 shared savings model, increased the sharing caps and removed the 25% withhold requirement on shared savings.

While initial industry reaction has been positive and the barriers to ACO certification and the risk of participation have been reduced, time will tell as to whether the changes will motivate health care providers to submit applications by the revised due dates of April 1, 2012, or July 1, 2012, pushed back from January 1. A likely outcome will be that many providers will evaluate the Final Rule closely and continue with their various clinical integration, merger, and acquisition strategies, but wait for the U.S. Supreme Court's decision on the constitutional challenges to the Affordable Care Act as well as to see how the Final Rule impacts those ACOs that seek certification in 2012.

The purpose of this Advisory is to provide a high-level summary of the Final Rules, followed by a more detailed analysis of each. We also have offered our comments and recommendations where appropriate.

Click [here](#) to read our Executive Summary of the Final Rules.

Click [here](#) read our Executive Summary and detailed discussion of the Final Rules.

Click [here](#) for a detailed discussion of the FTC/DOJ Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program.

Click [here](#) for a detailed discussion of the Interim Final Rule on Waivers of Fraud and Abuse Laws and the IRS Notice on Tax-Exempt Hospitals Participating in ACOs.

Partner Michael Callahan Quoted in *Chicago Tribune* Regarding New Regulations Allowing More Liberal Hospital Visitation Policies

Michael Callahan was quoted in the September 14 *Chicago Tribune* article "Hospital Doors Open Wider to Partners, Friends" about new federal and state regulations that expand the definitions of "family," "spouse" and "next of kin" to include partners and friends for hospital visitation and other medical purposes. These rules and revised hospital policies offer greater protection for the gay community, as well as unmarried couples, says Mr. Callahan, by allowing the patient and not the hospital or the physician to determine who will be allowed to visit and who can receive medical information about the patient. Click [here](#) to view the presentation.

2011 Presentations

Each year Katten's health care attorneys speak on a variety of topics of critical importance to health care organizations. Following is a sampling of these presentations from the past year.

Physician Employment: Contracting, Compensation & Financial Performance Improvements

HFMA Fall Seminar, November 2011

[Lou Glaser](#) addresses two areas crucial to successful physician-hospital alignment: the struggle to develop joint venture arrangements for ambulatory services and the structuring of strong collaborative physician employment agreements to achieve both mission and budgetary goals. Click [here](#) to view the presentation.

New Approaches to Physician Transactions

Illinois Association of Healthcare Attorneys Annual Symposium, October 2011

[Ethan Rii](#) examines current trends in hospital-physician integrated strategies and details various structural options, reimbursement and compensation issues and other issues to consider. Click [here](#) to view the presentation.

Clinical Challenges in Quality

36th Annual National Association for Healthcare Quality Educational Conference, September 2011

[Michael Callahan](#) and members of the NAHQ Ethical Challenges in Quality and Patient Safety Task Team examine the problem of retaliating actions taken against health care workers who report patient care quality concerns to their superiors. Click [here](#) to view the presentation.

Urology Under Attack: The Battle at the State Level

Western Section AUA Health Policy Forum, August 2011

[Howard Rubin](#) examines lessons learned from various state challenges to urologists and group practices in such areas as integrated cancer care, in-office patient referrals and state licensing board investigations. Click [here](#) to view the presentation.

Creative Business Structures and Strategies for Competing Into the Future

Radiology Business Management Association Executive Education Program, July 2011

[Ken Davis](#) discusses industry developments, an overview of key legal regulatory standards and a detailed breakdown

of the different business structures of physician practices, including sales, roll-ups, conversions to provider-based or under arrangements and joint ventures. Click [here](#) to view the presentation.

Impact of ACOs on Physician/Provider Membership Decisions

American Health Lawyers Annual Meeting and In-House Counsel Program, June 2011

[Michael Callahan](#) discusses the peer review, credentialing, antitrust and liability issues faced by hospitals and health systems participating in accountable care organizations relating to provider membership decisions. Click [here](#) to view the presentation.

When the Ledger Doesn't Add Up: Fundamentals of Repayment for Physicians

ABA Health Law Section Physician Legal Issues Conference, on June 2011

[Laura Martin](#) and former Katten partner Lisa Ohrin (now associate general counsel at Health Management Associates) address the types of overpayments in physician practices and the impact of "reverse" False Claims Act and the Affordable Care Act on auditing and refund practices, and provided practical tips for refunding overpayments. Click [here](#) to view the presentation.

Compliance Risk Areas Related to Educational Programs and Product Training

CBI's 7th Annual Medical Device and Diagnostic Compliance Congress, June 2011

[Laura Martin](#) analyzes the areas of compliance risk related to physician training and education compliance oversight initiatives with a focus on the OIG's Compliance Guidance and the AdvaMed Code for pharmaceutical manufacturers. Click [here](#) to view the presentation.

PSOs: To Participate or Not: Advantages, Disadvantages and Questions Answered

United HealthSystem Consortium's Joint Council Meeting: Maximizing Quality and Safety, Minimizing Risk, April 2011

[Michael Callahan](#) provides an overview of Patient Safety

Organizations, as set forth in the Patient Safety and Quality Improvement Act of 2005, with an emphasis on the comprehensive advantages and state and federal confidentiality protections applied to quality, risk management and peer review patient safety activities, and as applied to some hypothetical scenarios. Click [here](#) to view the presentation.

Physician and Vendor Relationships: Operationalizing Compliance with the Stark and Anti-Kickback Laws

Health Care Compliance Association: 2011 Compliance Institute, April 2011

Former Katten partner Lisa Ohrin provides an overview of Stark and the Anti-Kickback Statute, the legal standards under different hospital-physician arrangements, and lessons learned from corporate integrity agreements and TRO with respect to compliance investigations. Click [here](#) to view the presentation.

Legal Liabilities of Social Marketing and Creating a Corporate Policy

Radiology Business Management Association's Building Better Radiology Marketing Programs, March 2011

[Ken Davis](#) examines the various liability risks associated with social media strategies for physician practices, including patient rights, libel, HIPAA/HITECH, FTC guidelines and intellectual property rights. Click [here](#) to view the presentation.

Compliance Lessons Learned from Recent Investigations & Transactions

First Illinois HFMA Compliance Program, March 2011

[Laura Martin](#) provides an overview of the recent government enforcement trends and enhanced investigative tools employed by federal and state agencies, examines the lessons learned from recent cases and settlements, and provides practical tips for managing legal risks. Click [here](#) to view the presentation.

Contact Us

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