

THE MAGNET™



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NORTH CAROLINA'S SOURCE FOR IMPORTANT PHYSICIAN INFORMATION

HIPAA Security Rule Compliance Date Nears

Physicians across the country will be required to comply with the new HIPAA Security Rule by April 20, 2005. While physicians have had to comply with the HIPAA Privacy Rule for nearly two years, the Security Rule presents a new set of challenges with respect to electronic protected health information (PHI). To achieve and maintain compliance with the Security Rule, physicians, hospitals and other "covered entities" will have to implement a series of administrative, technical and physical security procedures. The rule will generally require physicians to do the following:

- Ensure the confidentiality, integrity and availability of all electronic PHI they create, receive, maintain or transmit
- Protect against any reasonably anticipated threats or hazards to the security or integrity of electronic PHI
- Protect against any reasonably anticipated uses or disclosures of electronic PHI that are not permitted or required under the rule
- Ensure compliance with the rule by their staff

The Security Rule focuses more on the end result—compliance—than the method by which physicians will achieve that end result. It was designed to be scalable, flexible and addressable through

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Risk Management Tips

Research-Related Litigation Prompts Risk Management Review

Clinical trials using human subjects are extremely important to the care of all patients, now and in the future. Clinical trials enable researchers to find ways to improve health, answer scientific questions and to find better ways to prevent, diagnose and treat diseases. However, trusted and renowned healthcare organizations have recently come under public scrutiny as reports of deaths linked to research make headline news. A rise in the incidence of research-related litigation has gained legal and risk management attention. As more MAG Mutual policyholders are engaging patients in clinical trials or have established Clinical Research Departments within their practices, it becomes incumbent upon them to completely understand both state and federal regulations governing human research and to be fully vested in patient safety.

In particular, the researcher should be sensitive to the following four areas especially vulnerable to liability:

- Research Fraud - Understand the most common acts of illegal conduct in clinical research
- Research Recruitment - Identify illegal recruitment practices and when financial incentives for research participation are appropriate
- Conflicts of Interest - Define the different types of conflicts of interest, understand why they are important and develop strategies for effectively identifying and managing them
- Informed Consent - Understand the differences between the legal and moral requirements of informed consent

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multiple approaches. The rule states that when deciding which security measures to use, physicians must take into account such things as the size, complexity and capabilities of their practices and their technical infrastructure, hardware and software security capabilities.

For more information on the HIPAA Security Rule, including the final rule itself, go to the Centers for Medicare and Medicaid Services (CMS) website: <http://www.cms.hhs.gov/hipaa/hipaa2/default.asp> ●

Practice Management

Frequently Asked Questions

Are you getting the most out of your billing, management and human resources? Are you HIPAA compliant? Do you have any upcoming changes in your business? These and many more answers to frequently asked questions are available at www.practice-management.org/FAQ.

Questions are divided into five categories:

- Medical Records
- Medicare
- Medicare (Georgia Specific)
- Fee & Coding
- HIPAA

This information is provided to give you quick answers to many questions we often hear from MAG Mutual-insured physicians. If you need more detailed information than what is provided on our web site, MAG Mutual's experienced consultants are available to help you with a variety of issues. Just call MAG Mutual Healthcare Solutions today toll-free at **888-249-7886**. ●

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Additional Reading:

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance. Faye Rozovsky, JD, MPH and Rodney K. Adams; Publisher: Jossey-Bass
2. www.clinicaltrials.gov
3. Clinical trial patients sue IRB members, Vida Foubister, AMNews staff, February 26, 2001
4. Clinical Trials Roadmap for Physician Practices. Christie L. Morgan CCRC; Publisher HcPro ●

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