

# PRACTICAL HEALTHLAW



Get to know GINA  
New law requires safeguarding  
of genetic information from misuse

EMTALA  
On-call physicians  
liable for violations

Reporting for duty: Are you  
complying with USERRA?

New restrictions on per-click  
payments in lease arrangements

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# Get to know GINA

New law requires safeguarding of genetic information from misuse

In May 2008, the Genetic Information Nondiscrimination Act (GINA) was signed into law. It bars health insurers and employers from discriminating against individuals or individuals' family members based on their genetic information.

The purpose of the act is to provide a national and uniform level of protection from genetic discrimination. Not all states have laws protecting genetic information, and among those that do, the laws are inconsistent. The expectation is that GINA will enable individuals to take advantage of genetic testing, technology, research and new therapies without fear of retaliation from health insurers or employers such as hospitals and other health care providers.

## WHAT IS "GENETIC INFORMATION"?

Under GINA, "genetic information" is broadly defined as:

1. An individual's genetic tests,
2. The genetic tests of family members, or
3. The manifestation of a disease or disorder in the individual's family members.

Genetic information doesn't include information about an individual's sex or age.

Under GINA, employers — including hospitals, health care organizations and health care providers — can't discriminate against employees or employees' family members based on their genetic information. Thus, the act protects your employees and their family members.

## HOW DOES GINA AFFECT HEALTH INSURANCE?

Title I of GINA addresses health insurance-related provisions. It amends several federal laws, such as the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHSA), and the Internal Revenue Code, to include anti-discrimination provisions.

GINA prohibits health insurers from:

- Adjusting premium amounts or establishing distinct eligibility rules based on genetic information,
- Requesting or requiring genetic tests, or
- Requesting, requiring or purchasing genetic information for underwriting purposes or in connection with enrollment.

GINA restrictions apply to insurers of group health plans, individual market plans, government plans and Medicare supplemental policies. In addition, GINA authorizes sanctions for group health plan sponsors that don't exercise reasonable diligence in ensuring their policies meet GINA's standards.



For example, suppose a health insurer has access to genetic information that shows an individual has a genetic likelihood of developing breast cancer. Under GINA, the insurer cannot raise premiums or deny enrollment based on this information. If it does, it will be liable for violations and monetary sanctions. Title I violations may result in penalties of up to \$100 per day for each beneficiary for whom the insurer is in noncompliance.

While the restrictions in Title I focus on health insurers, the same penalties are enforceable against employers — such as hospitals and other health care organizations — that sponsor employee health plans that fail to meet any of the act's requirements. GINA doesn't protect employers where a health insurer violates GINA and the employer sponsoring the health plan didn't exercise care in reviewing the insurer's policies. All hospitals and other health care organizations should review their health insurance policies covering employees to make sure they comply with GINA. And make sure plan participants are aware of their protections under the new law.

The health-insurance-related provisions of GINA take effect May 21, 2009.

## WHAT ARE THE EMPLOYMENT PROTECTIONS?

Title II of GINA encompasses employment-related provisions. It restricts public and private employers, such as hospitals and other health care providers, from genetic discrimination. Specifically, the act prohibits employers from:

- Failing or refusing to hire a prospective employee based on genetic information,
- Discharging or otherwise discriminating against an employee with respect to employment compensation, terms, conditions or privileges based on an individual's genetic information,
- Limiting, segregating or classifying employees because of genetic information in any way that would deprive them of employment opportunities or otherwise adversely affect their status as employees, or
- Requesting, requiring or purchasing employees' genetic information.

Title II has several exclusions. It exempts employers from liability under GINA where:

- The employer inadvertently receives protected information,
- Genetic information is used to comply with the Family and Medical Leave Act (FMLA) or other family and medical leave laws,
- The employer purchases information in publicly available commercial documents,

- The information is received through employer-sponsored wellness programs, or
- There are other circumstances as specified by GINA.

The Equal Employment Opportunity Commission (EEOC) will enforce the Title II provisions of GINA. Individual employees may have a cause of action against employers that intentionally discriminate based on confidential genetic information. Penalties for Title II violations may include the payment of back pay and front pay, reinstatement and attorneys' fees.

The EEOC will issue final regulations to carry out Title II by May 21, 2009. Employers will have until Nov. 21, 2009, to implement changes.

*GINA authorizes sanctions for group health plan sponsors that don't exercise reasonable diligence in ensuring their policies meet GINA's standards.*

## WHAT ABOUT PRIVACY?

The act also amends the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to treat genetic information as confidential health information, which provides additional protection for such information. If you're a "covered entity" under HIPAA, this applies to you. Ask your health care attorney whether you're a covered entity.

GINA also requires employers to maintain employees' genetic information in medical files that are separate from personnel files and treat such information as confidential. Generally, employers may not disclose this information unless the employee provides a written request or authorization.

## WHAT SHOULD YOU DO?

Before GINA takes effect, health care organizations and physician groups should review their health insurance policies to make sure they act in accordance with GINA's objectives. To ensure your compliance as an employer, update employment policies, handbooks and training materials to minimize the possibility for genetic discrimination or harassment. Incorporate GINA into existing orientation and training programs to ensure managers and supervisors are aware of the new law and the plan for compliance. Finally, implement a plan to ensure all genetic information is filed separately from other personnel information and kept confidential. ■

EMTALA

# On-call physicians liable for violations

Hospitals that participate in the Medicare and Medicaid programs must comply with various state and federal laws, including the Emergency Medical Treatment and Active Labor Act (EMTALA). Hospitals subject to EMTALA may incur liability for violations under its enforcement provisions. But did you know that on-call physicians at hospitals subject to EMTALA must also comply with the act to avoid liability?

## EMTALA AND ON-CALL LISTS

EMTALA governs how and when a hospital can refuse to treat a patient and transfer unstable patients to another hospital. It requires hospitals to “maintain a list of physicians who are on call for duty after the initial

examination to provide treatment necessary to stabilize an individual with an emergency medical condition.” The purpose of the on-call list is to identify and ensure that emergency departments are prospectively aware of those physicians, including specialists and subspecialists, who are available to provide care.

The law applies to both emergency department physicians and those on-call physicians required to assist in the medical screening examination and, if necessary, the stabilization and appropriate transfer of a patient.

## HOSPITAL AND STAFF

As stated above, the Medicare and EMTALA laws directly govern the actions of a hospital. Therefore, a hospital can be liable for EMTALA violations.

A hospital’s governing board is responsible for the hospital’s control and operation. This includes approving



the hospital's medical staff bylaws, rules and regulations that govern its physicians' responsibilities and duties, including on-call physicians. In addition, the governing board must ensure that the medical staff is accountable to the board.

By virtue of a hospital governing board's assignment of responsibilities, the hospital itself may be directly responsible for the actions of its medical staff, including on-call physicians. Moreover, EMTALA expressly holds hospitals liable for certain actions of on-call physicians. For example, a hospital may be held liable for an on-call physician's refusal or failure to come to the hospital when his or her services are necessary to assess and possibly stabilize or assist in the transfer of a patient.

### ON-CALL LIABILITY

Physicians are agents of a hospital. As such, under EMTALA, physicians, including on-call emergency physicians, may — in addition to the hospital — be held liable for violating the statute and its accompanying regulations.

For example, suppose that, after an initial examination, an emergency department physician determines a patient's condition requires the services of a physician on the hospital's on-call list. The emergency physician notifies the on-call physician, but the on-call physician fails or refuses to appear within a reasonable time. After making the determination that, without the services of the on-call physician, the benefits of transfer outweigh the risks, the emergency physician orders the transfer of the individual. In this scenario, the physician who authorized the transfer will not be subject to any EMTALA penalty, but a penalty may apply to the on-call physician who failed or refused to appear.

Hospitals should track these events. In fact, the act requires hospitals to record the name and address of any on-call physician who has refused or failed to appear within a reasonable time to provide the level of treatment required to satisfy his or her EMTALA obligations.



## EMTALA penalties for on-call physicians

Like hospitals, on-call physicians who violate their EMTALA obligations face a number of enforcement provisions. A failure to comply with federal and state laws and their accompanying regulations — including EMTALA — may result in termination from the Medicare and Medicaid programs.

The Office of Inspector General (OIG) may issue civil monetary penalties (CMPs) and exclude physicians from federal health care programs as well. CMPs range from up to \$25,000 per violation for hospitals with fewer than 100 beds to \$50,000 per violation for hospitals with 100 beds or over. Penalties are based on the size of the facility. The OIG can also assess up to \$50,000 per violation for physicians who commit gross and flagrant violations.

### COURTS AND CMS

Courts have concluded that EMTALA applies to the actions of on-call physicians. In *Burditt v. U.S. Dept. of Health and Human Services*, the Fifth Circuit Court of Appeals held that, because a physician agreed to be bound by the hospital's bylaws in an application for medical staff privileges, he was subject to EMTALA. The court also found that hospital physicians who treat hospital patients are the hospital's agents for purposes of such treatment. It reasoned that, because hospitals can act and become aware of information only through certain individuals, including physicians, any EMTALA violation by the physician is also an EMTALA violation by the hospital.

*Courts have concluded that EMTALA applies to the actions of on-call physicians.*

The Centers for Medicare and Medicaid Services (CMS) also has addressed the issue of EMTALA and on-call physicians. In commentary and proposed rules the agency has published in the Federal Register and in interpretive guidelines it has issued, CMS has specifically included on-call physicians as part of the ancillary services used to provide an appropriate screening exam to the patient as required by EMTALA.

### BE IN THE KNOW

EMTALA affects both hospitals that employ on-call physicians and physician groups that have employees on a hospital's on-call list. If you're in either of these situations, familiarize yourself with the EMTALA regulations that apply to on-call situations. Violations of these obligations could result in large financial sanctions and revocation of participation in federal health care programs. |

# Reporting for duty: Are you complying with USERRA?

In recent years, the number of uniformed service members both deploying to and returning from service has greatly increased. Health care organizations, like other employers, must understand their legal responsibilities under the Uniformed Services Employment and Reemployment Rights Act of 1994 (USERRA) in helping these men and women transition from military life back to the civilian workplace.

## THE LAW

The Department of Labor (DOL) administers USERRA through the Veterans' Employment and Training Service. The act applies to nearly all individuals who have served in the uniformed services, including, but not limited to, the Army, Navy, Marine Corps, Air Force, Coast Guard, Reserves, National Guard, Commissioned Corps of the Public Health Service and any other category of persons designated by the president of the United States in a time of war or emergency. USERRA also protects volunteers in the National Disaster Medical System.

For USERRA protections to apply to a returning service man or woman, the cumulative length of the absence from a position can't be more than five years. However, the law provides eight exceptions to the five-year rule. Commonly applicable exceptions include initial enlistments lasting more than five years, periodic National Guard and Reserve training duty, and involuntary active duty extensions and recalls, such as during periods of national emergencies.

## REEMPLOYMENT REQUIREMENTS

Under USERRA, the position to which you must reinstate an employee depends on the length of his or her military service:

**1. Up to 90 days.** Generally, you must reinstate an employee in a position the employee would have held if the employee had remained continuously employed, so long as the person is qualified for the position or can become qualified after you expend reasonable efforts to qualify him or her. If the employee isn't qualified and can't become qualified for such a position, you must reinstate the employee in the position in which the employee was employed on the date he or she commenced military



duties. If the employee can't become qualified for either position, you must reemploy the employee in the position he or she can become qualified for or is qualified for that is the most similar to his or her original job.

**2. 91 or more days.** You must follow reinstatement requirements similar to those for an employee who was absent for military service for up to 90 days, but there are some subtle differences. You must reinstate an employee in a position the employee would have held had the employee remained continuously employed — or in a position of like seniority, status and pay — so long as the person is qualified for the position or can become qualified after you expend reasonable efforts to qualify him or her. If the employee isn't qualified and can't become qualified for such a position, you must reinstate the employee in the position in which the employee was employed on the date he or she commenced military duties — or in a position of like seniority, status and pay. If the employee can't become qualified for any such position, you can reemploy him or her in a position of lesser status and pay, but it must be in the position he or she can become qualified for — with full seniority — that is the most similar to the above positions.

Regardless of how long your employee serves, you must provide refresher training and, in situations where the employee is no longer qualified due to technological advances, provide any necessary training to update his or her skills. USERRA also requires employers to make reasonable efforts to accommodate disabilities incurred or aggravated while in the uniformed services.

## HEALTH AND PENSION BENEFITS

Military service is considered service with an employer for benefits purposes and the vesting of certain retirement benefits. Generally an employer is liable for funding any resulting benefit obligation.

The law also protects employee health benefits. If an employee served for 30 days or less, he or she can't be required to pay more than the normal employee share of premiums. Employees who have served more than 30 days may elect to continue their employer's health care plan for up to 24 months, but may be required to pay up to 102% of the full premium.

## THE EFFECT

USERRA's primary purpose is to protect the employment and reemployment rights of uniformed service members. You need to be aware of its requirements, both for your sake and the sake of returning employees. ■

## NEW RESTRICTIONS ON PER-CLICK PAYMENTS IN LEASE ARRANGEMENTS

It's not uncommon for a hospital or physician group to lease the large medical equipment it uses. In many equipment leases, payments are contracted on a unit of service, or "per-click," basis. This means that, every time a hospital or physician group uses a leased piece of equipment, it has to pay the lessor.

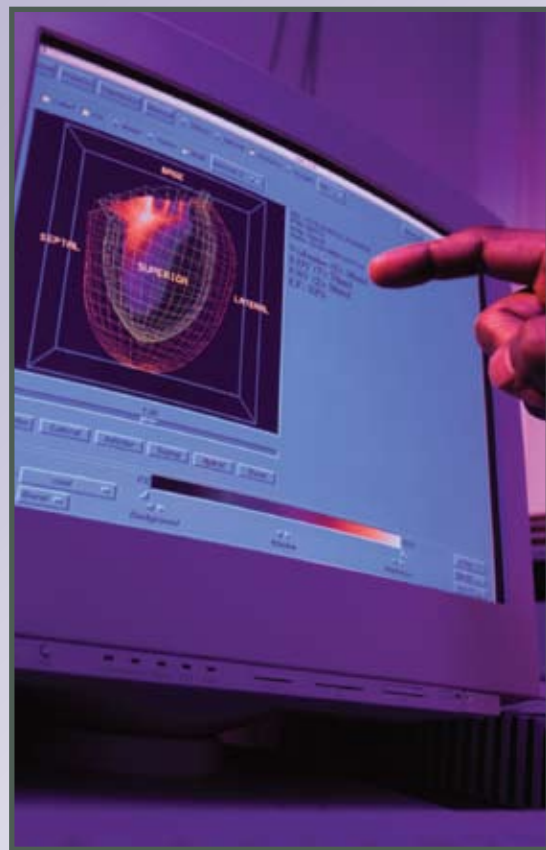
Currently, Stark Law (governing physician self-referrals) regulations permit per-click payments in equipment leases. This is true even where a physician-lessor receives such payments because the physician is referring patients to a designated health services (DHS) entity (such as a hospital) that is leasing the equipment.

But the Centers for Medicare and Medicaid Services (CMS) has expressed concerns with per-click lease arrangements, believing that they may "reward" physician-lessors for each referral they make. CMS believes such arrangements may lead to overuse. As a result, CMS issued a final rule revising the Stark Law regulations so that equipment leases may not allow per-click payments to a physician-lessor who is referring patients to a DHS entity lessee.

The prohibition on per-click payments will apply regardless of whether the lessor is the referring physician or an entity in which the physician has an ownership or investment interest. It also applies where the lessor is a DHS entity that refers patients to a physician lessee or a physician organization lessee.

Will these restrictions on per-click payments disrupt the introduction of innovative technology to communities? CMS doesn't think so. In fact, it has encouraged hospitals and other DHS entities to contract with nonphysician entities for such technology or to work with other area hospitals, whereby one hospital could purchase the technology and then contract with the others to enable them to provide the service "under arrangements."

CMS has delayed the effective date of the revised Stark Law regulations until Oct. 1, 2009, to give parties time to restructure arrangements. Examine your existing lease arrangements with your attorney before the deadline to determine if they will require restructuring to comply with the new rule.



## A message to our clients and friends:

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We understand the value of good information when making sound business decisions. *Practical Health Law* is written by Hall Render's health law attorneys, each with extensive experience handling the legal issues of health care providers. We trust the information in each issue will be a valuable resource. Our attorneys stand ready to respond promptly to your questions and needs; please contact us if there are specific topics you would like to see addressed.

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