



New Jersey Health Law

Bulletin

A summary of recent developments provided by the health care law firm **Garfunkel Wild, P.C.**

Regulations Proposed to Regulate Accountable Care Organizations

On March 31, 2011, the Centers for Medicare and Medicaid Services ("CMS") proposed new regulations (the "Regulations") under the Affordable Care Act (the "Act") to help health care providers coordinate care for Medicare patients in a more efficient manner through Accountable Care Organizations ("ACOs"). The Act requires CMS to establish a shared savings program (the "Program") to facilitate coordination among providers to improve the quality of care for Medicare fee-for-service beneficiaries and reduce unnecessary costs. ACOs will serve as the mechanism to achieve the goals of the Program. While ACOs are intended to target Medicare beneficiaries, it is anticipated that private payors will also contract with ACOs.

The Regulations serve to clarify the vast amount of questions surrounding the implementation of the Program. In conjunction with the Regulations, the Office of the Inspector General ("OIG"), as well as the Department of Justice ("DOJ") and Federal Trade Commission ("FTC"), has promulgated guidance regarding certain legal issues surrounding ACOs. In particular, the OIG has issued a notice with comment period outlining proposals for waivers of certain federal laws during the implementation and maintenance of ACOs. The OIG has solicited public input regarding the prospect of waiving the physician self-referral law ("Stark"), the Anti-Kickback Statute, and certain provisions of the civil monetary penalty law in connection with the Program. In addition, the DOJ and FTC has jointly issued an antitrust policy statement concerning en-

forcement implications of ACOs participating in the Program.

ACOs create incentives for providers to work together to treat individual Medicare patients across various health care settings. The Program will reward ACOs that lower costs while meeting performance standards on quality of care. However, the Program will also penalize those ACOs that fail to provide efficient, cost-effective care. Pursuant to the Regulations, providers must notify beneficiaries that they are participating in an ACO, and the implications that arise from such participation. The beneficiaries may then choose to receive services from the provider or seek care from another provider that is not part of an ACO. Providers must also notify beneficiaries that claims data may be shared within the ACO. Data sharing is necessary to coordinate the beneficiary's care and meet the ACO's goals. Beneficiaries may elect to opt-out of such data sharing arrangements.

In order to participate in the Program, providers must form or join an ACO that has applied to, and has been accepted by,

(Continued on page 2)

Physician Assistants Are Entitled To Overtime Pay Mandated By The Fair Labor Standards Act

Recently, the United States District Court for the Eastern District of Pennsylvania ruled that certain Physician Assistants ("PAs") will not be included in the salary-basis exemption to the Fair Labor Standards Act ("FLSA"). Thus, the PA at issue in the case was entitled to receive overtime pay (at a rate of time and a half) for all hours worked in excess of forty hours per week. This ruling will have a significant impact on the scope of practice of PAs.

The FLSA requires that employees receive overtime pay for all hours worked in excess of forty hours per week. However, individuals employed in a bona fide professional capacity are exempt from this requirement and need not be paid overtime. At issue in this case is the proper definition of bona fide professionals, and whether PAs should fall within the exception. There are two defini-

(Continued on page 2)

New Jersey Captive Insurance Companies to be Licensed by Department of Banking and Insurance

On February 22, 2011, New Jersey Governor Chris Christie signed a bill into law (the "Law") allowing a captive insurance company to be licensed by the Department of Banking and Insurance (the "Department") to do business in the State of New Jersey. As defined in the

Law, a captive insurance company is a closely held insurance company whose insurance business is primarily supplied by and controlled by its owners, and in which the original insured are the principal beneficiaries. The Law allows for pure (single parent) and group captive insurance companies, along with entities with limited liability company status, to be li-

(Continued on page 2)

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Proposed New Regulations to Extend Registration Requirements to Small Surgical Practices

On April 18, 2011, the Department of Health and Senior Services ("DHSS") proposed new regulations which intend to extend the registration and inspection requirements involving hospital-based operating rooms and outpatient surgery centers to all surgical facilities, including those with a single operating room. Currently, single-room surgical centers are regulated as private medical practices under the Board of Examiners. The proposed regulations will have the effect of requiring all surgical practices to register annually with the DHSS and creating standardized regulations across all surgical practices.

Pursuant to the proposed regulations, all surgical practices must submit to a uniform registration program and provide uniform information to the DHSS. Those surgical practices that are in operation on the effective date would be required to register with the DHSS or cease operation no later than ninety (90) days from the effective date. A surgical practice that has not commenced operation by the effective date but has filed specifications and/or other required building or zoning documents with the municipality in which it will be located would be required to register with the DHSS prior to commencing operation. All surgical practices to be registered in the future would be required to apply within two (2) years of receiving approval from the municipality in which they will

be located.

A registration will be valid for one year and will be subject to annual renewal. The DHSS is required to send to each surgical practice a renewal application within thirty (30) days of expiration. Along with the renewal application, the registrant would be required to submit a copy of its certification from the Centers for Medicare and Medicaid Services ("CMS") or other ambulatory care accreditation. The proposed regulations provide that the DHSS would approve applications for renewal provided that there had not been a material change in the surgical practice. The continuation of CMS certification or accreditation from an independent accreditation organization would be a condition of continued registration. In the event that a surgical practice fails to maintain such certification or accreditation, the registration would lapse.

The proposed regulations would also provide for standardized requirements for the transfer of ownership and relocation of all surgical practices. Importantly, a surgical practice would be permitted to apply for approval of a transfer of ownership by submitting a completed registration application at least ninety (90) days prior to the planned transfer of ownership. Additionally, a registered surgical practice would be permitted to relocate within twenty (20) miles of the existing surgical practice after submitting certain documentation set forth in the regulations. ■

Regulations Proposed to Regulate Accountable Care Organizations

(Continued from page 1)

CMS. Qualifying ACOs must agree to accept responsibility for at least 5,000 beneficiaries and establish a governing body to represent the ACO providers. The governing body must conduct routine monitoring and ensure proper reporting of the care delivered to CMS. Medicare will continue to pay individual providers for services as it currently does under the fee-for-service payment systems. The performance of each ACO will be assessed against a benchmark developed by CMS to determine whether the ACO qualifies to receive shared savings, or be held accountable for losses.

New Jersey has since extended the ACO concept to the Medicaid arena. A recent law introduced in New Jersey intends to create a Medicaid ACO Demonstration Project, which will enable providers to continue to receive Medicaid reimbursement directly from the Medicaid program while participating in certified Medicaid ACOs. An ACO that participates in a Medicare ACO project will not be prevented from participating in the Medicaid ACO Demonstration Project.

All providers should consult a licensed attorney before taking any action in connection with the implementation of an ACO or the Regulations. ■

Physician Assistants Are Entitled To Overtime

(Continued from page 1)

tions of bona fide professionals for purposes of the exemption. The first requires a person to be (1) compensated on a salary or fee basis at a rate of not less than \$455 per week, and (2) engaged in duties that require an advanced degree. The PA in question was not compensated on a salary or fee basis, so he was not exempt on this basis. An individual can also fall within the exemption if he or she holds a valid medical or law license. In the case of medicine, the exemption applies to physicians and other practitioners in the field of medical science. The parties contested whether the language "other practitioners in the field of medical science" includes PAs. The court deferred to the interpretation of the Department of Labor, which has refused to extend the exemption beyond actual physicians. Therefore, the PA was not deemed to fall within the scope of "other practitioners in the field of medical science" and was not included in the salary-basis exemption to the FLSA. Thus, the plaintiff at issue was entitled to overtime pay pursuant to FLSA for hours worked in excess of forty hours per week. ■

New Jersey Captive Insurance

(Continued from page 1)

censed in New Jersey. Additionally, the Law will make it possible to merge captive insurance companies from out of state jurisdictions into a New Jersey captive insurance company.

The Law will allow captive insurers to do business in the lines of life insurance, health insurance, annuities, indemnity, property and casualty, fidelity, guaranty and title insurance, and reinsurance. However, captive insurance companies must meet certain stringent requirements, including those relating to formation, examination, local office presence, ability to meet policy obligations, payment of certain fees and taxes and annual reporting. If violated, the Law authorizes the Commissioner of the Department to suspend or revoke the license of the violating insurer. The Law goes into effect on May 23, 2011. ■

LEGISLATIVE & REGULATORY UPDATE

Corporation Provided Right To Renounce Corporate Opportunity Doctrine

On March 1, 2011, Assembly Bill 3253 was signed into law. The law allows for New Jersey corporations to renounce, in part or in full, the Corporate Opportunity Doctrine (the "Doctrine"). Corporations may eliminate the Doctrine through its certificate of incorporation, or in a board resolution. In an attempt to eliminate personal gains at the expense of the corporation, the Doctrine requires fiduciaries to present all business opportunities to their corporation before pursuing those opportunities on their own.

New Standards for Electronic Prescribing Systems

Senate Bill 2781, introduced on March 11, 2011, seeks to amend the standards concerning electronic prescribing systems implemented by hospitals, medical or health service corporations, commercial insurers, health maintenance organizations and the Medicaid and NJ FamilyCare Programs. The bill would require that electronic prescribing programs contain a number of features that would enable such facilities to deliver efficient and safe prescription services. Specifically, the electronic prescribing programs must display a list of preferred and non-preferred products within a therapeutic category as well as a list of alternative drugs that are bioequivalent and abide by federal law. In addition, the electronic programs must contain a refill notification system for the prescriber and the patient.

Restriction of Botulinum Toxin Injections For Minors

This bill 3838, introduced to the Assembly on February 22, 2011, would restrict the administration of botulinum toxin ("Botox") to persons 18 years of age or younger for cosmetic purposes.

However, the bill would allow the use of Botox if deemed by the administering physician to be medically necessary. Pursuant to the bill, the State Board of Medical Examiners, in consultation with the Commissioner of Health and Senior Services, would promulgate regulations concerning this issue.

Professional Corporations Permitted to Use or Register Alternate Names

On March 1, 2011, the Governor signed Senate Bill 914 (the "Bill") into law, which expressly permits professional corporations to use or register an alternate name. The alternate name must contain the full or last name of one or more of the shareholders or adequately describe the type of professional service the corporation will be providing. Previously, the Professional Services Corporation Act was interpreted as restricting the use of alternate names. The Bill serves to clarify such interpretation.

This Bill also expands the scope of abbreviations of corporate names that professional corporations, limited partnerships and limited liability companies may use. In particular, corporations may use "PA" or "PC," in addition to the currently permitted "P.A." or "P.C." Limited partnerships may use the abbreviation "LP," and limited liability companies may use the abbreviation "LLC."

Nursing Home Reimbursement Adjustment for Cost of Energy Improvements

Assembly Bill 3791 was introduced on February 3, 2011 and would allow for an adjustment to the reimbursement rate structure of nursing homes that invest in energy efficiency improvements. Upon receiving prior approval by the Department of Health and Senior Services (the "DHSS"), nursing home facilities may

install equipment and devices that reduce their energy usage and produce a net savings in overall energy costs. In return, the DHSS will cover the full amount of costs incurred by that facility to install the equipment and devices.

Corporate Directors Maintain Rights to Indemnification Under Certain Circumstances

On March 1, 2011, the Governor signed Senate Bill 2493 (the "Bill") into law which prohibits a corporation from eliminating an officer or director's right to indemnification after the occurrence of an act or omission subject to legal action in a civil, criminal, administrative or investigative proceeding. Pursuant to the New Jersey Business Corporation Act, (the "Act") corporations may only eliminate or diminish an officer's right to indemnification if the certificate of incorporation or bylaws explicitly authorizes such action after the act or omission has occurred. The Bill shall take effect immediately.

Notice of Invitation for Certificate of Need Applications: Proposed New Hospital in Bergen County

Pursuant to 43 N.J.R. 751(a), the Department of Health and Senior Services ("DHSS") has published notice that it is inviting certificate of need applications for a proposed new general hospital to serve Bergen County. A maximum of one new general hospital may be considered for approval pursuant to this call. All applications must be submitted by June 1, 2011, and the DHSS anticipates that a completeness review decision will be made by August 6, 2011. The DHSS has initiated this call because a petitioner has presented documentation indicating that there may be a potential need for a new general hospital in this area of approximately 125 beds.

Issuance of this call does not constitute a finding of need by DHSS for any new general hospital affected by the call, and DHSS reserves the right to disapprove all applications submitted in response to the call, if the applicants have not satisfactorily demonstrated need. ■

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Office of Inspector General Advisory Opinion: *Certain Transportation Arrangements Between Hospitals and Physicians' Offices Do Not Violate Anti-Kickback Statute*

The Office of the Inspector General ("OIG") has issued a new advisory opinion which addresses a local transportation agreement (the "Agreement") between a hospital and nearby physicians' offices. Pursuant to the Agreement, an acute care hospital would provide complimentary local transportation to patients and their families from nearby physicians' offices if the patients require further treatment and cannot be transported themselves. The hospital certified that there are limited alternative public trans-

portation options available to patients, and a van service operated by the hospital would be able to respond more quickly and efficiently.

The OIG expressed that the Agreement could potentially generate prohibited remuneration under the Anti-Kickback Statute because the transportation could be offered to induce Federal health care program beneficiaries to obtain federally-payable items or services from the hospital. Despite such potential for prohibited remuneration, the

OIG determined that it would not impose administrative sanctions under the Anti-Kickback Statute and would allow the services at the specified hospital. The OIG supported its findings based on the following reasons: (1) the hospital would not selectively limit eligibility to targeted populations of federal health care program beneficiaries; (2) the services would be limited to a van owned by the hospital and driven by a certified EMT employed by the hospital; (3) the transportation services would be limited to the physicians' offices located within one-quarter of a mile from the hospital; (4) the hospital agreed not to advertise the arrangement; and (5) the hospital agreed not to charge the passengers or any third party payor for the services, including any federal health care program.

The OIG's opinion is limited to the specific facts presented, and therefore may not be relied upon by any other individual or entity. The OIG determined that this potential remuneration should be determined on a case-by-case basis. ■

About Garfunkel Wild, P.C.

Garfunkel Wild, P.C. (GW) is among the most active health care specialty law firms in the country, with offices in New Jersey, New York and Connecticut. It serves numerous New Jersey hospitals, licensed health facilities, medical practices, physicians and other health care practitioners, and health care related companies.

The firm specializes in addressing the complex legal, regulatory, business and financial needs of its clients: it helps clients negotiate favorable reimbursement rates from insurers and government; gain regulatory approval for facilities expansion or new services; merge, acquire or network with other organizations; and purchase or lease new technology and equipment. GW also assists numerous health care providers and others to comply with complicated, costly, and often onerous state and federal regulations.

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