News & Views from
Rath, Young and Pignatelli
Summer 2008

How's Your Health?

In This Issue

It's summer again. Time to review what happened in the legislature this year!!

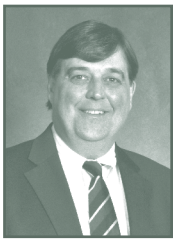
We report to you on New Hampshire's new Health First initiative, criminal background checks of licensed facility employees and regulations implementing the Patient Safety and Quality Improvement Act. State regulators are updating facility licensure requirements and streamlining the CON process. Federal regulators are at it again changing Medicare fee schedules and billing rules. We also include a report on the National Science Advisory Board for Biosecurity.

Health care providers operate in an ever changing landscape!

Enjoy your summer!

Lucy Hodder
Chair, Healthcare Law Practice Group

NHMSCAP



New Hampshire Legislative/Regulatory Update

By Attorneys Ann McLane Kuster and Steve J. Lauwers

HealthFirst Initiative: Wellness Plans

SB 540, Governor Lynch's HealthFirst initiative, received overwhelming bipartisan support from both Houses and will become effective in mid July of this year. HealthFirst has become part of the Governor's comprehensive plan to introduce affordable health care to the citizens of New Hampshire and focuses on lowering costs for the small employer market.

Beginning in October 2009, insurance carriers who cover more than 1,000 lives in the small group market must offer a new insurance product to small groups in New Hampshire that contains wellness features and programs. The Insurance Department is expected to consult with an advisory committee and then develop a regulation containing the specific features and programs that must be included in a wellness plan. The general goals are to: (i) promote wellness, primary care, preventive care and a medical home model; (ii) promote the use of cost effective care; (iii) promote quality of care by the use of evidence-based, best practice standards and patient-centered care.

Insurance carriers are "reasonably expected" to price the policy at or below a target rate of 10% of the prior year New Hampshire median statewide wage. This is substantially below the cost of small group coverage being sold today.

HealthFirst was modeled after a similar proposal by the Rhode Island General Assembly that was adopted last year.

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Small Employer Health Reinsurance Pool

SB 468 was introduced by Senator Hassan with the original intent to revise the board of directors of the small employer health reinsurance pool. The amended version, overwhelmingly supported by the House Commerce Comittee and adopted in early May, replaced the entire bill after the enacting clause and, most importantly, terminates insurance coverage through the reinsurance pool at the end of the year. The bill also makes changes to the vaccine and high risk pools: eliminating the exclusion for governmental plans from, and clarifying that foreign insurance carriers with plans in New Hampshire are included in, the assessment base for both the New Hampshire Vaccine Association and the high risk pool. Lastly, the Insurance Commissioner is given the authority to review the Vaccine Association and the reinsurance and high risk pools to ensure all three entities have participated in the assessment and reporting requirements. The Senate narrowly concurred with the House Amendment to SB 468 and the bill is currently awaiting the Governor's signature. If enacted, the law will become effective July 1, 2008.

Emergency Services

The Insurance Department issued a Bulletin on May 1st that seeks to limit the reimbursement by insurance carriers of "emergency services" to "licensed emergency facilities." Insurance carriers are advised in the Bulletin to limit their contracts accordingly or to reimburse patients for any associated co-pays or deductibles.

Other Legislation

The following additional bills were also passed by the Legislature:

Physician Regulation: HB 1153 eliminates the physician assistants advisory board, changes the examination waiver requirement for physicians licensed outside of New Hampshire and creates a new investigator position for the Medical Review Subcommittee of the Board of Medicine. The bill was signed into law by the Governor on May 12, 2008 and takes effect on July 11, 2008.

Retail Health Clinic Commission: HB 1484 creates a commission to study and develop legislation regulating retail health clinics and limited service clinics, including licensing, inspection and operational procedures. This bill has been signed by the Governor, it is effective immediately.

Criminal Background Checks: SB 420 requires every applicant for a health care facility license to submit with the application the results of a criminal background check for the applicant, the licensee or certificate holder if other than the applicant, the administrator, and each individual over 17 years of age who will be residing at the licensed facility. Currently, only residential facilities and home health care agencies are required to provide such background checks. The bill also temporarily limits fingerprinting and FBI background check requirements for nursing applicants to RNs and LPNs.

In addition, all new employees of such facilities who will have patient contact must submit criminal record authorization forms to the facility as of Januray 2009. Prior to hiring the employee, the facility must submit the form to the Division of State Police and review the results of the background check. (Although not entirely clear, this requirement does not appear to apply to existing employess.) This bill has been signed by the Governor and takes effect January 1, 2009.

Physician-Patient Communications: SB 433 amends the physician-patient privilege law by adding exceptions allowing physicians to release urine samples and the results of laboratory tests for drugs when they are related to diagnosis and treatment in connection with an incident giving rise to an investigation for driving under the influence. This bill has been signed by the Governor and takes effect September 5, 2008.

Stay Tuned . . .

The following bills were retained and referred to the House Committee on Health and Human Services but may be considered again in the next session:

Healthy Kids Coverage Gap: HB 1418 requires the Department of Health and Human Services to amend Medicaid eligibility requirements to ensure there is no gap in coverage for children transitioning from "healthy kids gold" to "healthy kids silver."

Privacy of Medical Information: HB 1587-FN expands the privacy protections provided under HIPAA by giving individuals greater access to their medical records, including the right to receive an audit trail showing how records have been accessed, and allowing individuals to elect to further restrict the disclosure of their health information.

Claims Data for Uninsured: SB 425 requires health care providers to submit claims data to the Department of Health and Human Services for uninsured individuals that they treat, and requires the Commissioners

of Insurance and Health and Human Services to collaborate on the establishment of a comprehensive uninsured health care database.

Expedited CON Review: SB 541 directs the Health Services Planning and Review Board to promulgate administrative rules that create an expedited certificate of need review process, designate projects eligible for such review and provide the process for such review.

For further information concerning these issues, please contact Steve Lauwers at sjl@rathlaw.com, or Ann Kuster at amk@rathlaw.com.

New Hampshire Health Care Law Update

By Attorney Lucy C. Hodder

❖ ***Health Facility Rulemaking:*** The rulemaking plan for the Department of Health Facilities Licensing, for licensed facilities is as follows:

- *He-P 804 Assisted Living Residence – Residential Care (adopted);*
- *He-P 818 Adult Day Programs (adopted);*
- *He-P 816 Educational Health Centers (adopted);*
- *He-P 814 Community Residences at the Residential Care Home and Supported Residential Facility (pending JLCAR);*
- *He-P 823 Hospice Care (due to office of Legislative Services by June 30, 2008);*
- *He-P 824 Hospice House at Supported Residential Care (draft being finalized);*
- *He-P 802 General Hospitals (draft being finalized);*
- *He-P 826, 827, 828 Specialty Hospitals – Psych, Rehab, Emergency Facilities (draft being finalized);*
- *He-P 815 Intermediate Care Facilities for the Mentally Retarded (being drafted);*
- *He-P 821 Equipment Management Organization (being drafted);*
- *He-P 822 Homemaker Provider (being drafted).*

❖ ***Prohibition Against Mandatory Overtime – New Form:*** The New Hampshire Department of Labor has a new form for the voluntary waiver of the prohibition against mandatory overtime for RNs. Last year R.S.A. 275:67, prohibiting overtime for certain nurses, was passed and became law. Nurses cannot be disciplined or lose any rights or benefits for refusing to work more than 12 consecutive hours unless an exemption applies. The exemptions include nurses participating in surgeries until the surgery is completed, nurses working in a critical care unit until another employee beginning a scheduled work shift releases him/her, nurses working in a home health care setting until relieved by another caregiver, a public health emergency, or a nurse covered by a collective bargaining agreement containing provisions addressing the issue of mandatory overtime. Employers can be exempt from the prohibition against mandatory overtime if an employee signs a waiver without coercion or pressure and the waiver is submitted to the Commissioner of the Department of Labor.

❖ ***Health Services Planning and Review Rulemaking:*** The HSPR Board is currently revising its administrative rules. The Subcommittee on He-Hea 100-300 rules is developing a streamlined CON process for hospital and long term care construction projects to address life safety code issues. The Subcommittee is also working with HSPR staff to finalize a form for "Not Subject To Review" Petitions. The Board recently adopted final rules for long term acute care hospitals. The Board is also finalizing rules regarding the standards of need for ambulatory surgical centers (He-Hea 900) and MRIs (He-Hea 600).

❖ ***ADA:*** The Department of Justice issued proposed regulations to revise ADA regulations under Title II and III, including specific standards for accessible design for public accommodation. See www.ada.gov.

❖ ***Medicare:*** CMS continues to seek changes to rules governing diagnostic imaging providers. On June 30, 2008 CMS proposed rules on independent diagnostic testing facility enrollment of physician office based imaging providers, changes to the anti-markup rule and revised fee schedules. Congress is also potentially modifying certification requirements for imaging providers and relieving physicians of a 10% fee cut.

For further information concerning these issues, please contact Lucy Hodder at lch@rathlaw.com.

Physician Reporting Under the Patient Safety and Quality Improvement Act

By Attorney Adam C. Varley

The Department of Health and Human Services ("HHS") recently published proposed regulations (the "NPRM") implementing the Patient Safety and Quality Improvement Act (the "Act"). The Act allows for the creation and registration of "Patient Safety Organizations" ("PSOs"), to which providers can report patient safety events for analysis, while potentially maintaining the information submitted and the response received as privileged and confidential. HHS is heralding the Act's creation of PSOs as a means for significantly improving patient safety. The impact and effectiveness of PSOs, however, will depend largely on how protective the Act's privilege and confidentiality provisions prove to be. This article explains the nature of PSOs and identifies the situations in which the confidentiality and privilege protections do not apply.

I. Creation and Registration of PSOs

A PSO is any "private or public entity or component thereof" that is registered with and listed by HHS.[1] An entity that wants to be registered as a PSO must submit a certification that the entity has policies and procedures in place to perform "patient safety activities," and that it will comply with the statutory criteria upon being registered. However, HHS has indicated that compliance with these requirements will be enforced only with random spot checks on 5-10% of PSOs, without any substantive review of most certifications.

Any entity or component of an entity can be a PSO, except for a health care issuer or a component of a health care issuer. (The NPRM proposes to also exclude from registration as a PSO any public or private entity that regulates providers.) If the PSO is an entity component it must maintain a firewall between itself and its parent and affiliate organizations. In addition, the mission of the component cannot conflict with the mission of any other affiliates.

Once registered, a PSO will be listed for 3-year renewable periods. However, every 2 years the PSO must demonstrate that it has bona fide contracts with at least 2 providers, for a reasonable length of time, and must disclose whether it has any other relationship with or is controlled by a provider. If a PSO violates the requirements of the Act (e.g., by inappropriately disclosing information), HHS can issue a notice of deficiencies. If the PSO does not take corrective action, the PSO will be delisted. After delisting, PSOs have 30 days to make an administrative appeal.

II. Use of PSOs; Exceptions and Limitations of Protections

The Act and NPRM seek to encourage providers to use PSOs by providing strong privilege and confidentiality protections. As a general rule, all "patient safety work product" must be treated as confidential and cannot be used against a provider in any criminal, civil or administrative proceeding, including disciplinary proceedings, and cannot be disclosed pursuant to the Freedom of Information Act. In addition, in most situations, this information continues to be privileged and confidential even after it has been disclosed. Generally, patient safety work product includes information reported to a PSO or developed by a PSO for conducting its activities. HHS has the authority to impose civil monetary penalties of up to $10,000 for unlawful disclosures of information.

HHS has also tried to make the PSO process as simple and flexible for providers as possible. No provider is required to work with any PSO. Nor is any provider required to enter into a contract with a PSO to receive the privilege and confidentiality protections.[2] In addition, HHS' regulatory authority only extends to PSOs, so it will not regulate providers that work with PSOs. Finally, providers have complete control over what information is disclosed to the PSO and may, by contract, be able to limit redisclosures that PSOs are permitted to make pursuant to the exceptions discussed below. There are, however, important limitations on the confidentiality and privilege protections.

First, certain information submitted to a PSO is not subject to the privilege and confidentiality protections. Most importantly, information that is created or main-

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[1] The Act is codified at 42 U.S.C. 299b-21-26.

[2] However, if the provider is a HIPAA "covered entity" and shares "protected health information" with the PSO, it must have a business associate agreement with the PSO.

[3] For purposes of the Act and NPRM, information created for reporting to or by a PSO is referred to as a "patient safety evaluation system."

New Canadian Guildelines on the Disclosure of Adverse Events

By Attorney Barbara J. Greenwood

The Canadian Patient Safety Institute (CPSI) recently released national guidelines on the disclosure of adverse events to patients and their families. The Guidelines reflect an emerging focus – in Canada and elsewhere, including here in the United States – on patient safety and the importance of open and honest disclosure of adverse events. The Guidelines are not binding on providers such as hospitals and physicians (whose operations and practices are regulated by the individual provinces), but are simply designed to encourage and assist providers in developing adverse event disclosure policies, practices and training methods.

An "adverse event" is not necessarily an error; it is defined as "an event which results in unintended harm to the patient, and is related to the care and/or services provided to the patient rather than to the patient's underlying medical condition." Examples of adverse events include hospital-acquired infections and medication errors.

According to the Guidelines, the initial disclosure should include, among other things, the facts of the harm and/or the event, the steps taken, the recommended options and decisions in the ongoing care of the patient, and an expression of sympathy or regret. Only this last element is controversial, in part because of a concern that an apology could be taken as an admission of legal responsibility.

Some provinces and States have enacted "apology laws" that make certain apologies for adverse events inadmissible in court for the purpose of proving liability. The scope of protection offered by such laws can vary dramatically.

The Guidelines can be found at *www.patientsafetyinstitute.ca.*

For further information concerning these issues, please contact Barbara Greenwood at bjg@rathlaw.com.

tained for purposes other than for reporting to or by a PSO is not protected.[3] This means that providers must be careful to maintain separate files for information that will be disclosed to a PSO and information that will be disclosed for other purposes. In this regard, HHS recommends that information disclosed for regulatory purposes be created, analyzed and sent to the agency, and copies placed in a separate file for PSO reporting, such that the set of documents and other related information sent to the PSO will still fall within the scope of the protections (even if the information submitted to the regulator does not).

There are also two sets of exceptions that apply to information that is subject to the privilege and confidentiality protections. First are a group of exceptions to both privilege and confidentiality. These exceptions are as follows: (1) disclosure in certain criminal proceedings; (2) disclosure as necessary by an individual to prevent an employer from taking an adverse employment action because of appropriate reporting under the Act by the individual; (3) disclosure if authorized by each provider identified; (4) nonidentifiable information (i.e., that does not identify providers, reporters or patients); and (5) information disclosed to HHS for enforcement purposes.[4]

The second group are exceptions just to confidentiality. These exceptions allow the patient safety work product to be disclosed but do not allow it to be used against a provider in any proceeding. The confidentiality exceptions are as follows: (1) disclosure of information to carry out "patient safety activities"; (2) disclosure of nonidentifiable information; (3) disclosure to entities conducting research for HHS if consistent with HIPAA; (4) disclo-

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[4] This last exception, which is the only required disclosure, was added by the NPRM. See 73 Fed .Reg. 8178, 8180.

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Physician Reporting Under the Patient Safety and Quality Improvement Act

sure by a provider to the FDA; (5) voluntary disclosure by a provider to an accrediting body; (6) disclosures otherwise authorized by HHS; (7) certain disclosures to law enforcement; and (8) disclosure, other than by a PSO, of information that does not include an assessment of quality of care or describe actions or failures by an identifiable provider. The NPRM also proposes to expand permitted disclosures to allow certain disclosures among PSOs and providers. However, these proposed disclosures can likely be limited by an agreement between the provider and PSO.

As noted above, even after a disclosure is made (either a permitted or prohibited disclosure) the information remains privileged and confidential with respect to any further use or disclosure. However, there are two exceptions to this continued protection as follows: (1) if the information is disclosed in a criminal proceeding, the confidentiality protections no longer apply; and (2) if nonidentifiable information is disclosed it is no longer subject to either the privilege or confidentiality protections.

III. Conclusion

The Act provides what HHS hopes will become a valuable tool in improving patient safety in the form of PSOs. PSOs do provide significant protections for physicians who wish to receive analysis of patient safety events without fear of disciplinary or malpractice actions. At the same time, providers must remain vigilant about the limitations of these protections. Most notably, the protections of the Act cannot be used to shield from disclosure information that was created or is maintained for a purpose outside the PSO process, even if that information is also submitted to a PSO for review. If providers are able to successfully navigate the limitations and exceptions, however, the PSO could indeed prove to be a valuable new resource.

For further information concerning these issues, please contact Adam Varley at acv@rathlaw.com.

Upcoming Events

July *2008*

On **July 30, 2008**, Attorneys Lucy C. Hodder and Ann McLane Kuster will be presenting at the 15th Annual Education Law Conference at the University of Southern Maine, Portland, Maine. The presentation is entitled "What Everyone Needs to Know About Investigations."

September *2008*

Rath, Young and Pignatelli co-sponsors New Hampshire's 2008 Nonprofit Leadership Summit on **September 22, 2008** at the Radisson Hotel in Manchester, New Hampshire.

Rath, Young and Pignatelli sponsors the New Hampshire Hospital Association 2008 Annual Meeting on **September 14-16, 2008** at The Mount Washington Resort at Bretton Woods, New Hampshire.

October *2008*

Rath, Young and Pignatelli sponsors the New Hampshire Medical Society Annual Scientific Convention on **October 17-19, 2008** at the Colony, Kennebunkport, Maine.

Employment Law Update

By Attorney Lucy C. Hodder

❖ ***Update Mandatory Posters:*** New Hampshire employers should update mandatory posters, which now require posting the definition of an independent contractor in a visible location. The definition of "employee" under New Hampshire law was changed effective January 1, 2008 to provide new standards for who constitutes an independent contractor. An individual must meet all 12 requirements to be treated as an independent contractor under New Hampshire law. Please check for free posters at the New Hampshire Department of Labor website *www.labor.state.nh.us/mandatory_posters.asp*.

❖ ***Retaliation Claims - U.S. Supreme Court:*** The United States Supreme Court has found that retaliation claims brought under the Civil Rights Act of 1866 (42 U.S.C. §1981) may be pursued as a stand-alone right of action. Previously, there had been a question as to whether retaliation claims brought under the racial discrimination statute can proceed without an underlying discrimination claim, and the Supreme Court has held they can. *Cracker Barrel OCS West, Inc. v. Humphries*, United States Supreme Court, May 27, 2008. Retaliation claims under Title VII, §1981 and the Age Discrimination in Employment Act can now survive as independent claims regardless of whether there is underlying discrimination. Thus, an employee who complains he or she was retaliated against for engaging in protected activity under most of the civil rights statutes is now clearly protected by these statutes.

❖ This fall, the United States Supreme Court will hear arguments in *Crawford v. Metropolitan Government of Nashville and Davidson County*, #06-1595. The Supreme Court will review whether or not the anti-retaliation provision of Title VII protects a worker from being dismissed because she cooperated with her employer's internal investigation of sexual harassment. The 6th Circuit had found that Title VII should only cover retaliation for protected activity involving a reporting or investigation of an EEOC complaint actually filed with the Equal Employment Opportunity Commission.

❖ ***Genetic Information Nondiscrimination Act:*** In May 2008, GINA was signed into law. The Act prohibits employers and insurance companies from discriminating against individuals on the basis of genetic information.

❖ ***EEOC Guidelines:*** The EEOC issued guidance on unlawful treatment of workers with caregiving responsibilities. See *www.eeoc.gov/policy/docs/quanda_caregiving.html*. While there is no specific protected class category for caregivers under Title VII or the other statutes enforced by the EEOC, the EEOC notes that caregivers often have rights under the Family and Medical Leave Act, and that unlawful discriminatory treatment arises where a worker with caregiving responsibilities is subjected to discrimination based on a protected characteristic under EEOC law, such as sex and/or race. Some of the numerous examples cited by EEOC outlining potential violations include:

- Sex-based stereotyping of working women;
- Denying a male caregiver leave to care for an infant under circumstances where such leave would be granted to a female caregiver;
- Subjecting a worker to severe pervasive harassment because his wife has a disability;
- Refusing to hire a worker who is a single parent of a child with a disability based on the assumption that caregiving responsibilities will make the worker unreliable;
- Making assumptions about pregnant workers, for example, that result in limiting a pregnant worker's job duties based on pregnancy related stereotypes; and
- Reassigning a woman to less desirable projects based on the assumption that as a new mother she will be less committed to her job.

For further information concerning these issues, please contact Lucy Hodder at lch@rathlaw.com.

CMS UPDATE - Stark Law Developments

By Attorney Barbara J. Greenwood

2009 IPPS Proposed Rule

CMS published the Fiscal Year 2009 Hospital Inpatient Prospective Payment System Proposed Rule (the "IPPS Proposed Rule") in the Federal Register on April 30, 2008 (73 Fed. Reg. 23528). Included in the IPPS Proposed Rule were several important proposed changes to the federal Stark law regulations. Any comments were due by June 13. Below is a summary of the most significant proposals.

❖ *"Stand in the Shoes"*

- Physician Stand in the Shoes Provision

The Stark II Phase III regulations published last fall included a new rule that provides that a physician will be treated as standing in the shoes of his or her "physician organization" with respect to the physician organization's compensation relationships with designated health services (DHS) entities such as hospitals. Thus, in order for the physician to refer Medicare patients for DHS, the arrangement between the physician organization (e.g., a group practice) and the DHS entity will now have to meet a direct compensation exception. (A typical example of a contract caught by this rule is a contract for a group practice to provide medical director services to a hospital.)

The IPPS Proposed Rule proposes two alternative approaches to address concerns raised by academic medical centers and integrated tax-exempt health care systems regarding the effect that the "stand in the shoes" rule would have on mission and other support payments to their affiliated physician practices. The first alternative proposes that the "stand in the shoes" provision not be applied if the only financial relationship between the physician and the physician organization is a compensation arrangement that satisfies one of the following direct compensation exceptions: employment exception, personal services exception, or fair market value exception. (Physician owners and investors would, however, continue to stand in the shoes of their physician organization.) The second alternative proposes to make no revisions to the "stand in the shoes" provision, but would create a new exception for compensation arrangements between DHS entities and physician organizations for certain non-abusive payments or arrangements, such as "mission support" payments. CMS is seeking comments on the proposals.

- New DHS Entity Stand in the Shoes Provision

CMS is proposing to revise the regulations to provide that an entity that furnishes DHS would be deemed to stand in the shoes of any organization (not just a DHS entity) in which it has 100% ownership. CMS is seeking comments on whether this "stand in the shoes" provision should apply where a DHS entity holds an ownership interest of less than 100% in another entity, or controls another entity.

Stand in the Shoe Conventions

To try to simplify the convoluted "stand in the shoes" analysis that now would be required in the case of chains of financial relationships involving multiple entities and physicians and physician organizations, CMS proposes certain conventions regarding which "stand in the shoes" principles to apply when, with the goal of ensuring that, once the principles have been applied, at least one compensation relationship will remain between the DHS entity and the referring physician for purposes of analysis under the Stark rules. In general, the physician "stand in the shoes provisions" will be applied first.

❖ *Period of Disallowance*

CMS is proposing to define the "period of disallowance" under Stark, that is, the period for which the physician could not refer patients for DHS to an entity and for which the entity could not bill Medicare, because a financial relationship between the referring physician and the entity fails to satisfy a Stark exception.

These proposed amendments demonstrate how seriously CMS regards even minor non-compliance. For example, CMS proposes that where the reason for non-compliance does not relate to compensation — e.g., where a signature on an otherwise compliant written agreement is missing — the period of disallowance would begin on the date the arrangement was first out of compliance and end on the date the arrangement was brought into compliance (e.g., the missing signature was obtained). So, if the hospital and the physician enter into a medical director services agreement effective January 1, but the agreement is not

signed by both parties until January 31, the period of the disallowance would be from January 1 to January 31, even if the agreement is otherwise legally effective as of January 1.

❖ *Hospital Disclosure of Financial Relationships with Physicians*

CMS has developed a "Disclosure of Financial Relationships Report," designed to collect information about financial arrangements between hospitals and physicians. CMS proposes to send the form to 500 hospitals, and will use the responses to determine whether the hospitals and physicians are in compliance with Stark, and to assist in future rulemaking efforts. CMS is seeking comments on the form.

❖ *Gainsharing*

"Gainsharing" typically refers to an arrangement where hospitals reward physicians' efforts to reduce costs, often by sharing a portion of the cost savings with the physicians; such arrangements implicate federal fraud and abuse statutes as well as the Stark law. CMS is soliciting comments on whether the physician self-referral law should include an exception for gainsharing arrangements. (The OIG has issued several advisory opinions approving certain gainsharing arrangements under the federal Anti-Kickback Statute and Civil Monetary Penalties Statute.)

❖ *Physician Ownership in Medical Device or Implant Companies*

CMS views physician ownership in medical device or implant companies as raising potential anti-competitive, quality of care, and overutilization concerns, for example, in situations where physicians investors will profit from ordering products to use on their own patients. CMS is soliciting comments as to whether the Stark law should be amended to address physician ownership in medical device or implant companies.

Other Future Stark Changes

In the proposed CY 2008 Medicare Physician Fee Schedule published last July, CMS sought comments on certain issues that are enormously important for many physician practices:

- Whether changes are necessary to the in-office ancillary services exception (including whether certain services should not be protected);
- Whether physicians can lease equipment to another provider on a per-click basis; and
- The use of percentage-based compensation in equipment leases or management services agreements.

CMS has signaled that these issues will be addressed in a final rule.

For further information concerning these issues, please contact Barbara Greenwood at bjg@rathlaw.com.

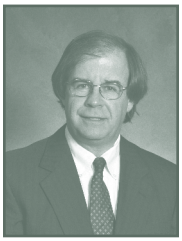
Litigation Update

By Attorney Kenneth C. Bartholomew

The Rath, Young and Pignatelli medical malpractice defense team, headed by Mike Pignatelli and Ken Bartholomew, has won four victories for doctors and hospitals in the past three months. Two defense verdicts came after jury trials in Hillsborough South Superior Court. The other two decisions were unanimous panel decisions in favor of a cardiologist and a neurologist.

The cardiology malpractice case involved a claim brought in the United States District Court for the District of New Hampshire. After winning our motion to apply New Hampshire's screening panel law to federal diversity actions, the case was presented to a panel that found unanimously in favor of the doctor, after which the plaintiff's counsel dropped his case.

For further information concerning these issues, please contact Kenneth C. Bartholomew at kcb@rathlaw.com.



Roles and Responsibilities of the National Science Advisory Board for Biosecurity

By Attorney Gilbert F. Whittemore

Over the past year I have served as Chair of the Section of Science & Technology Law of the American Bar Association. One aspect of this office is representing the Section publicly. One of the more intriguing of these events was my attendance at a recent meeting of the National Science Advisory Board for Biosecurity (NSABB). The NSABB was founded in response to the anthrax attacks of 9/11. Given the potential harm which could be done by a bioterrorist attack or a biosafety accident, the NSABB faces and awesome responsibility. Given the complexity of the science, it is also a responsibility with no quick and easy answers.

One major challenge facing the NSABB is educating researchers and the general public about the importance and complexity of these issues. At its most recent meeting, the NSABB was consulting with several organizations, including the ABA, on how best to alert and educate both the research community and the general public to the issues arising from research which can have a "dual use" – both beneficial but also potentially subject to serious misuse. At the meeting, I pointed out that lawyers, although not scientific or medical researchers themselves, often have clients who are such, and that lawyers thus can be an avenue for education. This article is an attempt to make good on that point.

The work of the NSABB will have implications for those involved in biological and biomedical research. As stated on its website (www.biosecurityboard.gov):

> "The NSABB has been established to provide advice to federal departments and agencies on ways to minimize the possibility that knowledge and technologies emanating from vitally important biological research will be misused to threaten public health or national security. The NSABB is a critical component of a set of federal initiatives to promote biosecurity in life science research.
>
> The NSABB is charged specifically with guiding the development of:
>
> - A system of institutional and federal research review that allows for fulfillment of important research objectives while addressing national security concerns;
> - Guidelines for the identification and conduct of research that may require special attention and security surveillance;
> - Professional codes of conduct for scientists and laboratory workers that can be adopted by professional organizations and institutions engaged in life science research;
> - Materials and resources to educate the research community about effective biosecurity; and
> - Strategies for fostering international collaboration for the effective oversight of dual use biological research.
>
> The NSABB is chartered to have up to 25 voting members with a broad range of expertise in molecular biology, microbiology, infectious diseases, biosafety, public health, veterinary medicine, plant health, national security, biodefense, law enforcement, scientific publishing, and related fields. The NSABB also includes nonvoting ex officio members from 15 federal agencies and departments."

The primary role of the NSABB is to advise on how best to address the risk posed by "dual use" research, defined as biological research which can provide benefits but also may threaten public health and safety.

Reports of the NSABB are available on its website at http://www.biosecurityboard.gov/news.asp. Of particular interest is the detailed June 2007 report, *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information*. This includes discussion of the responsibilities of both individual researchers and research institutions.

Since much research has potential for "dual use" broadly defined, the NSABB uses the term "dual use

of concern" for research of special concern, defined as "research that, based on current understanding, can be reasonably anticipated to provide knowledge, products or technologies that could be directly applied by others to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, or materiel." (*Proposed Framework*, p. 17). The NSABB has identified seven types of research falling within "dual use of concern":

1. Enhancing the harmful consequences of a biological agent or toxin, such as making a strain of influenza as deadly as the 1918 pandemic strain;
2. Disrupting the immunity or the effectiveness of an immunization without clinical and/or agricultural justification, such as inserting an immunosuppressive cytokine into a viral genome to render the antiviral immune response less effective;
3. Conferring to a biological agent or toxin, resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin to facilitate the ability to evade detection methodologies, such as conferring antibiotic resistance to agriculturally relevant microbes;
4. Increasing the stability, transmissibility, or the ability to disseminate a biological agent or toxin, such as changing genetic factors to increase activity for gene therapy might also increase transmissibility;
5. Altering the host range or tropism of a biological agent or toxin, such as expanding the variety of the same plant that a pathogenic agent could infect;
6. Enhancing the susceptibility of a host population, such as blocking the host's ability to generate an important immune signal;
7. Generating a novel pathogenic agent or toxin, or reconstituting an eradicated or extinct biological agent, such as reconstitution of the 1981 flu pandemic virus. "

Designating research as "dual use of concern" does not mean such research would be forbidden, but that special care must be taken to prevent deliberate misuse or accidents.

A major policy issue is whether such special care would best be assured by government regulation, or by voluntary compliance by scientists coupled with extensive professional education on the need for such special care. Not surprisingly, most researchers would prefer the route of voluntary compliance, but others point out that, if a misuse or accident should occur, even more extreme regulation would likely result and, of course, potential legal liability.

The outcome of this debate will influence the daily operations of many researchers and research institutions. The next stage of the debate is a Public Consultation meeting to be held by the NSABB on July 15, 2008, in Bethesda, Maryland. More information is available at http://www.biosecurityboard.gov/meetings.asp or from Allan C. Shipp, Director of Outreach, NIH Office of Biotechnology Activities, 301-435-2152 or at shippa@od.nih.gov.

For further information concerning these issues, please contact Gil Whittemore at gfw@rathlaw.com.

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New Faces

Rath, Young and Pignatelli Welcomes Tony Sayess to the Firm

Rath, Young and Pignatelli is pleased to announce that Attorney Antony K. Sayess has joined the firm. He will practice as a member of the firm's Tax Practice Group and Business and Finance Group.

Tony is a native of Concord, NH, and received his BS degree from UNH. He received a Masters from George Washington University, a law degree from the University of Virginia and his LLM in tax from New York University. Tony spent three years as a tax attorney with the Coudert Brothers in New York. He is relocating from Portland, Oregon where he has been working as a business and tax attorney with Landerholm Memovich, Lansverk & Whitesides, P.S.

Tony will be working out of our Concord, New Hampshire office and may be contacted by phone at (603) 226-2600 or e-mail (aks@rathlaw.com).