MEDICAL MALPRACTICE YEAR IN REVIEW

by Paul C. Troy, Esq. - Partner, Kane, Pugh, Knoell & Driscoll; Vice-Chair, PBA Healthcare Law Committee; Chair, Risk Management Subcommittee

As a service to our members whose practices include the litigation of malpractice claims, the following is a summary of some of 2000's noteworthy cases. It is not intended to be a treatise, but rather a way for the practitioner to catch-up on significant developments from the past year.

I. EXPERT WITNESSES
A. Rule 4003.6

A Philadelphia judge disqualified a defense attorney and his firm where one of the lawyers spoke with a subsequent treating physician in violation of Pa. R.C.P. 4003.6. In Jakobi v. Ager, PICS Case No. 00-0464 (C.P. Philadelphia 3/7/00), the physician’s deposition was scheduled, and he returned a call made to him by a defense attorney. An associate answered the call, and spoke with the physician for almost an hour. Defense counsel tried to minimize the damage by eliminating the associate from participation in the matter, but the court held that would be unacceptable. The defendant physician was given forty-five days to obtain new counsel.

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PA Department of Health Regulatory Update

by Lori McLaughlin, Esq., Chief Counsel

The Department of Health’s regulatory agenda for 2001 is as follows:


   The department is proposing to repeal drug and alcohol abuse prevention standards. These activities are not related to the treatment of drug and alcohol and can be monitored by the department through contracts with local authorities. Anticipated date for publication in proposed form is spring 2001.


   The amendments to existing regulations will establish uniform standards for all residential and non-residential services. Pursuant to the Pennsylvania Drug and Alcohol Abuse Control Act, 71 P.S. §§ 1690.101-1690.115. Anticipated date for release in final form is summer 2001.


   The department is proposing to revise and update current narcotic addiction treatment standards for the approval of narcotic addiction treatment programs to conform to updated federal regulations. Anticipated date for release in final form is spring 2001.


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Health Care Law Committee Presents CLE Program & Meeting In Pittsburgh Thursday, May 10, 2001

Join the Health Care Law Committee for a CLE program and committee meeting on Thurs., May 10, 2001 during the PBA Annual Meeting at the Omni William Penn in Pittsburgh.

Recent Developments and Hot Practice Tips for Health Care Providers CLE 8:00 - 9:30 a.m. (Breakfast sponsored by the committee)

With recent legislative activity and litigation aimed at providers, there are ever-increasing reasons for concern by lawyers who represent health care providers. This course will address these concerns in a practical and condensed format. Topics included are fraud and abuse, compliance issues, recent state and federal initiatives, and Pennsylvania’s new voluntary disclosure policy.

Faculty: Christopher Abruzzo, Esq., Director, Medicaid Fraud Control Unit, PA Attorney General’s Office; Thomas J. Blazusiak, Esq., Senior Attorney, PA Department of Welfare; Dan Mulholland, Esq., Horty, Springer & Mattern; and Adam Young, Esq., MHA, Regulatory Affairs, Highmark Inc. CLE Credits: 1.5 hours – Substantive

Following the CLE program, the Health Care Law Committee will meet: 9:45 - 11:00 a.m.

Call the PBA Member Service Center at 1-800-932-0311 for registration information

Message from the Chair
by Thomas J. Blazusiak, Esq.
PA Department of Public Welfare

Welcome to the Health Care Law Committee. We are very excited about all of the new activities in which you can participate.

During the past year the committee has been very active. The committee, in cooperation with the Dauphin County Bar Association and the Pennsylvania Society of Health Care Attorneys, sponsored “Hot Topics in Health Law,” an all-day conference for health lawyers held at the Pennsylvania Bar Institute in Mechanicsburg, Pa.

At the Committee/Section Day meeting in the fall, the committee had our largest turn-out ever. There were reports from the following subcommittee chairs:

a. hospitals
b. long-term care
c. behavioral health
d. newsletter
e. fraud and abuse
f. licensing
g. provider government relations

The committee published a newsletter containing news and feature articles on developments in health law and legislation. This issue is the latest newsletter.

The committee held a subcommittee chair conference call on Mon., Feb. 12, 2001 at which time plans were made for the future direction of the committee. Discussion included nominations for this year’s Excellence in Health Care Law Award. Last year’s recipient was Rollie Morris.

Plans now are being made with the FBI for a future seminar on a health law fundamentals to be held in June. Plans for a lunch and learn also were discussed.

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Pennsylvania Legislative Update

Bills introduced in the 2001-2002 session of the Pennsylvania Legislature (1/1/01 to 2/05/01):

- HB 1 (Vance) - an act providing for pharmaceutical assistance for the elderly
- HB 2 (Orie) - an act establishing a special fund for money received by the tobacco master settlement, establishing the Tobacco Settlement Investment Board, establishing an adult basic coverage insurance program, providing for tobacco use prevention, establishing the Uncompensated Care Program, establishing regional biotechnology research centers
- HB 48 (Schuler) - provides for information, research, and services relating to the prevention of birth defects
- HB 50 (Orie) - provides for domestic violence managed care response
- HB 86 (George) - providing for the ready access of managed care plan enrollees to urgent care services
- HB 96 (Fleagle) - further providing for advance directives for health care definitions and emergency medical services and providing for out of house nonresuscitation
- HB 135 (Orie) - provides for the Domestic Violence Health Care Response Program
- HB 137 (Orie) - amends the Domestic Violence Health Care Response Act providing for primary care physicians, emergency medical service organizations and nurses training
- HB 139 (Orie) - amends the Medical Foods Insurance Coverage Act, requiring coverage for treatment of certain intestinal disorders
- HB 143 (Orie) - provides for instruction of domestic violence for health care professionals licensed by the Boards of Medicine, Osteopathic Medicine or Nursing
- HB 190 (Readshaw) - prohibits discrimination in insurance coverage on the basis of genetic information or a request for genetic services
- SB 11 (Holl) - establishes a long-term care partnership program
- SB 18 (Holl) - amends the Newborn Child Testing Act further providing for required tests
- SB 21 (Mellow) - creates the Pennsylvania Antitrust Act prohibiting unreasonable restraints of trade
- SB 40 (Bell) - authorizes suits against providers of employer-sponsored health insurance plans in certain cases
- SB 64 (Holl) amends Insurance Company Law further providing for children's health care
- HB 25 (Williams) - Ensures the equitable coverage of prescription contraceptive drugs and devices and the medical and counseling services necessary for their effective use
- HB 37 (Thomas) - Amends the Children's Health Care Act providing for loan forgiveness for primary healthcare practitioners
- HB 42 (Scrimenti) - Further defines “maximum annual income” for PACENET eligibility
- HB 47 (Schuler) - Designates a percentage of the tobacco settlement be utilized for home and community-based long-term care services; establishes the Tobacco Settlement LTC Fund
- HB 85 (George) - Amends the Banking Code of 1965 providing for privacy protection for consumer information
- HB 121 (Orie) - Designates a percentage of the tobacco settlement funds for salaries of direct care staff working with persons diagnosed with mental disabilities in community-based mental health/mental retardation programs
- HB 160 (Curry) - Amends the Clinical Laboratory Act limiting the distribution of laboratory reports
- HB 238 (Godshall) - Designates a percentage of the tobacco settlement funds for cancer research facilities
- HB 244 (Godshall) - Provides for special leave of absence for organ and bone marrow donors as well as tax credits and duties for the Departments of Health and Revenue
- HB 285 (Blaum) - Establishes the Office of Consumer Advocate for Insurance as an independent office under the Attorney General
- HB 286 (Blaum) - Amends the Dental Law providing for functions of the Commissioner of Professional and Occupational Affairs and provides for anesthesia
- SB 83 (Holl) - Requires the Department of Aging to place certain information on the Internet, sets for duties for the Departments of Health and Aging
- SB 94 (Holl) - Mandates insurance coverage for cancer prevention and early detection programs
- SB 125 (Holl) - Establishes a donated dental services program for certain individuals
- SB 127 (Murphy) - Amends the Health Care Cost Containment Act providing for pharmaceutical advertising and promotional expense disclosure and

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cost containment
• SB 153 (Bell) – Amends the Medical Practice Act by providing for respiratory care practitioners and various guidelines for continuing education, suspension and penalties
• SB 154 (Bell) – Amends the Osteopathic Medical Practice Act by providing for respiratory care practitioners and various guidelines for continuing education, suspension and penalties
• SB 157 (Bell) – Extends the powers and duties of the Office of Consumer Advocate to matters relating to insurance
• SB 166 (Bell) – Amends the Newborn Child Testing Act providing for newborn child screening and testing
• SB 177 (Eadl) – Amends the Insurance Company Law of 1921 by providing for presumptive eligibility for free or subsidized health care insurance for children

Bills introduced in the 107th Congress
(01/01/01 to 02/05/02):

• H.R. 16 (Dingell, D-Mich.) - proposal for national health insurance
• H.R. 18 (Biggert, R-Ill.) - establishes additional provisions to combat waste, fraud, and abuse within Medicare
• H.R. 68 (Emerson, R-Mo.) - relating to the distribution chain of prescription drugs
• H.R. 72 (Lee, D-Tex.) - requires hospitals reimbursed under Medicare to establish and implement security procedures to reduce the likelihood of infant patient abduction and baby switching, including procedures for identifying all infant patients in the hospital in a manner that ensures that it will be evident if infants are missing from the hospital
• H.R. 154 (Pomeroy, D-N.D.) - increases to 100 percent the deduction for the health insurance costs of the self-employed
• H.R. 162 (Roukema, R-N.J.) - prohibits group and individual health plans from imposing treatment limitations or financial requirements on the coverage of mental health benefits and on the coverage of substance abuse and chemical dependency benefits if similar limitations or requirements are not imposed on medical and surgical benefits
• H.R. 186 (Slaughter, D-N.Y.) - Requires universal product numbers on claim forms submitted for reimbursement for durable medical equipment and other items
• H.R. 287 Carolyn McCarthy (D-N.Y.) - Requires group and individual health insurance coverage, group health plans, and Medicare +Choice organizations provide prompt payment of claims
• H.R. 292 Nadler (D-N.Y.) - Requires group and individual health insurance coverage and group health plans provide coverage for annual screening mammography for women 40 years of age or older if the coverage of plans includes coverage for diagnostic mammography

WANTED:
Subcommittee Chairs

The Health Care Law Committee is seeking a few good members to help with committee chair duties. These include chair of the Annual Meeting Program Subcommittee, the Legislative Subcommittee, the Lunch and Learn Subcommittee in Pittsburgh, the Lunch and Learn Subcommittee in Harrisburg, and the Lunch and Learn Subcommittee in Philadelphia.

Authors Needed

This newsletter depends on you for support. Any articles on the practice of health care law will be considered for publication. These articles may be features, current news, historical, editorial, etc. Practice tips are especially useful. Tell us your war stories.

Contact Editor Rob Quigley at (717) 237-5549
The Internal Revenue Service ("IRS") recently released temporary regulations interpreting Section 4958 of the Internal Revenue Code ("Code"); "Taxes on Excess Benefit Transactions." The regulations, published in the Jan. 10 Federal Register (66 Federal Register 2143), were effective upon publication. The regulations have the full force of final regulations and are "temporary" to the extent that they expire in three years. The recently published regulations are substantially similar to the proposed regulations issued in 1998. A summary of the "intermediate sanctions law," incorporating the recent regulations, follows.

Section 4958 imposes excise taxes on transactions that provide excess economic benefits to disqualified persons of organizations exempt from tax under Section 501(c)(3) or 501(c)(4) of the Code. Disqualified persons who benefit from an excess benefit transaction are liable for a tax of 25% of the excess benefit. Such persons also are liable for a tax of 200% of the excess benefit if it is not corrected within a specified period of time. Additionally, organization managers who knowingly participate in an excess benefit transaction are liable for a tax of 10% of the excess benefit. Such persons also are liable for a tax of 200% of the excess benefit if it is not corrected within a specified period of time. Additionally, organization managers who knowingly participate in an excess benefit transaction are liable for a tax of 10% of the excess benefit, up to a cap of $10,000. However, organization managers who rely on a reasoned written opinion by legal counsel, certified public accountants or accounting firms with relevant tax law expertise or qualified independent valuation experts generally will not be liable for the 10% tax.

Disqualified persons are those who were in a position to exercise substantial influence over the affairs of the organization at any time during the five-year period ending on the date of the transaction, as well as family members of those who were in a position to exercise substantial influence over the organization, and 35% controlled entities of a disqualified person. Persons who hold certain powers, responsibilities or interests are among those who are in a position to exercise substantial influence over the affairs of the organization, including (1) voting members of the governing body, (2) persons, regardless of title, who have or share ultimate responsibility for implementing the decisions of the governing body or supervising the management, administration, or operation of the organization (such as the president, chief executive officer and corporate organizational officers of the organization), and (3) persons, regardless of title, who have or share ultimate responsibility for managing the finances of the organization (such as the treasurer and chief financial officer of the organization).

A person also may be considered to be in a position to exercise substantial influence over the affairs of the organization if (1) such person is a substantial contributor to the organization (taking into account only contributions received by the organization during its current taxable year and the four preceding taxable years); (2) such person's compensation primarily is based on revenues derived from activities of the organization controlled by such person, (3) such person has or shares authority to control or determine a substantial portion of the capital expenditures, operating budget or compensation for employees of the organization; (4) such person manages a discrete segment or activity of the organization that represents a substantial portion of the activities, assets, income or expenses of such organization, as compared to the organization as a whole; (5) such person owns a controlling interest in an entity that is a disqualified person, or (6) such person is a non-stock organization controlled, directly or indirectly, by one or more disqualified persons.

Excess benefit transactions are those transactions in which an economic benefit is provided by a tax-exempt organization, directly or indirectly, to or for the use of any disqualified person, and the value of the economic benefit provided by the organization exceeds the fair market value of the consideration (including the performance of services) received for providing such benefit. In determining whether an excess benefit transaction has occurred, with certain limited exceptions, all consideration and benefits exchanged between a disqualified person and the tax-exempt organization, and all entities it controls, are taken into account. Fair market value is defined as the price at which property, or the right to use property, would change hands between a willing buyer and a willing seller, neither being under any compulsion to buy, sell or transfer property or the right to use property, and both having reasonable knowledge of relevant facts.

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Reasonable compensation means with respect to the performance of services only such amount as would ordinarily be paid for like services by like enterprises under like circumstances. Relevant factors to consider in determining reasonableness of compensation include the aggregate benefits provided to the disqualified person, the rate at which any deferred compensation accrues and the fact that a bonus or revenue-sharing arrangement is subject to a cap. Compensation for determining reasonableness includes all items of compensation provided by the tax-exempt organization in exchange for the performance of services, including without limitation:

1) All forms of cash and noncash compensation, including salary, fees, bonuses, severance payments and deferred and noncash compensation;

2) Unless excludable from income as a de minimis fringe benefit, the payment of liability insurance premiums for, or the payment or reimbursement by the organization of, any penalty, tax or expense of correction owed under Section 4958 of the Code, any expense not reasonably incurred by the person in connection with a civil judicial or civil administrative proceeding arising out of the person's performance of services on behalf of the applicable tax-exempt organization, or any expense resulting from an act or failure to act with respect to which the person has acted willfully and without reasonable cause; and

3) All other compensatory benefits, whether or not included in gross income for income tax purposes, including payments to welfare benefit plans, such as plans providing medical, dental, life insurance, severance pay, and disability benefits, and both taxable and nontaxable fringe benefits (other than fringe benefits described in Section 132 of the Code), including expense allowances or reimbursements and foregone interest on loans.

There is a special exception under Section 4958 for fixed payments, including payments determined by a fixed formula, made pursuant to an initial contract with a person who was not a disqualified person immediately prior to entering into the contract. Under this exception, to the extent a tax-exempt organization and a person, who is not yet a disqualified person, conduct negotiations and specify the amounts to be paid, the fixed payments will not be subject to scrutiny by the IRS. Any payments which are not fixed payments will be evaluated to determine whether they represent excess benefit transactions.

In addition, the IRS has created a rebuttable presumption of reasonableness, whereby payments under a compensation arrangement are presumed reasonable, and the transfer of property (or the right to use property) are presumed to be at fair market value, if each of the following three conditions are met:

1) The compensation arrangement, or the terms of the property transfer, was approved in advance by an authorized body of the organization composed entirely of individuals who did not have conflicts of interest with respect to the transactions.

2) The authorized body obtained and relied upon appropriate data as to comparability prior to making its decision, including, for example: compensation levels paid by similarly situated organizations, both taxable and tax-exempt, for functionally comparable positions; the availability of similar services in the geographic area; current compensation surveys compiled by independent firms; and actual written offers from similar institutions competing for the services of the disqualified person. In the case of property, relevant information includes, but is not limited to, current independent appraisals of the value of all property to be transferred and offers received as part of an open and competitive bidding process.

3) The authorized body adequately documented the basis for its determination concurrently with making the decision, including the terms and date of the transaction, the members who were present during debate and those who voted on it, the comparability data obtained and relied upon, any actions by any members have a conflict of interest; and documentation of the basis of the determination before the later of the next meeting or 60 days after the final actions of the authorized body.

Where all three elements are satisfied, the IRS only can overcome the presumption of reasonableness if it develops sufficient evidence to rebut the value of the comparability data relied on by the authorized body.

An excess benefit transaction is corrected by undoing the excess benefit to the extent possible and placing the organization involved in the excess benefit transaction in a financial position no worse than it

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B. Failure to Furnish Expert Reports

In Wolloch v. Aiken, ____ Pa. Super. ____, 756 A. 2d 5 (2000), a plaintiff failed to produce expert reports by the deadline of a case management order, even when that deadline was extended by thirty days at plaintiff's request. Defendant successfully moved for summary judgment. The following month, plaintiff produced expert reports and moved to vacate the summary judgment order.

The trial court denied the motion to vacate. The Superior Court reversed the motion, noting that with the exception of this deadline, discovery had proceeded without incident and that at the time of summary judgment, the matter was still five months away from trial.

In contrast, a similar summary judgment was affirmed in Miller v. Sacred Heart Hospital, ____ Pa. Super. ____, 753 A.2d 829 (2000). The court did not apply the sanctions analysis it had used in Wolloch, instead holding that its entry of summary judgment was not a sanction, but a failure by the plaintiff to establish a prima facie case.

II. USE OF TREATISES

In Aldridge v. Edmunds, ____ Pa. ____ 750 A.2d 292 (2000), the Pennsylvania Supreme Court held that treatises may be referenced on direct examination of an expert witness to explain reasons underlying the opinion, but may not be “made the focus of the examination,” and should be subject to “appropriate limiting instructions.” Aldridge, at 297.

Here, where a textbook was used on the direct examination of defendant's expert, the Supreme Court held that their use was in error because no limiting instruction was given and they became the focus of the examination, including poster board enlargements. However, the court did not award a new trial, finding that plaintiff's own expert had acknowledged the treatise was authoritative and that the points presented through the treatise essentially were undisputed.

III. PEER REVIEW PROTECTION ACT

Three different common pleas cases this year highlighted instances where documents were not shielded from discovery by the PRPA. The opinions were all fact specific. In Piper-Ochab v. Guthrie Clinic, Ltd., PICS Case No. 00-1035 (C.P. Lackawanna 1/20/00), a physician's application for employment with a clinic was held discoverable because the only evidence that the application had been submitted to the clinic's review committee was proffered after the court deadline for production of such evidence. The court also denied a motion for reconsideration.

In Tirado v. Lehigh Valley Hospital, PICS Case No. 00-0609 (C.P. Lehigh 3/14/00), a report made by the defendant physician regarding her care was deemed discoverable because the doctor used the report to prepare for her deposition. The court also noted that everything in the report was available from the medical records. The report specifically had been prepared at the request of the hospital for peer review purposes. The court held that the PRPA was meant only to shield documents prepared solely for purposes of peer review, and the doctor here used the report for the additional purpose of preparing for her deposition.

A doctor was compelled to testify about the discussions at a meeting with other hospital personnel that concerned her care in Johnson v. Wiseman, PICS Case No. 00-1000 (C.P. Bradford 3/22/00). The Court held that the substance of those discussions was discoverable because the meeting was not a formal meeting of a peer review committee.

IV. EMOTIONAL DISTRESS

The Pennsylvania Supreme Court emphasized the requirement that a plaintiff be present when the act or action at issue occurs in order to have a sustainable cause of action for intentional infliction of emotional distress. In Taylor v. Albert Einstein Medical Center, ____ PA ____, 754. A.2d 650 (2000), the decedent's mother was in an adjoining room to the one where a procedure occurred that led to her daughter's death. Because plaintiff had no contemporaneous observation of the alleged tort, a $500,000.00 verdict in her favor for intentional infliction of emotional distress was reversed.

V. HOSPITAL LIABILITY FOR DRUG ABUSE

The Superior Court reversed a $4.37 million verdict in favor of the widow of an anesthesiologist who died from cardiac failure secondary to a self injection of medications he obtained from the hospital for his patients. In Campo v. St. Luke's Hospital, ____
Pa. Super. ____, 755 A.2d 20 (2000), the Court held that while a hospital does have duties with regard to the dispensing of medication, those duties do not extend to the protection of the physician from his own addiction and resulting death. “Allowing recovery for the unfortunate but self-inflicted harm suffered by Dr. Campo is inconsistent with Pennsylvania authority encouraging personal responsibility for one’s own transgressions.” Id, at 27.

VI. INCREASED RISK OF HARM

In Weaver v. St. Christopher’s Hospital for Children, PICS Case No. 00-0183 (C. P. Philadelphia 1/01/00), plaintiff presented expert testimony not just that defendant’s negligence increased the risk of harm, but that defendant’s negligence directly caused an infant to suffer from short bowel syndrome. Because plaintiff’s expert opined as to direct causation, the trial court refused to give the standard charge on increased risk of harm and instead only gave the standard substantial factor charge. The jury found one of the physicians negligent, but that his negligence was not a substantial factor in causing the plaintiff harm.

VII. RES IPSA LOQUITUR

In Toogood v. Rogal, et al., PICS Case No. 00-2217 (Pa. Super. 11/15/00), the Superior Court affirmed a trial court’s decision to give a jury a res ipsa loquitur charge in a medical malpractice case. In other words, the jury was allowed to infer the existence of negligence and causation if they found that the injury was one that ordinarily does not occur in the absence of negligence. The case at issue was a Cortisone injection to back muscles where immediately upon injection the plaintiff felt severe pain and had difficulty breathing. After collapsing a few hours later, he immediately was diagnosed in the emergency room with a collapsed lung.

In the same opinion, the court noted that even though the physician who administered the injection had been granted summary based on the Dead Man’s Act, plaintiff could still sustain a cause of action for vicarious liability against the physician’s employer.

VIII. CORPORATE NEGLIGENCE

A trial court’s refusal to give a jury charge on corporate negligence was affirmed in Boring v. Conemaugh Memorial Hospital, PICS Case No. 00-1527 (Pa. Super. 7/25/00) where plaintiff alleged that nurses failed to utilize a hospital policy. The jury was charged on vicarious liability. This was a split decision.

In two separate decisions, common pleas courts held that the Corporate Negligence Doctrine did not extend beyond hospitals and health maintenance organizations. In Brewer v. Geisenger Clinic, Inc., PICS Case No. 00-0686 (C.P. Lackawanna 3/31/00), the court did not extend that theory to a clinic, and in Dowhouer v. Judson, PICS Case No. 00-0662 (C.P. Dauphin 3/10/00), the court refused to extend the doctrine to a private medical group.

IX. INFORMED CONSENT

Surgical patients must be told the manner and method of the surgery. Valles v. Albert Einstein Medical Center, PICS Case No.00-1731 (Pa. Super. 8/25/00).

X. DAMAGES

Plaintiffs in Pennsylvania may not sustain a cause of action for fear of contracting a disease. However, the Superior Court held in Fetherolf v. Torosian, PICS Case No. 00-1774 (Pa. Super. 8/30/00), that a plaintiff with cancer may sustain a cause of action for an increased risk of metastasis, since that would not be a new disease, but a progression of an existing disease.

XI. CAT FUND

The Cat Fund is not responsible for providing statutory excess liability coverage where a doctor failed to pay his annual surcharge to the Fund. See Dellenbaugh v. Medical Professional Liability Catastrophe Loss Fund, ____ Pa. ____ 756 A.2d 1172 (2000).

XII. DUTY TO THIRD-PARTIES

In Althaus v. Cohen, ____ Pa. ____ 756 A.2d 1166 (2000), the Pennsylvania Supreme Court held that a therapist did not owe a duty to a patient’s parents where the patient falsely accused the therapist of abusing her.

5. Newborn Screening – (28 PA. Code §28.1 et seq.)

The amendments to the existing regulations will add four diseases to the list of required diseases for which newborns must be screened. The amendments will also prescribe the manner by which specimens are to be collected and tested. Pursuant to the Newborn Child Testing Act, 35 P.S. §§ 621-625. Anticipated date for release in proposed form is spring 2001.


The amendments to existing regulations will add to the list of immunizations required for school entry and for entry into the seventh grade consistent with recommendations by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. Anticipated date for release in final form is spring 2001.


These regulations will facilitate the implementation of the Head Injury Program, which provides funds by classification of traumatic injury. Pursuant to the Emergency Medical Services Act, 35 P.S. §6934(e). Anticipated date for release in final form is spring 2001.


The amendments to existing regulations will include continuing education requirements for hearing aid fitters, provide for 30-day money back written guarantees on hearing aids and revise certification fees for consistency with the statute. Pursuant to Act 153 of 1998, amending the Hearing Aid Sales Registration Act, 35 P.S. §6700-101 et seq. Anticipated date for release in proposed form is spring 2001.


These new regulations to license and regulate hospices will, at a minimum, contain standards set forth in regulations for hospices certified as providers under the Medicare Program. Pursuant to the Act 95 (1998) amending the Health Care Facilities Act, 35 P.S. §448.101 et seq. Anticipated date for release in proposed form is summer 2001.


The amendments to existing regulations will provide lifeguard requirements for recreational swimming establishments, and add requirements for lifeguard certification and factors to be considered in determining adequate lifeguard coverage. Pursuant to Act 75 of 1998, amending P.S. §§672-680 (the Public Bathing Law). Anticipated release in final form in spring 2001.


The amendments to existing regulations will update the licensure standards for general and special hospitals. Pursuant to the Health Care Facilities Act, 35 P.S. § 448.101 et seq. Anticipated release in proposed form in fall 2001.


The amendments to existing regulations will amend Chapter 9, “Managed Care Organizations,” Subchapter A, “Health Maintenance Organizations,” Subchapter D, “PHOs and POs and IDS,” and...
Q&A

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QUESTION:
Our hospital routinely requires physicians who provide services under contract to agree that they will not have an ownership or investment interest in or enter into a compensation arrangement with a competing facility. We have also been thinking of amending our medical staff development plan to include such a requirement as one of the factors that will be considered by the Board when acting on applications for medical staff appointment. A group of doctors who are thinking of building a surgicenter have said that such a requirement violates the fraud and abuse laws and also said that the Board couldn’t adopt any criteria for medical staff membership that weren’t in the medical staff bylaws. Are they right?

ANSWER:
No, they are not right. There is nothing wrong with prohibiting physicians who do business with the hospital from competing with the hospital. Two recent legal developments support this conclusion.

With respect to possible fraud and abuse implications, HCFA made the following comments about restrictive covenants (in this case in the context of a practice acquisition) in a response to comments submitted about the new Stark II regulations: “A requirement to refer to a specific provider is different from an agreement not to establish a competing business. In other words, a covenant not to compete might prevent a physician from setting up a private practice or offering services that compete with the entity that purchased his or her practice. If an agreement also included a requirement that the physician refer business to the purchaser, the agreement would be suspect under the anti-kickback law.” 66 Fed. Reg. 879 (January 4, 2001). These regulations were drafted with substantial input from the Office of Inspector General, so presumably that agency, which is the primary enforcement agency for the fraud and abuse laws, does not believe that prohibiting physicians from competing with the hospital as a condition of contract or appointment would present problems under Stark II or the anti-kickback law.

As for the Board’s authority to adopt such a policy, the Supreme Court of South Dakota recently ruled that the Board could apply criteria for appointment that did not appear in the medical staff bylaws. In Mahan v. Avera St. Luke’s, 2000 WL 1946707 (S.D.), a hospital refused to process an application for medical staff appointment from an orthopedist employed by physicians who owned a competing surgicenter. The reason for the denial was the hospital’s determination to close orthopedics pursuant to its medical staff development plan. A lower court ruled in favor of the physicians stating that the hospital board lacked the ability to adopt a staff development policy not authorized by the medical staff bylaws. The South Dakota Supreme Court reversed, holding that even though medical staff bylaws constitute a contract in that state, the board has the authority to make business decisions without first consulting the medical staff. According to the court, “any powers supposedly granted under the Staff Bylaws must originate from, and be authorized by, the Board pursuant to the Corporate Bylaws. Their legal relationship is similar to that between statutes and a constitution. They are not separate and equal sovereigns.”

Message from the Chair
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Plans are set for the May 10 meeting in Pittsburgh. The committee will put on a continuing legal education program on healthcare, fraud and abuse, confidentiality and competition among healthcare providers. A breakfast meeting and formal committee meeting also will be held. You are invited to attend! See page 2 for more details.

Plans are being made to expand committee participation in the burgeoning areas of medical malpractice and risk management. The committee also is looking into joint efforts with other bar committees, including the committee on civil litigation and the committee on specialization.

For those of you who are members of the committee — our many thanks for your ongoing support. For those of you who practice health care law, please join us to share in these opportunities.
Subchapter E, “Quality Health Care Accountability and Protection.” These regulations will address operational standards, availability and access, complaints and grievances, health care provider contracts, utilization review and credentialing. Anticipated release in final form in spring 2001.

Intermediate Sanctions continued from page 5

would have been if the disqualified person was dealing under the highest of fiduciary standards. The organization is not required to rescind the underlying agreement; however, the parties may need to modify an ongoing contract with respect to future payments.

The IRS did not issue temporary regulations with respect to revenue-sharing transactions, and instead held in reserve a separate section governing such transactions. Any revised regulations governing revenue-sharing transactions will first be published in proposed form. In the meantime, revenue sharing transactions will be evaluated under the general rules governing excess benefit transactions outlined above.

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Pennsylvania Legislative Update continued from page 4

- H.R. 339 Engel (D-N.Y.) – Would provide coverage of outpatient prescription drugs under Part B of Medicare
- H.R. 344 Frank (D-Mass.) – Would eliminate the 5-month waiting period for eligibility for Social Security Disability benefits and the 24-month waiting period for disabled individuals to become eligible for Medicare
- H.R. 389 Weiner (D-N.Y.) – Requires coverage for the treatment of infertility

- S. 6 (Daschle, D-S.D.) - The new Patients Bill of Rights by Minority Leader Tom Daschle and 37 other Democrats
- S. 9 (Daschle, D-S.D.) - Proposes tax relief, including provisions aimed at health care costs
- S. 10 (Daschle, D-S.D.) - Provides for outpatient prescription drugs under Medicare
- S. 24 (Lott, R-Miss.) for Sen. Arlen Specter, R-Pa. - The Health Care Assurance Act
- S. 29 (Bond, R-Mo.) - Allows a 100 percent tax deduction for the health insurance costs of the self-employed
- S. 52 (Inouye, D-Hawaii) - Provides improved reimbursement under Medicare of clinical social worker services
- S. 104 (Snowe, R-Maine) - Requires the equitable coverage of prescription contraceptive drugs and devices, and contraceptive services, under health plans
- S. 186 Johnson (D-S.D.) – Provides access and choice for the use of generic drugs instead of nongeneric drugs under federal health care programs

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XIII. CAN YOU BELIEVE THIS?

The best case has been saved for last. In Brown v. Philadelphia College of Osteopathic Medicine, PICS Case No. 00-1772 (Pa. Super. 8/80/00), the plaintiffs were told that their newborn daughter tested positive for syphilis. Confronted with this news, Mr. Brown admitted that he had an affair with a co-worker during Mrs. Brown’s pregnancy. Two months later, a second test showed that the baby did not have syphilis. Other tests proved that neither parent had syphilis. The parents then sued PCOM alleging that its negligence with regard to the first syphilis test result caused Mrs. Brown physical and psychological damage, and lost earning capacity. Mr. Brown claimed loss of consortium, conjugal services and the companionship of Mrs. Brown.

It seems that some time after these events, Mr. Brown became physically abusive to his wife. Mrs. Brown was a police officer and on one occasion chased him out of the house with the aid of her service revolver, firing several bullets in his direction. They were both arrested, and she lost her job thereby giving rise to the claim for lost earning capacity.

A Philadelphia jury awarded $500,000.00 in damages to Mrs. Brown and $10,000.00 to Mr. Brown. The Superior Court reversed the award, finding that the legal cause of the alleged damages was not the positive syphilis test, but Mr. Brown’s affair and the violent acts committed by each spouse.