Secretary of Health to Speak at the Health Care Law Committee Meeting

Pennsylvania Secretary of Health Robert Zimmerman will speak at the Health Care Law Committee meeting on Nov. 29. The meeting will be held at the Holiday East in Harrisburg during the Pennsylvania Bar Association Committee/Section Day. Zimmerman, along with Lori McLaughlin, chief counsel for the Pennsylvania Health Department, will speak on initiatives and developments in Pennsylvania health care law.

Zimmerman was appointed Pennsylvania’s secretary of health by then-Gov. Tom Ridge on April 28, 1999. In this capacity, Zimmerman serves as the primary public health advocate and spokesman for Pennsylvania. He is the senior advisor to the governor on health matters, identifying health-care priorities and outlining objectives.

Zimmerman is charged with managing health needs assessment and resource development; assuring access to health care; health and disease prevention; assuring quality; and providing leadership in the area of health planning and policy development affecting Pennsylvania’s 12 million citizens. He oversees a cabinet-level agency with a $780 million budget and a complement of 1,465 full-time employees.

As secretary, Zimmerman has focused attention on improving the department’s quality of care oversight for nursing facilities, hospitals and managed care; expanding the department’s innovative community health partnerships and community-based planning (SHIP – the State Health Improvement Plan); addressing minority health issues, including the identification of health disparities and strategies to address them; advancing technology and e-commerce applications; and improving consumer information and data sharing.

Zimmerman has been instrumental in shepherding Pennsylvania’s plan for use of tobacco settlement dollars, working to fulfill former Gov. Ridge’s directive to dedicate 100 percent of those substantial resources to health-related initiatives. Considerable portions of this money will be applied to tobacco use prevention and cessation programs, broad-based health research, Federally Qualified Health Centers (FQHCs), and grants to rural hospitals.

Zimmerman has been a career public health professional with the Commonwealth of Pennsylvania for more than 30 years. At the time of his nomination as secretary of health, he was serving as deputy secretary for Medical Assistance Programs in the Department of Public Welfare, where he implemented Pennsylvania’s HealthChoices Medicaid managed care program, a case-mix reimbursement system for nursing facility services, and worked to expand home- and community-based services for seniors.

Previously, Zimmerman held numerous positions in the Department of Health, starting his career as a district public health educator and rising through the ranks to hold numerous senior level appointments. He developed and directed what was then a new Bureau of Primary Care Resources and Systems Development and served as director of various other bureaus, including Maternal and Child Health and the Women, Infant and Children (WIC) nutrition program. He became the first appointee to the commonwealth’s Senior Management System and received recognition for quickly turning the once troubled WIC program into what continues to be a national model. Other major accomplishments include developing the state’s HIV/AIDS programs and the drafting of the first State Health Plan.

An “enlisted military brat” born in Newport News, Va., on Nov. 7, 1948, Zimmerman moved frequently with his family, living in Alabama, Oklahoma and Japan, among other places. He settled in northeastern Pennsylvania, where he went to high school. He graduated from King’s College in Wilkes-Barre, Pa. (1970 – B.A., Sociology) and the Univ. of Tennessee in Knoxville (1972 – Master of Public Health). He and his wife Jean live in Cumberland County and have two children.
**Message from the Chair**

By Thomas J. Blazusiak, Esq.
PA Department of Public Welfare

**To Err is Human; Forgive, Don’t Forget**

Our members stand at the front line of the debate about quality of care and what to do about it. We know that the laws designed to encourage improvement in the quality of care are applied with various degrees of effectiveness in our states’ hospitals, clinics and medical offices. Our profession is also (ironically) the first to be blamed for the high cost of malpractice insurance and the cost of medical care. But studies suggest that the legal system’s involvement in medical malpractice is the sparrow that rides on the rhino’s back. The Institute of Medicine’s report on medical errors, “To Err is Human,” indicates that more people died last year in this country from medical errors than from automobile accidents - not from diseases, but from errors. Human beings make mistakes. Those who do great, important things, like medical professionals, should not be used as scapegoats for honest mistakes that will occur inevitably in this highly complicated area of endeavor.

Reviewing the actions of those responsible and modifying their behavior requires skill, compassion and justice. We should support these efforts both as members of the public and as practitioners.

**Web Med and Liability**

The Internet provides more information to more people, including clients and patients, but almost no one would say that it provides better information. Disclaimers to online medical and legal advice abound, and most sound like the disclaimers at the end of automobile ads on the radio.

Consent is still a state of mind that exists between the patient and the caregiver. It is hard enough to give good medical advice face-to-face when in a one-on-one relationship.

Lawyers who represent clients who practice on the Web are wise not to rely too heavily on the legal “chicken soup” of disclaimers. Legal chicken soup, by the way, is something that makes you feel better. It probably won’t hurt, and it may help - or it may not.

The Web has its place in medicine, but, like everything else, it must be used with care.

**Medicaid Managed Care Rule Relaxed**

U.S. Health and Human Services Secretary Tommy G. Thompson, in the Aug. 20, 2001, Federal Register (66 Fed. Reg. 43613), eased up on the time frames that MCOs have to decide appeals in cases where a dispute exists regarding life-saving treatment.

The DHHS rule would extend to MA patients the same protection Congress is considering establishing for privately insured patients. The changes include the following:

- Establish appeal procedures that allow three “working” days to hear appeals in life-threatening situations.
- Allow plans to lock in patients for up to 12 months instead of six months. Patients, however, could drop out of a new plan without cause in the first 90 days.
- Restrict the language and format of marketing materials.
- Permit states to require six months of guaranteed eligibility for more Medicaid enrollees.

**Screening Mammograms Added to Fee Schedule**

In the Aug. 2 Federal Register (66 Fed. Reg. 40372), DHHS proposed to add screening mammograms to the Medical Physician Fee Schedule.

Since Tommy Thompson became secretary, 910 Medicaid and State Children's Health Insurance Program (SCHIP) upgrades have made almost a million more people eligible for coverage.

**Cost Requires Bush Administration to Cease Delay**

In Gray Panthers Project Fund v. Thompson No. 01-CV-1374 (DDC Injunction issued Aug. 9, 2001), Julie Henry Kennedy was ordered to mail enrollment materials to Medicare beneficiaries. The court ruled that Thompson’s lawyers’ argument that because they were slow they should get more time was similar to that of a child who kills his parents and then seeks pity as an orphan.

**Don’t Miss the Health Care Law Committee Meeting Nov. 29**

The Health Care Law Committee will meet during the PBA Committee/Section Day at 11:00 a.m. at the Holiday Inn East in Harrisburg. Pennsylvania Secretary of Health Robert Zimmerman will be the featured speaker. For more information, please contact Jennifer Zimmerman at the PBA at 800-932-0311, Ext. 2286.

This is the place to be for all Pennsylvania health care attorneys

**Health Care Law Committee**

Chair: Thomas J. Blazusiak
Editor: Robert A. Quigley
Publisher: Pennsylvania Bar Association
PBA Committee Coordinator: Jennifer Zimmerman
PBA Newsletter Liaison: Linda Nguyen
Electronic Records and Signatures in Health Care and the Interplay of E-Sign, HIPAA and UETA

By Darice M. Nelson and Christian Hebling

The health care industry is highly regulated by a complex statutory and regulatory framework at every level. Electronic commerce in such a highly regulated industry presents some challenges to say the least. States have approached e-commerce in a myriad of ways, leaving consumers and businesses confused as to whose law applies. Through its legislative efforts, Congress attempted to provide for uniform standards across state lines by passing the Electronic Signatures in Global and National Commerce Act (S. 761, 106th Cong. (2000), 15 U.S.C. Sections 7001 et. seq.), an act which essentially pre-empts many of the conflicting state laws heretofore governing e-commerce. The Federal Electronic Signatures in Global and National Commerce Act ("E-Sign") seeks to foster electronic commerce by addressing some of the legal barriers and standardizing the rules for electronic transactions. Electronic records and signatures are essential elements of many electronic transactions, particularly in health care.

The interplay of E-Sign, the Uniform Electronic Transactions Act drafted by the National Conference of Commissioners on Uniform State Laws (UETA), the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and various enacted and proposed regulations implementing HIPAA must be considered if electronic records and signatures are to be used in health care transactions.

E-Sign

E-Sign provides that, notwithstanding any statute, regulation or other rule of law governing any transaction in or affecting interstate or foreign commerce, a signature or other record may not be denied legal effect solely because an electronic signature or record was used in its formation. Most provisions of E-Sign took effect on Oct. 1, 2000. On March 1, 2001, portions of the law governing record retention became effective with respect to records required by a federal or state statute, regulation, or other rule of law administered or promulgated by a state regulatory agency.

Records

E-Sign provides guidance on how records may be stored and retained electronically. If a document is required to be retained by law, an electronic version of the document will be acceptable if the electronic document accurately reflects the information in the record and is accessible to all relevant people in a form that may be accurately reproduced at a later date, whether by printing, electronically transmitting or other means. No specific type of technology is mandated by E-Sign. The law is technology neutral, allowing individual parties to choose the technology that best suits their needs. The term "electronic" is defined broadly in E-Sign and means related to technology having electrical, digital, magnetic, wireless, optical, electromagnetic or other similar capabilities. Under E-Sign, the term "transaction" means an action or set of actions relating to the conduct of business, consumer or commercial affairs between two or more persons. The term "electronic record" means a contract or other record created, generated, sent, communicated, received or stored by electronic means.

Certain kinds of records are excepted from E-Sign. Those records include: court orders or notices and other official documents required to be executed in connection with court proceedings; notices of cancellation or termination of utility services; notices of default and acceleration, repossession, foreclosure, eviction or the right to cure under a mortgage or lease agreement for an individual's primary residence; notices of the cancellation of health insurance or benefits or life insurance benefits; notices of the recall of a product or material failure of a product that risks endangering health or safety; and any document required to accompany the transportation or handling of hazardous, toxic, or other dangerous materials. Additionally, E-Sign is not applicable to laws governing family law matters such as adoption and divorce, nor does E-Sign apply to writing or signature requirements imposed under laws governing the creation and execution of wills, codicils or testamentary trusts, or certain sections of the Uniform Commercial Code. The E-Sign exception for wills raises at least one question for health care providers and that is whether living wills which are signed or created electronically will be effective.

A general familiarity with E-Sign is critical for any entity conducting electronic health care transactions inasmuch as such transactions are heavily regulated by federal and state agencies. Three of E-Sign's subsections specifically preserve the authority of federal and state agencies to establish standards governing the retention or filing of records. Section 104(a) of E-Sign preserves the authority of state and federal agencies to require that records filed with the agency comply with specified standards and formats. Section 104(b) allows state and federal agencies to issue regulations that interpret E-Sign, within the scope of their authority, so long as there is a substantial justification for the regulations and so long as the regulations are consistent with E-Sign and technology neutral. Section 104(b) also allows state and federal agencies to specify performance standards to assure the accuracy, record integrity, and accessibility of records that are required to be retained. The standards may require a nonelectronic format if there is a compelling governmental interest relating to law enforcement or national security justifying the requirement, and the requirement is essential to attaining such interest.

All three of these subsections are limited by Section 101(b)(2), which requires a governmental agency to agree to use or accept electronic records or electronic signatures, except with respect to contracts to which the governmental agency is a party. Accordingly, while it is clear that an agency can specify standards and formats for electronic records or electronic signatures which must be retained by a party or filed with the agency, it does not appear that the agency can require a non-electronic format without establishing a compelling reason for doing so.

Signatures

Under E-Sign, the term "electronic signature" means an electronic sound, symbol or process attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record. Again, no particular technology is required by E-Sign for electronic signatures. Instead, the law allows the parties to select the method of authentication...
Electronic Records and Signatures continued from page 3

that best suits their needs and security concerns. Both HIPAA and UETA provide more guidance on authentication of electronic signatures than does E-Sign.

Special Consumer Protections
The term “consumer” means an individual who obtains, through a transaction, products or services which are used primarily for personal, family or household purposes. E-Sign imposes special requirements on anyone obligated to provide written disclosures to consumers. Those special requirements are imposed to ensure that consumers can make fully informed decisions about electronic transactions and to provide some protection for consumers. Essentially, E-Sign provides that the consumer must have affirmatively consented to receive the required information electronically. Before consenting, the consumer must receive a clear and conspicuous notice about the consumer’s right to obtain information on paper, the right to withdraw consent and the procedures for doing so, whether the consent relates to a single transaction or for categories of records and how to obtain a paper record, among other things.

Under E-Sign, threshold questions in health care are whether a proposed arrangement is a transaction for purposes of E-Sign, whether the transaction is occurring or in interstate commerce, whether a consumer is involved and what exceptions, if any, apply. If it is assumed that E-Sign applies to electronic health care transactions (and in most cases that may be a reasonable assumption), there still are many unanswered questions about how electronic commerce in health care should be conducted.

HIPAA
HIPAA was originally intended to improve the availability of health insurance for American workers and their families. Another goal of HIPAA was to reduce the administrative costs and burdens of health care by establishing uniform standards for health care data and facilitating electronic health care transactions. The section of HIPAA relating to electronic health care transactions and discussed in this article is also referred to as the “administrative simplification provisions of HIPAA.”

Because of the sensitive nature of health care information, HIPAA also requires rules to be issued addressing standards to protect the privacy and security of health information communicated electronically. Extensive rules have been proposed regarding, among other things, electronic signatures, privacy and security in covered health care transactions. The only final HIPAA rules issued under the administrative simplification provisions are those pertaining to standards for electronic transmission of health care data.

HIPAA applies to health plans, health care clearinghouses or health care providers who transmit any protected health information in electronic form in connection with a covered transaction. Under the proposed HIPAA regulations, the term “transaction” means the exchange of information between two parties to carry out financial and administration activities related to health care. Such transactions generally include: health claims; health care payments; coordination of benefits; enrollment and disenrollment in a health plan; health plan premium payments; referral certifications and authorizations.

HIPAA will pre-empt contrary state law, with certain exceptions. Exceptions are recognized for state laws which: address controlled substances; require the reporting of disease, injury, child abuse, and the like; where state law on the privacy of health information is more stringent than HIPAA or the secretary of the Department of Health and Human Services (HHS) determines the state law in question is necessary.

Records
HIPAA does not define the term “records.” Instead, the proposed regulations define the term “health information” broadly as any information, whether oral or recorded in any form or medium that: (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the part, present or future physical or mental health condition of an individual, the provision of health care to an individual, or the past, present or future payment for the provision of health care to an individual. The breadth of this definition would extend the reach of HIPAA beyond electronic records to potentially any health information or records within the possession or control of the entities referenced.

Essentially, the proposed HIPAA regulations would limit the use or disclosure of an individual’s health information by a covered entity to carry out treatment, payment or health care operations, in which case the consent of the individual is not required or pursuant to an individual’s authorization. The proposed HIPAA regulations address the content of notices or information that must be provided by covered entity to individuals, but the method of communication is not explicitly addressed.

Questions about notices to individuals that arise when considering the interplay of HIPAA, E-Sign and UETA include whether the consumer protections in E-Sign will be applicable to communications between patients and health care providers or other entities covered by HIPAA. As noted above, a consumer for purposes of E-Sign is an individual who obtains, through a transaction, products or services which are used primarily for personal, family or household purposes. If one assumes that a patient who receives health care or purchases insurance is obtaining such products or services for personal use, then must the patient be forever classified as a consumer with respect to that entity such that the consumer protections of E-Sign would apply to all communications with the patient? Will a patient be obtaining services for personal use if he or she is given an annual physical as required, or paid for by an employer? If an individual obtains products or services while using a computer at work, there may also be uncertainty about whether the products or services are for personal or business purposes. These are just a few of the uncertainties facing the health care industry as it moves to embrace e-commerce. Hopefully, the final HIPAA regulations will provide some additional guidance on these and other issues now that E-Sign has become law.

Electronic Signatures
An electronic signature under HIPAA means the attribute affixed to an electronic document to bind it to a particular party. An electronic signature secures the user authentication (proof of claimed identity) at the time the signature is generated; creates the logical manifestation of signature (including the possibility for
Message from the Editor

By Robert A. Quigley, Esq.
Duane, Morris & Heckscher, LLP

Welcome to the Health Care Law Committee Newsletter. The newsletter is published several times a year and features articles written by your peers on timely and informative subjects.

Participation in the Health Care Law Committee, and the newsletter in particular, allows members to share their experience with others throughout the state who face similar issues on a daily basis. The members of this committee are some of the most active health care law practitioners in Pennsylvania; we present a unique resource for one another; however, the resource is only as good as the individuals who participate in the activities of the committee.

Attendance at committee meetings is the first step towards becoming an active participant. Additionally, the committee is often searching for chairs for its various subcommittees. Participation as an active member in the Health Care Law Committee is a valuable and rewarding experience.

It has been my pleasure to serve the editor of the committee's newsletter. This experience has permitted me to learn a great deal about health care issues that I may not be exposed to on a daily basis while allowing me to meet and network with many of you throughout the state.

I want to thank each of the contributors to this newsletter for their time and effort. I also want to thank the chair of the Health Care Law Committee, Tom Blazusiak, for all his support and hard work. Tom has been a strong leader for the committee.

For those of you who have not taken an active role in the committee yet, I encourage you to do so. Feel free to forward any articles on the practice of health care law to my attention. I will make every attempt to make sure your contribution is featured in the next newsletter.

Electronic Records and Signatures

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The use of electronic records and signatures in health care transactions may also be affected by state law. E-Sign does not wholly pre-empt state law. Rather, it allows a state to “modify, limit or supercede” E-Sign through the passage of a law which either: (1) parallels the official version of UETA, without any variations which are technology-specific or inconsistent with E-Sign, or (2) specifies alternative procedures or requirements for the use or acceptance (or both) of electronic records and electronic signatures that are consistent with E-Sign and not technology-specific.

UETA provides generally that, so long as the parties to a transaction agree to an electronic transaction, a signature or other record may not be denied legal effect solely because it is in electronic form. UETA also provides that a contract may not be denied legal effect solely because an electronic signature or record was used in its formation. Under UETA, electronic signatures and records satisfy laws that require signatures or written records, provided that laws other than UETA, which require that records be sent, communicated, or transmitted by a particular method must, with limited exceptions, be followed. To date, 23 states have adopted UETA in some form. Parties utilizing electronic signatures and records in health care transactions governed in whole or in part by state law must, to the extent that the state has enacted a law like UETA, which is consistent with E-Sign, look to the state law to resolve any questions regarding the validity of the transactions.

The key provisions and definitions of E-Sign are substantially similar to UETA. However, some differences exist. UETA provisions which are not addressed in E-Sign include: the time when messages are deemed sent or received; errors in electronic contracting; and attribution of electronic signatures. Attribution of electronic signatures will be critical in health care transactions in that HIPAA and other sources of substantive state and federal law may have to be met. Another difference between UETA and E-Sign is the consumer protections E-Sign imposes, which are not found in UETA.

One point that UETA makes clear is that a transaction covered by UETA remains subject to other applicable substantive law. This is an important point to remember for those conducting electronic transactions in the highly regulated health care industry.

Summary

In sum, there is one safe rule to follow when determining which laws or regulations govern a particular health care transaction involving the use of electronic records or signatures: closely consider all of them. Assuming each is consistent with E-Sign, it is highly likely each will apply.

Threshold questions must be considered to determine the applicability of E-Sign, UETA and HIPAA to electronic transactions in health care. To analyze a health care transaction, it will be necessary to consider the following: who are the parties; are any of the parties explicitly covered by the laws under consideration; what is the nature of the proposed transaction; what information or records does the transaction involve; is the proposed transaction (such as signing a will) excluded from application of one of the laws; and, of course, what other federal and state substantive requirements apply? These analyses will be expedited by learning E-Sign, HIPAA and UETA, and developing systems and procedures that comply with the laws. Initially, for the traditional health care industry, this will be a cumbersome process. At some point, a case by case analysis will no longer be practical. Either further regulatory guidance will be necessary or the health care industry must become more efficient in designing mechanisms to comply with all of the laws governing electronic records and signatures. The promises and potential cost savings of electronic commerce are too tempting, and the cost pressures within health care are too great to risk being left out of the e-commerce revolution.
Hotel Savings Now Available for PBA Midyear Meeting

Those who register for the PBA Midyear Meeting now through noon on Nov. 30 are eligible for special hotel savings offered by the Fiesta Americana Condesa Cancun. The hotel is now offering savings of $30 per night for a single occupancy room and $52 per night for a double occupancy room. You must register by noon on Nov. 30 to take advantage of this special price.

Also, Young Lawyers Division members can save even more! If you are among the first 25 YLD members who register and you attend the YLD business meeting in Cancun, you will receive a $500 rebate.

Trade the white snow for white sand and come to Cancun, Mexico, for the PBA Midyear Meeting Jan. 23-26, 2002. The meeting features a special price package that includes hotel accommodations, meals and beverages at the hotel, three themed evening events and all non-motorized water sports (kayaking, windsurfing, etc.).

The headquarters hotel for the Midyear Meeting is the luxurious Fiesta Americana Condesa Cancun, a five-star resort with breathtaking views of the Caribbean. The hotel has a multilingual staff, travel agency, car rental agency, shops, a purified water system, restaurants, 24-hour room service and currency exchange. Take advantage of all the on-site amenities - a swimming pool, three indoor lighted tennis courts, water sports, a spa with more than 40 skin and hair treatments, a fitness center with the latest in cardiovascular and strength-training equipment, beach and pool volleyball, as well as a multitude of daily recreational activities.

Child care is available for children ages 4 to 12 at the Fiesta Kids Club. The club offers extensive activities that include games at the pool and beach, video games, dance contests, movies, a safari and treasure hunt, and more. The club is open from 9 a.m. to 6 p.m. Monday through Saturday; the cost is included in the PBA Children’s Package. Other babysitting arrangements may be made through the hotel at an additional cost.

Motorized sports such as suba diving, deep sea fishing, mangrove tours, jungle tours and more are available at an additional cost.

Hotel Savings Now Available for PBA Midyear Meeting continued on page 10

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The following is a selection of some of the health care related legislation introduced thus far in the Pennsylvania General Assembly during the fall 2001 legislative session. Of particular interest are SB 1102 and HB 1959 which would regulate mandatory overtime in health care facilities. The text of these bills can be found on the Internet at http://www.legis.state.pa.us/WU01/LI/ Bl/billroom.htm.

**Pennsylvania House**

**HB 1902**
This bill establishes a state-run Pharmacy Best Practices and Cost Control Program which would permit the commonwealth to enter into prescription drug fair pricing coalitions.

**HB 1959**
This bill seeks to regulate mandatory overtime and excessive duty hours of health care workers.

**HB 1970**
This bill would require long-term care nursing homes to maintain certain staffing levels deemed to protect the health and safety of residents and employees.

**HB 2000**
This bill creates the Psychologists Continuity of Care Act to allow psychologists admitting privileges to health care facilities.

**Budget Increase**
President Bush announced his fiscal year 2002 budget on April 9, including tax credits for the uninsured, fees for submitting paper claims to Medicare, a 13 percent jump in medical research spending, and new moves to restrict the Medicaid upper payment limit loophole. It would increase outlays for the Department of Health and Human Services by $38 billion, or nearly 9 percent, to $469 billion.

**Kickbacks**

**Cost Report Fraud**

**N.Y. Bust**
Adult Care Provider: In what New York Attorney General Eliot Spitzer called the largest criminal Medicaid fraud case in history, a

**Of Interest**

**HB 2007**
This bill would regulate human embryonic stem cell research in Pennsylvania.

**Pennsylvania Senate**

**SB 1152**
This bill amends the Pharmaceutical Assistance Contract for the Elderly Fund.

**SB 1050**
This bill establishes a Long-term Care Partnership Program which would provide for the protection of assets of long-term care insurance policyholders and for long-term care insurance.

**SB 1088**
This bill provides for a hepatitis C prevention, screening, treatment and education program.

**SB 1094**
This bill regulates by electronic means the dispensing of controlled substances by pharmacists in Pennsylvania.

**SB 1102**
This bill seeks to regulate mandatory overtime and excessive duty hours of health care workers.

**Brooklyn, N.Y., man with political clout pleaded guilty April 6 to 15 counts involving fraudulent billings by his Parkshore Adult Health Care Center.**

**OIG Plays Golf**
The DHHS OIG, in Advisory Op. No. 01-02 (Dept Health and Human Servs. Office of Inspector Gen. March 20, 2001), gave its “fore” to a nonprofit health center’s role in encouraging an annual golf tournament that raises $50,000 a year in support of the center’s mission in an underserved Hispanic community.

**Patient Lawsuit Over Sale of Pharmacy Records**
New York Supreme Court Judge Charles Edward Ramos ruled that a man with AIDS can press a lawsuit alleging that his privacy rights were violated when a local pharmacy went out of business and sold its prescription records to the CVS Corp. The case, Anonymous v. CVS Corp., No. 604804/1999 (N.Y. Sup. Ct., Manhattan City, March 1, 2001), also named as defendants the local drug store, Trio Drugs and the pharmacist.

**Christian Healing**
The U.S. Supreme Court let stand a May 2000 8th U.S. Circuit Court ruling allowing Medicare to continue paying for limited amounts of non-medical care in 21 Christian Science nursing homes and similar facilities. An Iowa group, Children’s Healthcare, had challenged the Medicare provision allowing such payments. Children’s Healthcare is a Legal Duty Inc. v. Mullan, No. 00-914, cert. denied (U.S. April 2, 2001).
Excellence in Health Care Law Award Presented

At the annual meeting held in Pittsburgh, the Health Care Law Committee was proud to present its 2000 Excellence in Health Care Law Award jointly to John Horty and Eric Springer in Pittsburgh. These two individuals are nationally prominent figures in health care law.

Eric Springer has edited and authored several books and has written widely in health and legal journals. He has served as a member of the faculty of the Estes Park Institute, he is an honorary fellow of the American College of Hospital Executives, a charter member of the American Academy of Hospital Attorneys, as well as a fellow of the Public Health Association. He serves as a director of DQE, the Make-A-Wish Foundation, and he is a member emeritus of the Board of Directors of the University of Pittsburgh Medical Center. He also serves as a member of the Campaign Conduct Administrative Committee for the United Steelworkers of America.

John Horty is the president and editor of Horty Springer publications: ACTION KIT for Hospital Law, ACTION KIT for Hospital Trustees, and Medical Staff Leader Handbook. He serves as president of the National Council of Community Hospitals in Washington, D.C., which represents community hospitals from across the country. He is past chair of the Board of Directors of St. Francis Central Hospital, past chair of St. Francis Medical Center and past vice-chair of the Board of St. Francis Health System in Pittsburgh. Mr. Horty also serves as chair of the Estes Park Institute of Englewood, Colo., a nonprofit corporation that presents educational programs for health care executives, physician leaders and trustees. He is also president and chair of the Indigo Hospital Association of Pennsylvania. Mr. Horty is an honorary fellow of the American College of Health Care Executives, a recipient of the Award of Honor of the American Hospital Association, and holds an Honorary Life Membership in the American Hospital Association.

At the award ceremony, it was disclosed that John Horty is quite a renaissance man. He coached Mike Ditka in basketball at the University of Pittsburgh.

The Health Care Law Committee congratulates these two fine individuals.

The Pennsylvania Department of Health Revises its Managed Care Regulations

By Norris Benn Jr., Esq., Director Complaints and Grievances & Associate Counsel and Kearline M. Kell-Jones, Director, Regulatory Compliance, Health Partners Inc.

On June 9, 2001, the Pennsylvania Department of Health (“Department”) issued new managed care regulations. The regulations follow the Pennsylvania General Assembly’s issuance of new patient protection measures under the Quality Health Care Accountability and Protection Act, commonly known as Act 68. Act 68, among other things, focuses upon consumer protection for individuals enrolled in managed care plans. It also regulates traditional HMOs and health care plans using a gatekeeper to manage the utilization of health care services.

Under Pennsylvania law, HMOs are regulated by both the Department and the Insurance Department. The regulations promulgated by the Insurance Department pursuant to Act 68 became effective on March 11, 2000. The Insurance Department regulations focus exclusively upon the framework of Act 68. However, instead of focusing exclusively on the regulatory framework of Act 68, the Department revamped its entire managed care regulations. The Department’s new managed care regulations, in addition to addressing the consumer protection components of Act 68, significantly alter several longstanding regulatory procedures of the Department. This article will highlight some of the Department’s new managed care regulations recently promulgated unrelated to Act 68.

Pursuant to Section 9.678 of the new regulations, managed care plans are now given the option of permitting non-participating providers to provide on-call services for participating providers. Thus, under the regulations, providers who have not executed a participating provider agreement with a managed care plan can conceivably treat members of the plan when serving in an on-call capacity for the participating provider. Under this scenario, providers not credentialed by the managed care plan could treat members of the managed care plan when a participating provider is unavailable.

The regulations (Section 9.722) also mandate that the Department review all contracts between managed care plans and providers prior to implementation of the contract. The Department did not previously require review prior to implementation. The regulations afford the Department 45 days to review the contract. If the...
Unanticipated Outcomes Policies for Hospitals: Some Dos and Don’ts

By Dan Mulholland, Horty, Springer & Mattern, P.C.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) now specifically requires, in its Patient Rights and Organization Ethics chapter, that, “Patients and, when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes.” Standard RI.1.2.2.

The intent of this standard is described as follows: “The responsible licensed independent practitioner or his or her designee clearly explains the outcome or any treatments or procedures to the patient and, when appropriate, the family, whenever those outcomes differ significantly from the anticipated outcomes.” These seemingly innocuous statements are fraught with serious and complex legal and operational issues. In order to comply fully with this standard and create a framework within which liability exposure can be limited, hospitals would be well advised to adopt and implement a formal policy on unanticipated outcome disclosure.

The first part of any policy usually defines key terms. This is especially important in the case of an unanticipated outcome policy because what must be disclosed — “unanticipated outcomes” — often overlaps with other, more serious things, such as “errors” or “sentinel events,” which may require more than just disclosure and which have even more serious legal ramifications. For example, an “unanticipated outcome” is any outcome of patient care that differs significantly from what was anticipated to be the result of a treatment or procedure. An unanticipated outcome may or may not rise to the level of a sentinel event and may or may not involve an error. Making these distinctions clear both when drafting the policy and explaining it will be crucial.

Next, the policy should describe the procedure to be followed by physicians and other personnel at the hospital when disclosing unanticipated outcomes to patients and/or their families. Given that the content of the communication, as well as how it is communicated, could make the difference between winning or losing any malpractice suit that may follow, it makes sense to approach the disclosure as a joint effort between the physician and the hospital. Representatives of the hospital, such as the VPM or Risk Manager, should review the situation with the physician and plan what to say and how to say it. A representative of the hospital should also attend the meeting between the physician and patient and/or family members. And the policy should require that to the extent that the situation warrants, sentinel events or issues that require further analysis pursuant to the medical staff peer review process be appropriately referred for follow-up action.

Documentation should be addressed in the policy as well. The policy should not only focus on what should go into the report (regarding the conversation with the patient and/or family members); it should also focus on where, how and by whom the report should be retained. For instance, it doesn't make sense to place this information in the medical record where it could easily be accessed in a subsequent legal action. Rather, it is better to treat documentation of discussions of unanticipated outcomes as if they were peer review documents. The extent to which such records will be considered privileged and not subject to discovery or use at trial will vary from state to state depending on the specific language of the state's peer review law. But given that the process of unanticipated outcome disclosure can reasonably be categorized as one designed to improve the quality of care and/or review the same, a colorable argument can be made in most jurisdictions that it fits within the typical statutory peer review privilege, in much the same manner as sentinel events analysis and reporting.

Finally, the policy should address training of physicians, other practitioners and staff. This training should go beyond simply explaining the new policy. It should include examples of what should and should not be said to patients and/or their families about an unanticipated outcome. What should not be said is far easier to identify than what should be said in any particular instance. Obviously, statements accepting legal responsibility for an adverse outcome or pointing the finger of blame at someone else involved in the care process should be avoided. Specific strategies as to the extent of disclosure that would usually be appropriate as well as training in counseling techniques would be helpful, too. In many cases, all the right words can be spoken, but if they aren't presented with the right tone of concern and compassion, the situation will become far worse.


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

UPS Delivers for the PBA

The PBA UPS benefit gives lawyers premium overnight mail service at discount prices—regardless of the size of the firm.

This special package deal offers discounts on:

- Next-day air letters
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Call UPS, 800-325-7000, and refer to #CP470002718 when you call.
National Briefs

Medicare Spending Up

Medicare spending jumped 8.4 percent in the first 10 months of fiscal year 2001, according to the Congressional Budget Office – that’s almost three times the rate from a year earlier.

PPS & GME Final Rulemaking

The final rule for the Inpatient Prospective Payment System and graduate medical education rates and costs for fiscal year 2002 appeared in the Aug. 1 Federal Register (66 Fed. Reg. 39827). Some changes will affect Medicare billing for teaching hospitals. Only time spent by residents on research that is actually “associated with the treatment or diagnosis of a particular patient” will count as indirect medical education.

Prospective Projects


Fewer DRG Errors

OIG said its audit of hospital records for 1997-98 found just $5 million in potential duplicate payments. Previously, the DOJ had recovered more than $60 million for noncompliance from almost 3,000 hospitals.

Patient Rights Bill Passes House

In a close vote (218-213) on Aug. 2, the House passed the Bipartisan Patient Protection Act (H.R. 2563), which will now go to a conference with the Senate. No Republicans voted against the bill, and only five Democrats voted for it. As amended, the bill caps pain and suffering and punitive damages at $1.5 million each and requires patients to exhaust a grueling medical review process before heading to court. It would preempt stronger state patients’ rights statutes and let health plans select the reviewers.

PBA Midyear Meeting

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through AquaWorld, located in the hotel, visit the Web site at www.fiestaamericana.com.

Attendees can earn up to six substantial and one ethics CLE credits and still have plenty of time to “catch some rays.” Topics include a survey of consumer finance, “predatory” lending allegations, alternative dispute resolution and more.

The three evening functions include the Caribbean Night (Wednesday), Magic M ayan Night (Thursday) and a “Special Surprise” event (Saturday). Caribbean Night will take place poolside, overlooking the Caribbean. Attendees will be treated to a spectacular island show following a buffet of local specialties. Local vendors will also display their work. Dine in the ancient pre-Hispanic civilization of the Mayan culture Thursday, when ancestral ruins and scenes from nearby Mayan cities will set the tone for the evening. Enjoy exotic drinks and an array of international and regional culinary delights. As for Saturday’s Special Surprise event, be prepared to be impressed!

Global Settlements

Seventy-seven New York hospitals agreed to repay Medicare $1.7 million for improperly billing patients transferred from hospices. The hospices, not Medicare, should have paid those bills, New York Attorney General Eliot Spitzer said in a July 23 press release.

In a groundbreaking statewide settlement involving over 60 hospitals and practice groups, Pennsylvania providers and the commonwealth resolved their long-running disagreement involving teaching physicians billing for resident-provided services. Attorney David Loder represented the Hospital and Healthcare Association of Pennsylvania. Tom Blazusiak represented the commonwealth.

Medicare Settlement

Our Lady of Lourdes Regional Medical Center in Lafayette, La., agreed to pay the government $247,182 to settle a probe concerning whether the center over-billed Medicare for patients who were transferred, nor discharged.

Peer Review Practices

The Nevada Supreme Court recently ruled that a hospital peer review board was not immune (under the Health Care Quality Improvement Act) from a lawsuit by a whistle-blowing psychiatrist who was fired for disrupting a Reno hospital’s operations. Clark v. Columbia/HCA Info. Servs., 117 Nev. Adv. Op. No. 42, No. 2995 (Nev. June 21, 2001), or online at www.leg.state.nv.us/scd/117NEvAdvOpendo42.html

Generic Price Suit


Golfers won’t want to miss the PBA “Cancun Classic.” It will take place Friday morning at the Hilton, an Aoki-designed par-72 course. The last PBA golf tournament filled quickly, so register early to be part of this event.

There will also be plenty of time to do some off-site exploring. A visit to the five-million-year-old caves of Aktun Chen offers an easy walk with views of fantastic stalactite and stalagmite formations and a crystal-clear underground lake. Journey to the walled Mayan city of Tulum, an archeological showcase located on a cliff overlooking the ocean. Take a snorkeling adventure to the world-class reefs at El Garrafon on Isla Mujeres. Swim with the dolphins at Hel-Ha, a 10-acre ecological reserve that contains one of the world’s largest natural aquariums and a lagoon for snorkeling.

The 2002 PBA Midyear Meeting truly offers something for everyone in a picturesque location. Don’t miss it! Call the PBA at 1-800-932-0311, Ext. 2231, or visit www.pabar.org for more information or to register.
Nominations Now Open for the 2001 Excellence in Health Care Law Award

The PBA Health Care Law Committee is seeking nominations for its 2001 “Excellence in Health Care Law Award.” As the name implies, this award is given to a health care law attorney whose expertise and professionalism demonstrate the best of our profession. We would like to recognize the recipient at this spring’s Health Law Institute. Therefore, we need to receive nominations no later than Dec. 31, 2001.

There are no particular requirements for this award; however, we have included the following suggestions to help you identify your nominee:

❍ Professionalism
❍ Participation in health care law activities
❍ Impact on students of health care law
❍ Impact on professional development of health care attorneys
❍ Impact on health care law on a statewide or national basis
❍ Integrity
❍ Accomplishments, inside and outside of health care law
❍ Motivation

Please complete the following and return with letter of nomination by FAX or mail to:

Paul C. Troy, Esquire
Vice Chair, Health Care Law Committee
Kane, Pugh, Knoell & Driscoll
510 Swede Street
Norristown, PA 19401-4886
FAX: (610) 275-2018

Nominations will be accepted until Dec. 31, 2001

Nominee:______________________________________________________________

Firm, School, Organization:______________________________________________

Nominated By:__________________________________________________________

Your Address:__________________________________________________________

Your Phone:_____________________________________________________________
Department of Health Revises Regulations
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Department fails to respond within the 45 day-period, the contract is deemed approved. However, the Department reserves the right to require changes to the contract following the 45 day review period in the event it subsequently develops concerns relative to the contract. Similarly, all material changes to any contract between a managed care plan and providers must be submitted to the Department 10 days prior to implementation of the changes.

Additionally, Section 9.603 of the regulations also permits the Department to issue technical advisories to assist managed care plans in complying with the new regulations. The technical advisories will provide guidance in complying with the regulations but will not have the force of law. The Department will publish notices of technical advisories in the Pennsylvania Bulletin. The Department previously issued technical advisories, but the prior regulations did not specifically articulate this power.

Section 9.711 of the regulations permits managed care plans and providers to agree to an informal dispute resolution system for the review and resolution of disputes between the health care provider and the managed care plan. The regulations require the inclusion of an agreed upon informal dispute resolution system in the provider contracts with the managed care plan. Additionally, the regulations permit alternative dispute resolution between a provider and the managed care plan. However, among other things, an alternative dispute resolution system must be impartial, provide for final review and be included in the contracts between the health care provider and the managed care plan.

The Department has comprehensively reviewed and modified its previous managed care regulations to reflect the consumer protection components of Act 68. These regulations focus upon the General Assembly’s legislative intent of protecting the rights of managed care enrollees. In addition to issuing regulations pursuant to Act 68, the Department significantly altered its entire managed care regulations. This article provides a brief overview of the new changes to the existing regulations unrelated to Act 68. For a more comprehensive analysis of the new changes to the regulations, please refer to the regulations.