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A Message from the Section Chair

I want to begin my first message to the members of the Health Law Section by thanking each of you for your involvement. I also want to ask each of you for your assistance in making this Section a stronger one for us, its members.

As you know, the purpose of the Section is to expand knowledge of health care law and to increase our understanding of how the legal system impacts upon the delivery of health care, our major domestic product. To this end, many of our committees hold regular meetings which produce valuable information of benefit to all who practice in the Health Law area. The Section is strong because it represents a variety of viewpoints; while many of us have providers as clients, the involvement of representatives of consumers, insurers and government is key to full discussion and understanding.

This Fall we have scheduled two very important events.

On November 12 there is a seminar featuring a session devoted to telemedicine, a growing area of practice in which technological developments are outstripping the response of the legal system. Significant questions are raised as to whether a regulatory system designed in the early days of the 20th century can keep pace with the rapid development of technology which obliterates distance and makes instantaneous communications between remote locations an everyday occurrence. There are also well-founded concerns in such an accelerating system for quality of care as well as relationships between professional and patient. The seminar will also feature a presentation by Henry Greenberg, General Counsel of the New York State Health Department, and an afternoon session devoted to Government Investigation and the Provider Response. This seminar, which is to be held at the Parker Meridien Hotel in New York City, should be of value to all who practice in the area.

In January, at the Annual Meeting, our Section will continue its tradition of presenting an informative program concerning public issues. In addition, there will be a presentation by the Office of General Counsel of the State Health Department concerning the Governor's program initiatives for the 1999 Legislative Session.

I am proud to be associated with this fine group of practicing lawyers. I trust that as the year moves forward into 1999, we will experience still more active involvement by the membership.

Jerome T. Levy

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From the Editors

We would like to take this opportunity to welcome Jerry Levy, the new Chair of the Health Law Section. Thanks for volunteering your time and energy to this endeavor.

This issue of the *Health Law Journal* begins with an article by Ari Markenson. Mr. Markenson discusses the increased use of, and guidelines for, corporate compliance programs. We have also reprinted an article by Robert Swidler on the legal issues surrounding human cloning. Howard Krooks has also contributed to this issue with his Elder Law Update. Finally, Margaret Murray has one again submitted her 'Net Worth column, providing useful guidance for online research.

We are currently accepting articles for review for the Winter and Spring issues. The deadline for the Winter issue is October 25, 1998, and the deadline for the Spring issue is March 1, 1999. Please see the back cover for more information regarding the procedures for submitting articles.

Barbara Atwell and Audrey Rogers

Compliance Programs in the Health Care Industry: An Overview

by Ari J. Markenson, J.D., M.P.H.*

I. Introduction

The current development of compliance programs in the health care industry can be directly linked to increased enforcement of fraud and abuse laws and regulations. An awareness of this trend in enforcement is essential to a discussion of compliance programs. Additionally, a discussion of compliance programs is generally limited to organizational providers. Smaller providers, such as individual physician practices, generally have remained outside the push toward compliance programs. This is directly due to the fact that smaller providers generally have not been targeted by federal and state investigators. To a limited degree, they are simply not worth the investigative effort.

In recent years, the federal government has begun to diligently enforce health care fraud and abuse laws. Federal and state agencies[1] have targeted large physician group practices, hospitals, home health care agencies, clinical laboratories and nursing homes for violations of federal and state laws and regulations. The president and the agencies responsible for enforcement have each commented on the nationwide effort to stop fraud and abuse in the health care industry.

President Clinton, in his fiscal year 1999 budget, revealed his ten-step plan to fight fraud and abuse in the Medicare program. The president's plan includes increased investigations and auditing, and additional targeting of hospitals, nursing homes and home health agencies. The plan is expected to save Medicare $2 billion over the next five years.[2]

In a 1997 open letter to health care providers, Ms. June Gibbs Brown, the Inspector General for the Department of Health and Human Services (DHHS), asked providers to join her in eliminating fraud and abuse in the health care industry. The letter explained that, with new resources and authority, the OIG would be stepping up its enforcement activities with increased investigations and audits and strengthening its collaboration with the Health Care Financing Administration (HCFA), the Department of Justice (DOJ), and other federal, state and local law enforcement entities.[3] Recent enforcement activities have focused on interns and residents at teaching hospitals,[4] practices in the long-term care industry,[5] false claims by providers[6] and quality of care issues.[7]

In response to increased enforcement, compliance with federal and state mandates has become more important than ever. The *Random House Dictionary* defines "compliance" as the act of conforming, cooperation or obedience. Compliance is nothing new to health care providers. Faced with a myriad of federal and state regulations, providers have always been required to be in "compliance" with law and regulation. However, while providers have been aware of federal and state mandates, oftentimes interpretation of those mandates can be difficult. Federal and state regulation can be highly technical, and traditional interpretations can be of little assistance. Providers may continue on a path of interpretation under the impression that they are in compliance when, in fact, federal and state regulators may see things differently.

Several providers have recently fallen victim to misinterpretations of Medicare billing regulations and guidelines. For years, health care providers had been guided by industry practice and the Medicare fiscal intermediaries (FI), the private companies responsible for administering payments to providers under the Medicare program. However, innocent billing errors are no longer treated as simple mistakes. Providers can't simply return the overpayment to their FI without opening themselves up to increased scrutiny and possible civil and/or criminal prosecution.[8]

In addition to the change in interpretation, technology has also been a significant factor in enforcement. The age of computerized billing has led to a wealth of data at the hands of fraud investigators. Increases in utilization of particular services could trigger an HCFA audit. Investigators routinely screen billing looking for increases in high reimbursement or other services. Without adequate documentation of medical necessity and changes in acuity of patient populations, providers will find themselves in trouble with investigators. Increases in technology have also led investigators to statistically project possible false billings from looking at representative samples of patient records. Investigators review sample records, determine that there are false billings and extrapolate a total percentage of false billings based on the provider's total patient population.

A recent quote from Dr. Uwe Reinhardt, a health care economist at Princeton University, best describes the existing enforcement climate which has led to implementation of compliance programs. In describing the enforcement activities of the federal government, Dr. Reinhardt remarked: "[F]or every one place they hit, ten other places are trembling in their boots and cleaning up their act. . . . It's like cops on a highway. They can't go after every speeder, but knowing that the one they go after could be you, keeps people more honest."[9]

II. Legal and Regulatory Environment

Health care providers have several sources of law and regulation applicable to the operation of their organization. Major sources of law and regulation include Medicare and Medicaid participating provider regulations, federal and state fraud and abuse laws, state health care, U.S. Occupational Safety and Health Administration (OSHA), U.S. Environmental Protection Agency (EPA) and U.S. Department of Labor regulation and general legislation regarding the operation of business entities.

There is no question that health care is a highly regulated industry. However, the largest sources of risk are currently associated with the enforcement of fraud and abuse and participating provider requirements in the Medicare and Medicaid programs.

In 1997, the Department of Justice, in cooperation with the DHHS, released its Fraud and Abuse Control Program as mandated by the Health Insurance Portability and Accountability Act (HIPAA).[10] The program document contains the following areas of cooperation between agencies: (1) coordination between federal, state and local law enforcement programs to control fraud and abuse; (2) conduct of investigations, audits, evaluations and inspections relating to the delivery of and payment for health care; (3) facilitation of the enforcement of the civil, criminal and administrative statutes; (4) provision of industry guidance, including advisory opinions, safe harbors and special fraud alerts relating to fraudulent practices; (5) establishment of a national data bank to receive and report final adverse actions against providers; (6) coordination and exchange of information; and (7) confidentiality procedures for the provision and use of data.[11]

The depth of the Fraud and Abuse Control Program proves how seriously the government is concerned about fraud and abuse.

The following is a brief description of sources of federal and New York State fraud and abuse regulation, which make up the backbone of recent enforcement activity.

A. Federal Fraud and Abuse Law

1. 31 U.S.C. § 3729—Civil False Claims Act

The federal civil False Claims Act (FCA) makes it illegal for any person to knowingly present, or cause to be presented, to an officer or employee of the U.S. government a false or fraudulent claim for payment or approval. Liability under the act is a civil penalty of not less than $5,000 and not more than $10,000 plus three times the amount of damages which the government has sustained as a result of the fraudulent act. A *qui tam* action may be brought pursuant to the civil FCA.[12]

2. 18 U.S.C. § 287—Criminal False Claims Act

The criminal False Claims Act makes it a felony—with penalties of no more than five years in prison and possible fines—for anyone to make or present a claim to any person or officer in the civil, military or naval service of the United States, or any department or agency thereof, knowing such claim to be false, fictitious or fraudulent.

3. 42 U.S.C. § 1320a-7b—Federal Medicare/Medicaid False Claims and Anti-Kickback Statute

Under this statute it is a felony to make false claims or statements in connection with a claim for payment under the Medicare or Medicaid programs. The statute prohibits: (1) knowingly and willfully making or causing to be made any false statement or representation of a material fact in any application for any benefit or payment under the Medicare or Medicaid programs; (2) knowingly and willfully making or causing to be made any false statement or representation of a material fact for use in determining rights to a benefit or payment; (3) having knowledge of the occurrence of an event affecting someone's right to continued benefits and failing to disclose such event, with an intent to secure such benefit or payment in a greater amount or quantity than is due or when no such benefit or payment is authorized; (4) converting any benefit or payment rightfully belonging to another; and (5) presenting or causing to be presented a claim for physician's services knowing the individual who provided the service was not a licensed physician.[13]

Additionally, the statute prohibits the offering, giving, receiving or soliciting of illegal remuneration. Anyone who knowingly and willfully solicits, pays, offers or receives any remuneration, in cash or in kind, directly or indirectly, overtly or covertly, to induce or in return for arranging for or ordering items or services that will be paid for by Medicare or Medicaid, will be guilty of a felony and fined or imprisoned for not more than five years, or both.

The statute does provide certain exceptions and safe harbors, such as (1) a discount or other reduction in payment that is properly disclosed and appropriately reflected in any cost reports or claims made; (2) any amount paid by an employer to an employee; (3) amounts paid by vendors to group purchasing organizations; and (4) any practice defined as a safe harbor by DHHS. DHHS safe harbors include (1) investment interests, (2) space rental, (3) equipment rental, (4) personal services and management contracts, (5) sale of practice, (6) referral services, (7) warranties, (8) certain discounts, (9) employees, (10) group purchasing organizations and (11) certain waivers of beneficiary coinsurance and deductible amounts.[14]

4. 42 U.S.C. § 1395nn—Federal (Stark) Physician Self-Referral Law

The statute prohibits a physician from making a referral to an entity for the furnishing of designated health services, for which payment otherwise may be made under Medicare/Medicaid, where the physician has an immediate family member or financial relationship with the entity. The statute further prohibits the entity from presenting or causing to be presented a claim to the program for a designated health service furnished under a prohibited referral. Designated health services under the statute include: (1) clinical laboratory services; (2) physical therapy services; (3) occupational therapy services; (4) radiology and other imaging services; (5) radiation therapy services and supplies; (6) durable medical equipment and supplies; (7) parenteral and enteral nutrients, equipment and supplies; (8) prosthetics, orthotics, and prosthetic devices and supplies; (9) home health services; (10) outpatient prescription drugs; and (11) inpatient and outpatient hospital services.

There are certain exceptions to the referral prohibitions written into the statute. These additional exceptions include: (1)

physicians' services as a group practice, (2) in-office ancillary services, (3) prepaid health plans, (4) DHHS regulatory safe harbors, (5) specific amount of ownership in publicly traded companies, (6) rental of office space, (7) rental of equipment, (8) employment relationships, (9) personal service arrangements, (10) physician incentive plans and (11) physician recruitment.

5. 18 U.S.C. §§ 1961-1968—Federal Racketeer Influenced and Corrupt Organizations Act (RICO)

The criminal RICO laws generally make it unlawful for any person to receive income derived, directly or indirectly, from a pattern of racketeering activity or through collection of an unlawful debt. A pattern of racketeering activity is established primarily through the commission of at least two acts of racketeering activity. In the health care fraud context, several acts of false claims may give rise to a criminal RICO action.[15] There is also a civil RICO statute that permits private parties to sue under similar circumstances.[16]

6. 18 U.S.C. § 1001—Federal False Statements Statute

The False Statements Statute prohibits anyone from knowingly and willfully falsifying, concealing or covering up a material fact by any trick, scheme or device. Additionally, it prohibits making any false, fictitious or fraudulent statements or representations, and/or making or using any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry. A violation of the statute carries a prison term of no more than five years or a fine as prescribed under the statute.

7. 18 U.S.C. § 1343—Federal Mail and Wire Fraud Statute

The federal Mail and Wire Fraud Statute generally prohibits the use of the mail to advance a scheme of fraud.[17] The statute prohibits anyone who has devised or intends to devise any scheme or artifice to defraud, or obtain money or property by means of false or fraudulent pretenses, representations or promises, to transmit or cause to be transmitted by means of wire, radio or television communication in interstate or foreign commerce, any writings, signs, signals, pictures or sounds for the purpose of executing such scheme or artifice.

The statute provides for a penalty of a fine and/or imprisonment of not more than five years, or both. If the violation affects a financial institution, such person shall be fined not more than $1 million or imprisoned not more than 30 years, or both.

B. New York State Fraud and Abuse Law and Regulation

1. New York Public Health Law § 238(a-c)—New York State's Anti-Kickback Law

This law generally makes it illegal for any practitioner authorized to order clinical lab, pharmacy, x-ray or imaging services to make a referral to another provider where that provider is either an immediate family member or has a financial relationship with the referring provider.

2. New York Public Health Law §§ 585-588—New York State's Clinical Laboratory Law

This statute makes it illegal for any purveyor of clinical lab services to bill or receive payment from any person other than the recipient of their services. Additionally, it is illegal for any clinical lab to receive any kickback or illegal remuneration in exchange for referrals for clinical lab services.

3. 18 NYCRR § 515.2—Unacceptable Practices under the Medical Assistance Program

This regulation describes anti-kickback, improper record keeping, unnecessary services and other practices which, if committed under the Medical Assistance (Medicaid) Program, would constitute an administrative violation.

In enforcing the above-mentioned laws and regulations, government agencies have focused on several major areas of suspected fraud and abuse. For example, HCFA and several other agencies have identified areas of significant concern in their investigative efforts. These areas include, but are not limited to, the following: (1) billings for services that were never rendered; (2) misrepresenting diagnoses to justify payments; (3) soliciting, offering or receiving illegal remuneration in exchange for services; (4) unbundling or "exploding charges"; (5) falsifying certificates of medical necessity, plans of treatment and medical records to justify payment; (6) billing for services not furnished as billed, such as upcoding billings; (7) fraudulent or improper cost reporting; (8) grant or program fraud; (9) experimental devices; (10) resident and intern physicians' billings; (11) dual billings to federal programs; (12) quality of care abuse and neglect in long-term care; (13) refusals to accept or treat patients; (14) improper discharge planning; (15) free equipment deals from Part B providers and suppliers; and (16) serious increases in utilization of particular items and services.

All of these sources of law and regulation, and their increased enforcement, have led to the trend toward compliance programs. Compliance programs assist organizational providers in ensuring their proper performance within the current regulatory framework. The above sources are all important factors to take into consideration in understanding, developing and implementing compliance programs for organizational providers.

III. Compliance Programs

Many organizational providers in the health care industry are implementing compliance programs. As mentioned earlier, increased enforcement, use of the False Claims Act and the Office of the Inspector General for the Department of Health and Human Services are all factors responsible for this trend.

In the recent past, the FCA became a serious concern for defense industry contractors faced with enforcement by agencies alleging fraudulent claims. The defense industry developed ways to police itself internally to ensure against future FCA prosecutions.[18] Currently faced with similar prosecutions, many in health care have begun to learn the merits of "compliance."

Compliance programs, contrary to popular perception, are more than simply useful tools to keep federal enforcement from knocking at a provider's door. Compliance programs are tools for managers and administrators to ensure that providers, employees and agents are all properly following applicable regulatory mandates. With large organizational providers, compliance programs establish an administrative role and internal management tool for ensuring that an entity is operated within all federal and state guidelines.

There are many real advantages to implementing a compliance program. These advantages include:

- Minimizing a provider's potential liability in connection with audits by OIG, HCFA, the FBI and state regulators.
- Reducing the potential for *qui tam* (whistle blower) lawsuits brought by employees, suppliers, competitors and the like.
- Demonstrating a provider's good-faith effort to comply with federal guidelines, which can significantly reduce penalties assessed for cited violations.
- Fostering better record keeping, which can facilitate the resolution of disputes regarding Medicare/Medicaid and private payor denials, improve the ability to defend malpractice claims, and assist management and quality assurance programs.
- Initiating increased screening of potential employees, which can reduce overall liability from dangerous and/or unskilled individuals.
- Reducing the potential for fraud and abuse by keeping top management apprised of compliance requirements and educating staff about proper billing practices.
- Decreasing a provider's exposure to anti-kickback penalties by instructing employees about the regulations that govern illegal compensation arrangements.
- Minimizing the likelihood of a government-imposed mandatory compliance program as a condition of settling a violation.[19]

Compliance programs should be tailored to a provider's individual needs and administrative goals. No provider should use a canned compliance program. Nearly all regulators have remarked that an effective compliance program must be one which a provider has taken seriously and developed with this other organization in mind.

A compliance program is generally comprised of several elements, such as: a high level manager or administrator (compliance officer) who is responsible for ensuring the provider is following its program and who is aware of all pertinent regulation; a written compliance plan and manual with stated policies; procedures and standards; an internal assessment tool; a survey or audit mechanism for managers to review the organization's compliance; and a direct communication mechanism for employees to report issues concerning compliance.

A. High-Level Managerial Responsibility

Management and/or administration should either choose a compliance officer from within or create a new position. However, like any other position, a designation of an employee from within may make the process of adapting to a program more effective. A compliance officer from within may work more effectively with managers, department heads and others to implement the program. A new employee, whether with experience in compliance or not, may still need to learn the organization's unique qualities before developing policies, procedures and the entire program.

While there may be many attributes to consider with regard to choosing a compliance officer, there are two basic and general rules to follow. In order to address several concerns, the compliance officer should generally not be within the organization's legal department. Attorney-client issues and other confidentiality issues may arise when using legal counsel to act as a compliance officer. Furthermore, legal counsel may be needed to perform auditing and other activities that should not be commingled with the compliance program.

Another rule to follow is that the compliance officer should be at a high level in the administrative framework. The officer should have direct access to the highest levels of the organization, such as owners, boards, CEOs, etc., as well as legal counsel. Where issues arise concerning possible voluntary disclosure of wrongdoing, the officer should be able to address those issues directly to the highest levels of the organization. For example, if significant billing and/or purchasing irregularities are discovered, the compliance officer should have the ability to report those issues directly to the board, the CEO and legal counsel.

B. Compliance Plan, Manual, Policies and Procedures

Providers should develop and draft a written compliance plan and manual. As mentioned earlier, an internally developed plan and manual customized to the needs of the particular organization will always be more useful and effective in the overall implementation of a program. The plan should be a document that describes the significant elements of the program, schedules implementation and generally maps out how the provider will adopt the program.

In order to implement a plan and a manual, providers should start from the top and secure the cooperation and commitment of the governing body of the organization. This can generally be done through a formal board resolution or some other mechanism.[20]

After securing the commitment of the governing body, managers and administration should educate themselves. They should determine and understand all applicable laws and regulations concerning their organization. Legal counsel to the organization should be consulted to help educate top-level management. Additionally, management should sit down, read and understand the laws that are applicable to their organization. Managers should then determine how those relevant laws could represent significant risks for the organization. The compliance officer should set up team meetings with the administrative staff and department heads. These meetings should be used to determine significant areas of risk. The compliance officer should determine each department's knowledge and ability regarding laws and regulations that affect their area of the organization and the organization as a whole.

For example, billing departments are often extremely skilled in current procedural terminology (CPT) or other types of coding, yet many of them have never read the certification on the back of an HCFA 1450 form (the general billing form for billing Medicare Part B).[21] The certification generally requires that the organization submitting the bill certify that the bill is correct and completely in compliance with relevant laws and regulations. The beginning of the certification reads "NOTICE: anyone who misrepresents or falsifies essential information requested by this form may upon conviction be subject to fine and imprisonment under federal and/or state law."[22] An effective program overall should ensure that each time an HCFA 1450 is submitted it is done correctly and all documentation to support the claim exists.

Another example would be to talk to purchasing staff. Purchasing staff may understand and appreciate that they cannot accept a brand new TV for using a particular vendor. However, they may not realize that accepting enteral feedings pumps at no charge as long as enteral feeding supplies are purchased from a particular vendor may be and most likely is a prohibited transaction.

The next step is developing policies and procedures. Policies and procedures should be based on identified risk areas. The compliance committee should apply current law and regulation to the organization's practices through policies and procedures. The policies and procedures should specifically be developed to comply with relevant regulation and prevent and/or limit potential risks. For example, a useful policy and procedure for billing personnel may require them to ensure that the proper clinical documentation exists to substantiate all claims they process.

Billing is only one topic area for compliance policies and procedures. An organization should cover general topic areas including, but not limited to, such areas as purchasing, medical records, corporate records, administrative and governing body, compliance officer and committee, confidential reporting, OSHA and EPA, and employee standards.

C. Employee Standards

Once policies and procedures have been written, they should be compiled and a written manual for employees and the organization as a whole should be developed and implemented. Employees should be trained in how to understand and implement the new compliance policies and procedures.

Employees should also be informed of the new standards to which they will be held. Employee standards should generally require disciplinary action for failing to meet the expectations and mandates of specific policies and procedures. One of the most important points to understand in developing compliance programs is that they should be effective. Employees should know this is not a new scheme hatched by administrators to make their workday longer and more difficult. They should understand the importance of the adoption of a compliance program and that they will be held accountable. However, employees should also be properly educated as to what is expected of them. New employees should receive compliance training within the first few months of their employment.

D. Internal Assessment Tool

Taking introspective looks at the organization is the best way to ensure compliance. The compliance officer and committee should develop auditing functions, and the compliance officer should continually perform audits in different areas of the organization. Additionally, a yearly comprehensive audit should be performed.

An example of smaller, more focused audits would be to focus on the purchasing of direct care supplies every four to six months. The compliance officer should interview purchasing staff and gather purchasing records. The officer should determine if staff are complying with their obligations based on the standards developed. Auditors should review purchasing records for evidence of impropriety and error.

In contrast, a comprehensive audit should look at all aspects of the compliance program. Annually or semi-annually, the organization should take a serious and comprehensive look at itself. Auditors should take several days or weeks, depending on the size of the organization, and collect representative samples of information and documents to determine the organization's current compliance status.

In general, all types of audits should be standardized and reproducible. The auditors should know what they are looking for and have standards for determining that the organization has complied with law and regulation concerning the areas being audited.

E. Direct Communication Mechanism

Employees should have direct and confidential access to the compliance officer. Internal reporting will help the organization police itself; e-mail, confidential mail, a phone hot-line or other mechanism should be used. However, the organization should make it perfectly clear that reporting mechanisms are confidential and will not in any circumstance lead to action against the individual reporting the information.

In addition to the general features above and the fraud and abuse regulation mentioned earlier, a compliance program should address other regulatory issues, such as state health care regulation and federal OSHA, EPA, discrimination and other pertinent laws.

An effective program will establish a culture of compliance in an organization. In addition, it will keep employees and administrators constantly aware of their responsibilities and obligations. There are certain additional factors which an organization should take into consideration when developing a compliance plan.

In general, compliance programs should also take into account federal sentencing guidelines and the OIG guidance. The federal sentencing guidelines are standards used by the federal judiciary to determine sentencing and punishment for criminal conduct. Chapter 8 of the federal sentencing guidelines pertains to the sentencing of organizations. Chapter 8, section 8C2.5(f) provides that "culpability generally will be determined by the steps taken by the organization prior to the offense to prevent and detect criminal conduct."[23] The guidelines allow organizations with compliance programs possible mitigation of a criminal sentence if they can demonstrate they have a program with several elements. Federal sentencing guidelines for organizations generally require (1) the demonstration of established policies which show the organization's commitment to the compliance program, (2) high-level administrative responsibility for oversight of the compliance program and activities, (3) a reporting procedure and mechanism for administration to become aware of compliance issues, (4) due care to ensure that individuals with a propensity for criminal conduct are not delegated significant authority and (5) effective staff training.

Additionally, the OIG's compliance guidance is a great source of information concerning what it expects from a provider attempting to police itself through a compliance program. The OIG released two separate compliance documents, one for clinical laboratories and another for hospitals. The OIG Model Compliance Plan for Clinical Laboratories was published in the Federal Register on March 3, 1997,[24] and the OIG Compliance Program Guidance for Hospitals was published in the Federal Register on February 23, 1998.[25] Some of the major points addressed in the OIG's hospital guidance include the following: (1) written policies and procedures that address standards of conduct, risk areas, claim development and submission, medical necessity, anti-kickback and self referral concerns, bad debts, credit balances and compliance as an element of a performance plan; (2) a designated compliance officer and a compliance committee; (3) effective employee training and education; (4) lines of communication; (5) enforcement of standards through well-publicized disciplinary guidelines; (6) auditing and monitoring; and (7) response to detected offenses and development of corrective action initiatives.[26]

A provider should evaluate how each of the laws mentioned earlier affects its organization. Providers should take an introspective look at themselves and determine significant risk areas based on fraud and abuse and other pertinent regulation. For larger organizations it may be difficult to implement a compliance program all at once. In that case, it becomes important to use a so-called staggered approach.

Large organizations should begin developing a program with fraud and abuse issues in mind and later expand the program to incorporate additional areas. The advantage to developing an initial program aimed at fraud and abuse and then building from there is in an organization's ability to immediately, effectively address the recent significant areas of risk. Employees may be overwhelmed by a broad sweeping plan aimed at all aspects of regulation. A staggered building approach should provide for much more effective implementation.

IV. Conclusion

It would seem from recent developments in the health care industry that compliance plans are the most significant factor in an attempt to stave off increased enforcement activity. There is a very slim chance enforcement activity will slow by any rate; the stakes are simply too high. The federal government is saving billions for the Medicare Trust Fund as it steps up enforcement and recoups moneys incorrectly paid. Additionally, the federal government has publicly expressed hopes that private health care costs will be reduced as private insurers begin to adapt health care fraud investigation and enforcement techniques.

Attorneys, and the providers they represent, should educate themselves on recent enforcement activities and compliance initiatives. In the near future, the implementation of compliance programs should only lead health care fraud investigators to those truly criminal and/or fraudulent acts which require prosecution. Additionally, providers should enjoy effective and efficient operation within legal and regulatory mandates.

Endnotes

1. Agencies involved in enforcement include: The Department of Health and Human Services (DHHS), Office of the Inspector General (OIG); DHHS-contracted private Medicare fraud contractors; the Department of Justice; the Federal Bureau of Investigation (FBI); state Medicaid fraud control units; the Defense Criminal Investigative Service; the Office of the Inspector General of the Department of Veterans Affairs (VA-IG); the Office of the Inspector General of the Office of Personnel Management (OPM-IG); the Office of Inspector General of the Department of Labor (DOL-OIG); and the New York State Department of Health (NYSDOH).
2. *Clinton 10-Step Plan to Fight Fraud Includes Doubling of Provider Audits*, 2 HCFR 42, Jan. 28, 1998.
3. DHHS-OIG, "Open Letter to Health Care Providers." *See* http://www.os.dhhs.gov/progorg/ oig/modcomp/ltrhcp.html.

4. Physicians at teaching hospitals (PATH) investigations. *See United States v. Clinical Practices of the University of Pennsylvania (CPUP)* (E.D. Pa. Dec. 12, 1995). U.S. Attorney used False Claims Act to claim physician billings at CPUP were fraudulent because they were for resident time spent with patients. Under Medicare, hospitals are reimbursed separately for graduate medical education (GME). GME payments are supposed to cover the cost of residents providing care to patients. This case ended in a government-imposed compliance plan and $30 million settlement agreement. *See also Greater New York Hospital Association (GNYHA) v. United States*, (S.D.N.Y, No. 98-civ-2741, filed 4/16/98). GNYHA filed suit over recent investigations concerning physician Medicare billings and resident physicians' services. Many New York hospitals have been targeted with similar investigations as in the *CPUP* case. GNYHA is claiming that, in many instances, hospitals are being audited for practices as far back as 1990 with rules promulgated in 1995 and 1996. Similar lawsuits against the U.S. government have been filed in California and New Jersey.

5. Operation Restore Trust (ORT) focused on practices in the long-term care industry and was introduced in 1995. Initially a two-year fraud and abuse enforcement program aimed at 5 states' long-term care industry, the program was later expanded to cover 17 states with additional funding from the Health Insurance Portability and Accountability Act of 1996 (HIPAA). It has been estimated the program has a rate of return of $23 for every dollar spent. In 1998, President Clinton announced his intention to expand the program to all 50 states.

6. False Claims Act demand letters have become a recent issue in these investigations. *See New Jersey Hospital Ass'n (NJHA) v. United States* (D.C.N.J., No. Civ 98-1421, filed 3/26/98). NJHA is suing over a practice that many hospitals have found to be overreaching by DHHS and DOJ. In an effort to resolve suspected Medicare overbillings, hospitals are sent demand letters that demand recoupment while threatening use of the FCA. NJHA argues that the use of these letters, in effect, adjudicates these disputes without affording any adjudicative process to resolve the dispute.

7. *See United States v. GMS Management-Tucker, Inc*. (E.D. Pa. No. 96-1271). This case involved a quality-of-care fraud investigation using the FCA. The complaint alleged that GMS-Tucker "schemed to bill and collect . . . for services associated with the care rendered to the elderly residents of Tucker House Nursing Home when, in fact, that care was not adequate." The U.S. Attorney claimed a nursing facility must provide quality care in order to participate in the Medicare program. In turn, GMS Management-Tucker, Inc. failed to provide proper nutrition to several residents and therefore was not entitled to reimbursement. *See also United States v. Chester Care Center* (E.D. Pa., No. 98-CV-139, settlement 1/13/98).

8. D. Bencivenga, *Examining Health Care: Yesterday's Error May Be Today's Fraudulent Act*, N.Y.L.J., Oct. 30, 1997.

9. K. Eichenwald, *U.S. Auditing Five Hospitals In New York: Part of a National Effort to Stop Medicare Fraud*, N.Y. Times, April 5, 1998, p. A31.

10. HIPAA, H.R. 3103, P.L. 104-191, 104th Congress.

11. *Health Care Fraud and Abuse Control Program and Guidelines*, U.S. Department of Justice, Jan. 1, 1997

12. *See United States ex rel. Roy v. Anthony*, 914 F. Supp. 1504 (S.D. Ohio 1994). *Qui tam* relator claimed physicians owned shares in imaging company which paid them based on the number of referrals to the imaging company. *See also Mruz v. Caring Inc.*, (D.C.N.J., No. 97-1468, 1/28/98). Civil RICO suit filed by executives who claimed they were fired for filing *qui tam* suit. *See* 31 U.S.C. § 3730.

13. *See United States v. Halper*, 490 U.S. 435 (1989). Manager of a health care entity successfully argued double jeopardy clause. He was sentenced to imprisonment and restitution. Supreme Court felt that $130,000 civil statutory fine would constitute second punishment in relation to $585 actual loss to Medicare. *See also United States v. Lorenzo*, 768 F. Supp. 1127 (E.D. Pa. 1991). Dentist billed Medicare for oral cancer screenings done during routine exams. Court said Medicare cannot be billed for such exams unless specifically requested by a treating physician.

14. *See United States v. Greber*, 760 F.2d 68 (3d Cir., 1985). Radiologist formed company that billed Medicare, then paid referring physician an "interpretation fee."

15. *See United States v. Durst* (E.D. Pa. No. 97-621, filed 11/18/97). Prescription drug scheme by four pharmacists and physician alleged to defraud Medicare.

16. *See Blue Cross/Blue Shield of Alabama v. Caremark Inc.* (N.D. Il., No. 98C1285, filed 3/2/98). Civil RICO suit by 22 private insurers for fraud in connection with physician referrals.

17. *See United States v. Sandman* (D.C. MA CR-97-40026-NMG, 10/27/97). Massage therapist fraudulent claims for services never performed. *See also United States v. Osteen* (D.C.S.C., No. 6:97-103, 11/19/97). Chiropractor charged with billing unnecessary nerve and vascular tests.

18. *See* "Defense Industry Initiative on Business Ethics and Conduct." Defense industry trade organization designed to help the industry with compliance and other business ethics issues. http://www.dii.org.

19. *See United States v. The Clinical Practices of the University of Pennsylvania* (E.D. Pa. Dec. 12, 1995). Federally imposed compliance program after audit found serious false billing claims to Medicare program. *United States v. First American Health Care of Georgia, Inc.* (D. Ga. Oct. 10, 1996). Federally imposed compliance plan and settlement involving long-term care provider. Found that provider had submitted cost report claims for personal items marketing and travel expenses and many other non-reimbursable items. *United States v. Bethany Medical Center* (D. Kan. July 1996). Federally imposed compliance program on hospital that illegally paid physicians for referrals from area nursing homes. *Bioran Medical Laboratories* (D. Ma. Feb. 21, 1996). Federally imposed compliance plan for clinical lab that made physicians order unnecessary test by bundling them in test screen packages.

20. *See* Sample Board Resolution, Section I, Exhibit A, *Health Care Compliance Manual*, American Health Lawyers Association, 1997.

21. *See* HCFA 1450 Form or (UB-92). A copy of the form can be downloaded at http://www.hcfa.gov/medicare/edi/1450info.htm.

22. *See* note 20 *supra*.

23. *See Federal Sentencing Guidelines Manual*, United States Sentencing Commission, 1997.

24. *See Model Compliance Plan for Clinical Laboratories*, The Department of Health and Human Services, Office of the Inspector General, Federal Register, March 3, 1997 (62 Fed. Reg. 9435).

25. *See Compliance Guidance for Hospitals*, The Department of Health and Human Services, Office of the Inspector General, Federal Register, February 23, 1998 (63 Fed. Reg. 8987)

26. *See* note 24 *supra*.

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Human Cloning: Legal Issues

by Robert Swidler*

It is presumptuous to write about legal aspects of cloning a human being from another living human's cell.[1] First, the event has not yet occurred.[2] Moreover, no federal statute or regulation specifically addresses human cloning.[3] A few other states have statutes restricting human cloning, but those laws are quite new.[4] There are no court decisions about human cloning or clones. Any legal discussion of the topic thus involves a greater-than-usual degree of speculation.

However, human cloning now appears scientifically possible. Accordingly, it is useful to try to identify and address the difficult, sometimes strange, legal issues that are apt to arise from the practice—issues ranging from whether it is lawful to attempt or accomplish human cloning, to a consideration of the rights of the resulting cloned person.

I. Current and Proposed Restrictions on Human Cloning

In the wake of the announcement by Scottish scientists of the cloning of a sheep by nuclear cell transfer, federal and state legislators advanced a variety of proposals to prevent or punish attempts to clone a human. Moreover, the National Bioethics Advisory Commission, in its June 1997 report *Cloning Human Beings*, called for federal legislation, effective for five years, "to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning."[5] However, despite legislative interest and the National Bioethics Commission's recommendations, few laws have been enacted to date.

A. Criminal Statutes

As of this writing, there is no federal or New York State law that makes it a criminal offense to clone or attempt to clone a human being. Senators Trent Lott (R-Miss.), Christopher Bond (R-Mo.) and William Frist (R-Tenn.) sponsored a 1998 bill to make it a federal criminal offense to engage in human somatic cell nuclear transfer,[6] but the bill was defeated in a vote on the Senate floor, reportedly due to concerns about its impact on medical research.[7]

Bills pending in several states would criminalize human cloning. In New York, proposals by State Senator John Marchi (R-Staten I.) and Assemblywoman Elizabeth Connelly (D-Staten I.) would add two new felonies to the Penal Law: "Cloning of a Human Being" and "Conspiracy to Clone a Human Being."[8] Their bills provide that "a person is guilty of cloning when such person grows or creates a human being from a single cell or cells of a genetically identical human being through asexual reproduction." Both legislators have also advanced an alternative civil penalty proposal, mentioned further below.[9] Another bill by Assemblyman Gregory Becker (D-Nassau), and numerous co-sponsors, would make it a felony to "directly or indirectly, engage in, participate in, finance, or do any act in furtherance of human cloning."[10]

However, while no federal or state law expressly criminalizes such activity, any scientist who seeks to clone a human being should be warned: the federal laws enforced by the Food and Drug Administration, discussed further below, may create a basis for criminal prosecution. Moreover, the ingenuity of motivated U.S. attorneys and local district attorneys should never be underestimated.

B. Civil Penalties

No federal statute currently imposes a civil penalty (e.g., a monetary fine) on anyone for human cloning. Several current federal bills, if passed, would impose such penalties. For example, H.R.923, introduced by Vernon Ehlers (R-Mich.), would make it "unlawful for any human person to use a human somatic cell for the process of producing a human clone" and impose a "civil penalty" of up to $5,000 for such offense. Another bill, S.1611, proposed by Senators Kennedy (D-Mass.) and Feinstein (D-Calif.) would also impose as a fine the greater of $1 million or three times the pecuniary gain or loss resulting from the violation. Moreover, federal food and drug laws, discussed below, may already provide a basis for the imposition of civil penalties.

In New York, matching bills by Senator Marchi and Assemblywoman Connelly would declare a five-year moratorium on human cloning and impose a civil penalty of up to $1 million on a facility and $250,000 on an individual, or two times any pecuniary gain realized, whichever is greater.[11] A bill by Senator Roy Goodman (R-Manhattan) would impose a civil fine of $250,000.[12]

In the absence of a specific statute authorizing a civil penalty for human cloning, it bears noting that the New York State Department of Health (DOH) has general authority to impose civil penalties for violations of the Public Health Law and DOH regulations.[13] DOH could conceivably seek to impose a civil penalty on a facility that participated in cloning, contending that such activity violates PHL sections or regulations governing the activities of hospitals or tissue banks, or governing human subject research—topics discussed below. So far, there is no indication of DOH's inclination in this regard.

C. Constitutional Aspects of Restricting Cloning

Some commentators have raised the issue of whether cloning is protected by a constitutional right to procreative liberty and thus cannot be prohibited, at least in some circum-

stances.[14] For example, a couple whose only child is dying, and who are no longer capable of bearing children, may claim that cloning their child is their only procreative option, and thus protected.

To be sure, a line of Supreme Court cases establishes a constitutionally protected right to privacy that restrains the state from interfering with an individual's or a couple's decision about whether or not to have children.[15] There is also support—though less weighty—for the proposition that the right to privacy protects non-coital assisted reproduction.[16] But cloning is apt to be viewed as a unique practice, dissimilar to reproduction in both means and end result. Moreover, cloning lacks support in custom, tradition and family life—the cultural values that were the impetus for courts to protect reproductive activity involving a man's sperm and a woman's ovum. Nor does cloning implicate issues of bodily integrity or marital intimacy that figure in protected procreation. In sum, it seems doubtful that the Supreme Court would rule that a constitutional right to procreative liberty prevents a state from prohibiting or restricting cloning.

D. Regulation of Human Subject Research

Federal regulations protect human research subjects from undue risk and ensure their informed consent.[17] In general, those regulations apply to federally funded research, and to all research at institutions that have signed multiple assurance agreements. Covered research cannot proceed unless an institutional review board (IRB) reviews the proposed research and finds, among other things, that the risks to subjects are minimized; that the risks are reasonable in relation to benefits, and that the subject will be fully informed of those risks—including risks to the embryo or fetus, if the subject is or may become pregnant.[18]

Additional regulations impose further restrictions on research involving fetuses, pregnant women and human in vitro fertilization (IVF), but those provisions apply only to federally funded research.[19] Since there is no federally funded research on human cloning, only the general human subject regulations could apply to cloning research, and then only at institutions with multiple assurance agreements.

With respect to the prospect of human cloning research at covered institutions, the National Bioethics Advisory Commission concluded that it would be difficult for an IRB to approve human cloning research because of the "serious question about physical harms that might result" to the embryo or fetus.[20] Significantly, the commission's rationale leaves open the possibility of IRB approval if and when research with animals yields a safe, reliable technique.

The federal regulations do not reach privately funded human subject research at institutions that have not signed multiple assurance agreements. Nor do they reach private non-research clinical activity, such as fertility clinics. In varying respects, state laws may address such activity. In New York, a state statute on the "Protection of Human Subjects," Public Health Law Article 24-A, was enacted specifically to cover human subject research that escapes the scope of the federal regulations.[21] In general, the statute requires voluntary informed consent by or on behalf of the human subject, and review of the research by a human research review committee. But the extent to which the protections of Article 24-A would apply to human cloning is not clear. First, the statute only reaches "human research," which is research involving some intervention upon the body of the human subject and which is not required for diagnostic or treatment purposes. While the removal of a somatic cell from one person and the implantation of the embryo in a woman's womb would probably qualify as an "intervention," the statute, like the federal statute, would not appear to reach cloning performed for some therapeutic reason, such as infertility.

Even with respect to instances of human cloning that would constitute human research under Article 24-A, the statute would not necessarily preclude such activity. Rather, it subjects such activity to state-qualified IRB review to determine, among other matters, the need for the research, whether the rights of the subject are adequately protected and whether the risks are outweighed by the benefits.

Professional guidelines on use of gametes and embryos for research also emphasize the need to obtain informed consent from donors of oocytes, spermatozoa and embryos, to justify the clinical value of the study and to obtain IRB approval.[22] Adherence to those standards would not appear to preclude research on human cloning, although IRB approval would be difficult to secure.

E. Food and Drug Regulations

The federal Food and Drug Administration (FDA) regulates products, drugs and devices intended to prevent, treat, or diagnose diseases or injuries.[23] Biological products require premarket approval, adherence to investigational new drug (IND) procedures, and the submission of both product license applications and establishment license applications.[24] The FDA has broad authority to enforce compliance with these requirements. Federal laws also authorize criminal prosecution of violators.[25]

In 1993, the FDA issued a statement of its authority over "human somatic cell therapy products and gene therapy products."[26] It asserted that "cells subject to licensure as final biological products when intended for use as somatic cell therapy include cells manipulated in a way that changes the biological characteristics of the cell population."[27]

Recently, Secretary of Health and Human Services (HHS) Donna Shalala asserted in a letter to the Biotechnology Industry Organization, a major biotechnology trade group, HHS's position that the FDA "has jurisdiction over experiments that would involve the cloning of humans and is prepared to exercise that jurisdiction.[28] If correct, scientists who

seek to perform human cloning must adhere to IND procedures and other FDA requirements—requirements which would effectively preclude proceeding.

It is not clear if the courts would uphold this expansive view of FDA jurisdiction. Certainly, human cloning is distinguishable from other "biological products" in several respects, not the least of which is the purpose of the procedure, which arguably is not to prevent, treat, or diagnose diseases or injuries.

F. Regulation of Hospitals

Hospitals are subject to federal and state regulations, the latter of which are quite extensive in New York.[29] Even so, no regulations cover human cloning. Hospitals that participate in cloning must adhere to general requirements applicable to research and assisted reproductive clinical activity (e.g., staffing, record-keeping, quality assurance, incident reporting, etc.), but do not encounter any notable regulatory obstacle to the activity, or bases for sanction. Similarly, JCAHCO standards for accreditation of hospitals would not appear to preclude the activity.

G. Regulation of Gamete Banks

New York State regulations govern the operation of "tissue banks," a general category that includes "gamete banks."[30] The regulation defines "gamete bank" to mean "a facility which acquires, processes, stores, and/or distributes human semen or oocytes for use in assisted reproductive procedures, including but not limited to artificial insemination."[31] Accordingly, the acquisition of ova for human cloning—which would likely be regarded as an "assisted reproductive procedure"—could subject a facility to various regulatory requirements.[32]

Specifically, a gamete bank must be licensed, must meet administrative and staffing requirements, must have a medical advisory committee and must screen donors for diseases and other factors. While none of these requirements would preclude human cloning, the web of regulations afford DOH ample basis to obstruct clinical human cloning, if it decided to do so.

H. Professional Misconduct

State law governs the licensure of medical and other professionals, and the standards for professional conduct. Predictably, none of the categories of professional misconduct set forth in the New York Education Law explicitly covers human cloning.[33] Moreover, none could reasonably be read to encompass such activity. However, if laws are passed that make engaging in human cloning a criminal offense, such conduct would automatically become a basis for professional discipline.

I. Malpractice Liability

In general, the physician or scientist who engages in cloning does not appear to be subject to an exceptional degree of malpractice liability risk, and may be at lower risk than other reproductive specialists. Consider the following plausible scenario: A couple wishes, for whatever reason, for the husband to be cloned. A physician agrees to make the attempt and, employing the somatic cell transfer technique, creates an embryo and implants it in the wife. The resulting child is born live, but severely impaired and the couple sues.

To establish malpractice, a plaintiff must prove that the physician failed to adhere to the applicable standard of care in the field, and that as a result, the patient sustained an injury.[34] As an initial matter, the plaintiffs in the hypothetical case above would have difficulty identifying a standard of care for human cloning (except with respect to ancillary aspects such as screening of the donor tissue or sterilization of equipment). The technique is experimental. Thus the probable limit of the physician's obligation (apart from the informed consent requirement, discussed below) is to perform the experimental technique in a non-negligent manner—i.e., with such care, skill and diligence as a similar professional would ordinarily exercise.[35] Accordingly, the physician who attempts human cloning may be at less risk for malpractice than the physician engaged in other assisted reproductive techniques, where practice norms are more discernible and exacting.

To be sure, plaintiffs might contend that an attempt to clone a human, even if skillfully performed after obtaining full informed consent (discussed below), is such a departure from the standard of care for reproductive medicine as to constitute malpractice per se.[36] But such theory would rest on a novel extension of the concept of a standard of care—an extension that, if adopted, could unduly impede innovations in medicine.

A physician may also be held liable for the injuries of the patient if he or she fails to obtain the patient's informed consent, and the patient is injured as a result. With respect to cloning, the physician must adequately disclose the risks, benefits and alternatives to the procedure.[37] The disclosure undoubtedly would have to include explicit disclosure of the procedure's experimental nature, and probably would have to be thorough enough to establish, in essence, a knowing assumption of risk by the patient.[38] In the example above, if the physician sufficiently disclosed the experimental nature of the procedure and the risk of an impaired baby to the couple, he or she should have no liability based on lack of informed consent. Moreover, New York's informed consent statute provides numerous defenses and is strikingly protective of physicians.[39]

Notably, in the event the parents could prove medical malpractice or lack of informed consent with respect to the cloning, precedents in this state regarding pre-birth malpractice establish that the parents can recover only their economic losses—i.e., the additional costs of raising an impaired child. They cannot recover damages for psychic or emotional harm.[40]

Whether the child himself or herself has a cause of action in the example above is an interesting question. Under New York case law, a child cannot sue for injuries caused by *pre-conception* medical malpractice,[41] but can sue for injuries caused to him or her when "*viable but in utero.*"[42] The rationale is that the child must be sufficiently in existence at the time of the malpractice to acquire an independent legal interest. But the cloning process involves activity prior to "conception" (if the transfer of nuclear material can be called that), activity after "conception" but pre-implantation, implantation and pregnancy care. It would be challenging—to say the least—for the child to establish that the malpractice occurred at a stage when he or she was sufficiently "in existence" to acquire a legal interest.

The child might also wish to assert a "wrongful life" claim—i.e., a claim that the physician should not have attempted to clone at all; that but for such wrongful conduct the child would not have been born and thus would not have sustained his or her impairment or emotional harm. However, New York, like most states, does not permit "wrongful life" suits, in part because of the difficulty in accepting plaintiff's premise that non-existence is preferable to existence.[43]

Other malpractice scenarios could arise, but the examples above illustrate that such scenarios would be addressed through established malpractice principles, and that such principles appear not to expose practitioners of human cloning to exceptional liability.

II. The Right Not to Be Cloned

The somatic cell transfer technique raises the possibility that a scientist could obtain cells from a person (the "source") without his or her knowledge or agreement, and clone a genetically identical human being from such person (the "clone"). That prospect raises some novel questions—does a source have a right not to be cloned? Does a source have a property interest in his or her cells? Can scientists clone a celebrity without his or her permission? If the question ever arises, courts will almost certainly recognize a right not to be cloned.

To begin with, a variety of common law tort principles independently and collectively protect an individual's interest in avoiding unwanted intrusions against his or her body and body parts—in various circumstances the intrusion may be deemed a battery, conversion or invasion of privacy.[44]

More to the point, the right not be cloned is supported by recent cases involving in vitro fertilization. In *Davis v. Davis*, reproductive specialists created several embryos by IVF for a Tennessee couple, attempted to implant one, and froze the others. The couple later divorced, whereupon the ex-wife sought to obtain the frozen embryos to implant in her or to transfer to another woman. Her ex-husband opposed her, contending that he had a right not to have offspring created against his will. The Supreme Court of Tennessee agreed: While it recognized the important interest of both parents and the "special status" of the embryos, it ultimately held that the husband should not be compelled to become a father against his will.[45]

Davis was difficult because each of the disputants contributed gametes toward the creation of the embryos. Even so, the final ruling gave priority to the right to avoid genetic parentage. The New York State Task Force on Life and the Law, in its recent report on assisted reproductive technologies, has also noted with support a gamete donor's right "not to be made a genetic parent against one's will."[46]

To be sure, the right to avoid genetic parentage does not strictly include a right not to be cloned, since a clone is biologically more akin to a sibling than a child. But if the underlying interest in *Davis* is viewed as an interest in control over one's genetic reproduction; such interest applies with even greater force on the case of cloning, where the genetic material is entirely from only one person. Accordingly, it is likely that courts would rule that a person cannot be cloned against his or her will.

Developments in biotechnology have raised other relevant questions concerning the extent to which individuals retain the right to control the use of their cells. In the noted case *Moore v. Board of Regents of the University of California*, physicians used blood samples taken from a patient to create a cell line and secured a patent for the cell line worth an estimated $3 billion. The patient sued, alleging that the physicians converted his property. The Supreme Court of California rejected his suit, holding that, under California law, the patient did not retain an interest in his cells once they were removed from his body. It also reasoned that the patented cell line was factually and legally distinct from the cells removed from his body, and thus not his property.[47]

However, *Moore* cannot be read to support the ability of researchers to engage in human cloning from discarded cells. First, Moore could assert only a property interest, whereas a person challenging the use of his or her cells for cloning can assert the compelling interest in avoiding reproduction—an interest analogous to the one identified in *Davis.* Moreover, the *Moore* decision was driven, in large part, by the court's wish not to jeopardize biotechnological advances important to public health; a court will be far less indulgent of cloning.

III. Family Law Issues

Assisted reproductive technologies and surrogacy already pose new challenges in identifying a child's parents for various legal purposes, particularly custody and child support. Notably, a child may already have at least six persons who might be found to be the child's legal parent: the genetic father, the genetic mother, the birth mother, the birth mother's husband and the adoptive parents. Some of these contenders may relinquish their potential claims prior to conception (e.g., a sperm or egg donor) or after birth (e.g., a birth mother who consents to adoption). But in the absence of such step, a dispute over legal parenthood may ensue. Traditionally, courts

will only identify one person as the child's lawful father and one person as the child's lawful mother. However, the bifurcation of maternity into its genetic and gestational components raises the possibility that a court may identify two lawful mothers, each of whom may have custody rights or support obligations.

Cloning by the somatic cell transfer technique further complicates matters. Under the technique, genetic material can be taken from the cell of one person, infused in the denucleated ovum of a second woman, and implanted in the womb of a third woman. Should the question of parenthood arise, only one item is clear: Under common law principles, the woman who bears the child will likely be deemed a lawful mother.

Determining the identity of the other parent(s) will draw courts into less-charted territory. However, they can be expected to look to genetic connection, age and the parties' expectations. Thus, the person who supplied the genetic material (the "source") would likely be deemed the clone's biological "parent" if he or she is an adult. However, if the source is also a child, the source may be viewed as the clone's sibling, while the source's parents may be deemed the clone's parents. A dispute over parenthood among various contenders would likely be resolved by resorting to the most basic principle: the best interests of the child.

Another novel issue is posed by the status of the second person, who supplies an ovum but not its genetic material.[48] There is neither precedent for nor even a name for this person's reproductive contribution. Such person is neither a genetic nor gestational mother, but has supplied a necessary biological component to the process. If a dispute over maternity were to arise and was not resolved by the parties' prior agreement, one might hazard a guess that, due to such woman's lesser biological connection to the clone, a court would find that she has fewer legal rights and responsibilities than the genetic relative or birth mother.

IV. Rights of the Clone

Some commentators fear that cloning will be used to create human beings for their anatomical parts, or for other exploitative purposes. But a human clone would be a human being, and thus in this country would have the rights of other citizens. In particular, the prohibition of slavery in the Thirteenth Amendment would forbid subjecting a clone to involuntary servitude. More broadly, the Fourteenth Amendment equal protection clause would require the federal government and states to afford clones the same rights as non-clones. These principles alone are enough the assure that the legal system will not support the involuntary exploitation of clones.

Moreover, prior to birth, the clone embryo or fetus is apt to have the same rights as other embryos and fetuses. Those rights are limited, are still being identified and are subject to a woman's right to abortion. But they do include, for example, the right, upon birth, to sue for damages for pre-birth intentional or negligent acts that cause the resulting child to be injured.[49]

These principles do not ensure the non-exploitation of clones. For example, cloning could be used to try to create an individual who, by genetics and child-rearing, can be expected to perform a service or furnish a value, even if not compelled to do so. If scientists clone Mark McGwire and train the resulting child to play baseball, they may well "grow" a valuable athlete. But assisted reproduction technologies have already introduced possibilities for manipulative breeding. Moreover, parents have always had children for a variety of reasons, some altruistic, some self-centered, even exploitative. As explained above, the law will afford clones the same protections as others; presumably, additional safeguards would be added as needs are identified.

V. Conclusion

This discussion was not offered to support any specific policy regarding human cloning, but to examine legal issues raised by the practice. Clearly, additional issues could be identified, and those identified could be analyzed further. But one point that resounds through this discussion is that the issues raised by cloning, though unique in some respects, are fundamentally similar to those confronted by the law in other contexts. In particular, new assisted reproductive technologies have raised several essentially similar legal questions, including consent to research on embryos, malpractice in assisted reproduction, the right to avoid genetic parentage and the determination of parentage.

Thus, a web of settled and emerging legal principles already in place addresses many of the issues raised by human cloning. An understanding of that web of principles is needed to inform the debate on the need for new laws.

Endnotes

1. For the purpose of this article, "human cloning" or "cloning" refer only to the creation of a human being from the cells of an already born human, whether by the somatic cell nuclear transfer technique used to create Dolly, or some other yet-to-be-devised approach.
2. In contrast, the cloning of human embryos by deliberate "twinning" has occurred. See Gina Kolata, *Scientist Clones Human Embryos, and Creates an Ethical Challenge*, N.Y. TIMES, Oct. 24, 1993 at A1.
3. However, the federal appropriations act for FFY 1997-98 prohibits funding for the creation of a human embryo and defines an embryo to include organisms derived by "fertilization, parthenogenesis, *cloning*, or any other means from one or more human gametes or human diploid cells." Pub. Law 105-78 § 513.
4. *E.g.,* California, 1997 Cal. ALS 688 (1997) (prohibiting human cloning); Michigan, 1998 Mi. ALS 108 (same); Missouri, 1998 Mo. SB 722 (prohibiting use of state funds for human cloning research); Rhode Island, 1998 R.I. ALS 189 (prohibiting human cloning).
5. National Bioethics Advisory Commission, *Cloning Human Beings* (1997) at iv.
6. S.1601, introduced Feb. 3, 1998.
7. *See* Caroline Daniel, *Conflicting Aims Leave Ban on Human Cloning in Limbo*, WASHINGTON POST, July 26, 1998, p. A8.

8. Senate Bill No. 2877-B (1998), Assembly Bill No. 5383-B (1998). For the record, the NYS Bar Association Committee on Biotechnology, which I chair, issued a Legislative Report in opposition to S.2877, contending that the proposal to criminalize cloning was premature and lacked a sufficient secular rationale.
9. Senate Bill No. 5993-A (1998), Assembly Bill No. 9116 (1998).
10. Assembly Bill No. 9183 (1998).
11. Senate Bill No. 5993-A (1998), Assembly Bill No. 9116 (1998). The NYS Bar Association Committee on Biotechnology issued a Legislative Report in opposition to these bills, contending that they were premature and lacked a sufficient secular rationale.
12. Senate Bill No. 6071-A (1998).
13. NY Public Health Law § 12 (PHL).
14. *See* Kathryn D. Katz, *The Clonal Child: Procreative Liberty and Asexual Reproductio*n, 8 ALB. L. J. SCI. & TECH. 1 (1998); *Note: Human Cloning and Substantive Due Process*, 111 HARV. L. REV. 2348 (1998); *See also*, John A. Robertson, *Embryos, Families and Procreative Liberty: The Legal Structure of the New Reproduction*, 59 S. CAL. L. REV. 939 (1986).
15. *See, e.g.*, *Carey v. Population Services International*, 431 U.S. 678, 685 (1977) ("among the decisions that an individual may make without unjustified government interference are personal decisions relating to marriage, *procreation*, contraception, family relationships, and child rearing and education").
16. *E.g.*, *Lifchez v. Hartigan*, 735 F. Supp. 1361 (N.D. Ill.), *aff'd sub nom. Scholberg v. Lifchez*, 914 F.2d 260 (7th Cir. 1990).
17. 45 CFR part 46.
18. 45 CFR § 46.116(b)(1).
19. 45 CFR §§ 46.201-46.211.
20. National Bioethics Advisory Commission report at 88.
21. PHL art. 24-A.
22. *E.g.*, Ethics Committee of the American Society for Reproductive Medicine, *Informed Consent and the Use of Gametes and Embryos for Research*, 68 FERTILITY AND STERILITY 780 (Nov. 1997). The NIH Human Embryo Research Panel came to similar conclusions.
23. *See* Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* and Public Health Service Act, 42 U.S.C. §§ 262 *et seq.*
24. 42 U.S.C. § 351(c); 21 CFR parts 312, 601.
25. 21 U.S.C. § 333.
26. 58 Fed. Reg. 53248, Oct. 14, 1993.
27. 58 Fed. Reg. 53248, para. III-A(2).
28. Letter from Donna Shalala to Carl Feldbaum, dated April 9, 1998. *See also*, *F.D.A. Stand on Cloning Raises Even More Questions*, N.Y. TIMES, Jan. 21, 1998, A-14.
29. PHL art. 28; N.Y. Comp. Codes R. & Regs. tit. 10, part 405 (NYCRR).
30. 10 NYCRR part 52.
31. 10 NYCRR § 52-8(g).
32. However, the regulations do not reach gametes acquired strictly for research purposes.
33. N.Y. Education Law §§ 6509, 6530. However, professional misconduct includes "conduct in the practice of medicine which evidences moral unfitness to practice medicine." Education Law § 6530(20). Some might contend that cloning experimentation falls within this category.
34. *See Pike v. Honsinger*, 155 N.Y. 201, 209-210 (1898).
35. In fact, in New York courts will enforce a patient's agreement not to sue a physician for injuries resulting from an experimental and inherently dangerous procedure. *Schneider v. Revici*, 817 F.2d 987 (1987); *Colton v. New York Hospital*, 98 Misc. 2d 957 (Sup. Ct. 1979).
36. See Thomas Moore and Matthew Gaier, *Experimental Treatment, Part II*, NY LAW J., Sept. 1, 1998, p. 3, at p. 6, col. 6 (suggesting that a recent Appellate Division decision, *Charell v. Gonzalez*, 673 N.Y.S.2d 685 (1st Dep't 1998) might be read to suggest that non-conventional treatment can in certain circumstances be malpractice *per se*.)
37. PHL § 2805-d.
38. *See Charell v. Gonzalez*, *supra*.
39. PHL § 2805-d(4).
40. *Tebbutt v. Virostek*, 65 N.Y.2d 931 (1985).
41. *Albala v. City of New York*, 54 N.Y.2d 269 (1981).
42. *Woods v. Lancet*, 303 N.Y. 349 (1951).
43. *E.g.*, *Alquijay v. St. Luke's-Roosevelt Hospital*, 63 N.Y.2d 978 (1984).
44. *See* W. P. Keeton et al., PROSSER AND KEETON ON TORTS (5th ed.) § 9 (battery); § 15 (conversion); § 117 (privacy).
45. 842 S.W.2d 388 (1992). More recently, the New York State Court of Appeals decided a similar dispute in which a woman sought custody of frozen "pre-zygotes" for purposes of implantation, while her former husband opposed being made a father against his will. The Court of Appeals rejected the wife's petition, but did so on the basis of the parties' prior written agreement to donate the pre-zygotes in the event of a custody dispute. Accordingly, the decision does not add or detract from the notion of a right to avoid procreation. *Kass v. Kass* ___, N.Y.2d ___ (May 7, 1998).
46. NYS Task Force on Life and the Law, *Assisted Reproductive Technologies* at 314 (1998).
47. 793 P.2d 479 (Cal. 1990).
48. Actually, the child may acquire some DNA from the mitochondria in the egg, and thus have some minor genetic relationship to the egg donor.
49. *See* note 31.

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Elder Law Update

by Howard S. Krooks*

The Elder Law Update column is designed to provide members of the Health Law Section with information regarding recent legislative changes and case law in the field of elder law. In this edition, I discuss the decision of the New York Court of Appeals in *Golf v. New York State Department of Social Services*,[1] regarding the allocation of income and resources to the community spouse of a nursing home resident who applies for Medicaid benefits. In addition, I provide an update regarding *Estate of Jeannette Dionisio v. Westchester County Department of Social Services*,[2] a recent case in the area of Medicaid eligibility involving the execution of a waiver of the right of election by a spouse who subsequently applied for nursing home Medicaid benefits. Also, I provide an update regarding *Commissioner of the Department of Social Services of the City of New York v. Benjamin Spellman*,[3] in which the Appellate Division, First Department, upheld the decision of the Supreme Court, New York County, which denied a community spouse's motion to dismiss an action commenced by the Department of Social Services to recover Medicaid benefits paid on behalf of the institutionalized spouse. Finally, I have included an update regarding section 4734 of the Balanced Budget Act of 1997, which shifted potential criminal liability from those who transfer assets (as was the case under the former section 217 of the Health Insurance Portability and Accountability Act of 1996) to those who counsel or assist such individuals for a fee in connection with an application for nursing home Medicaid benefits.

The New York State Court of Appeals Holds that Local Departments of Social Services May Apply the Income-First Rule in Allocating Income and Resources to a Community Spouse

Before I discuss the *Golf* case, a brief synopsis regarding the Medicaid concepts involved in the case would be useful. The scenario in which the *Golf* issue typically arises involves a husband (for example) who goes into a nursing home whose wife remains in the community. As a "community spouse,"[4] the wife is permitted under New York law to have as much as $80,760[5] in resources and up to $2,019 of monthly income (known as the Minimum Monthly Maintenance Needs Allowance, or "MMMNA") without impacting on her husband's eligibility to receive Medicaid nursing home benefits. As long as the husband, known as the "institutionalized spouse,"[6] has less than $3,500 in resources, and is not otherwise ineligible for benefits, he may qualify for Medicaid to cover the cost of care provided to him in the nursing home. Suppose, however, that the community spouse has more than the $80,760 in resources permitted under Medicaid regulations but less than $2,019 in monthly income. Can the community spouse keep more than $80,760 in order to generate enough income to raise her monthly income to $2,019 or must her husband's income first be allocated to raise her monthly income to the MMMNA (resulting in her having to spend down her assets to the $74,820-$80,760 level known as the "community spouse resource allowance" or "CSRA").[7]

It is preferable to seek an "enhanced CSRA" (an allocation of the resources first) since the income of the institutionalized spouse generally ceases upon the institutionalized spouse's death, leaving the community spouse without a future source of income and resources only up to the CSRA amount of between $74,820-$80,760. On the other hand, an enhanced CSRA provides the community spouse with additional resources which will generate additional income for the community spouse even after the institutional spouse dies. Thus, the enhanced CSRA approach (allocating resources first) provides the best spousal impoverishment protection for the community spouse, similar to the protection afforded funds held by a community spouse in an individual retirement account (pension funds belonging to an ineligible or nonapplying legally responsible relative which are held in individual retirement accounts or in work-related pension plans, including plans for self-employed individuals such as Keogh plans, are disregarded for budgeting purposes under 18 NYCRR section 360-4.6(b)(2)(iii)).

Prior to the Court of Appeals' decision in *Golf*, the Appellate Division, Fourth Department, held that "the resources of the institutionalized spouse should be attributed to the community spouse to the level of the MMMNA *before* income from the institutionalized spouse is attributed to the community spouse [emphasis added]." The position of the New York State Department of Social Services that income should be transferred first is stated in an administrative directive[8] which provides that "[t]he community spouse may be able to obtain additional amounts of resources to generate income when the otherwise available income of the community spouse *together with the income allowance from the institutionalized spouse* [emphasis added] is less than the maximum monthly income allowance."

Despite the Appellate Division holding, the New York State Department of Social Services upheld the application of the income-first rule in several fair hearing decisions involving upstate departments of social services, which took the position that their policy of applying the income-first rule was correct since *Golf* "was in litigation" (referring to the fact that the New York State Department of Social Services appealed the Appellate Division's decision to the New York State Court of Appeals). The Court of Appeals resolved the resources-first vs. income-first conflict in its April 3, 1998, decision, holding that

the state's interpretation of federal and state Medicaid regulations as allowing it to apply the income-first rule was reasonable, and therefore the Appellate Division decision was reversed.

Under applicable Medicaid law, if either spouse establishes that income generated by the community spouse resource allowance established by the social services district (the aforementioned $74,820-$80,760 in New York) is inadequate to raise the community spouse's income to the MMMNA (the aforementioned $2,019 per month in New York), the Department of Social Services "*shall* establish a resource allowance for the spousal share of the institutionalized spouse adequate to provide such minimum monthly maintenance needs allowance [emphasis added]."[9] The majority opinion in *Golf* noted that the state's definition of "community spouse's income" to include both the community spouse's personal income and the income of the institutionalized spouse was in accordance with public policy and not explicitly prohibited by the regulations. Therefore, a community spouse is entitled to an enhanced resource allowance only if his and his spouse's combined income is insufficient to provide him with the MMMNA. The one dissenting judge, Judge Bellacosa, asserted that there was no statutory authority for defining the community spouse's income to include both the income of the community spouse and the income of the institutionalized spouse. Judge Bellacosa further stated that the New York State Legislature's addition of the term "resource allowance" to the relevant statutory provision (where the federal law is vague and just states that an "amount" must be applied to raise the community spouse's income to the MMMNA, without specifying whether the amount should be income or resources) is a legislative directive to apply the resources-first rule. The Court of Appeals' narrow interpretation of the federal and New York State Medicaid scheme is consistent with a series of Court of Appeals and lower court decisions recently decided.[10]

Motion for Leave to Appeal *Estate of Jeannette Dionisio v. Westchester County Department of Social Services* Is Denied

As I reported in the Winter 1998 issue of the *Health Law Journal*, the Appellate Division, Second Department, held in *Estate of Jeannette Dionisio v. Westchester County Department of Social Services*[11] that the Westchester County Department of Social Services correctly calculated and imposed a penalty period as a result of the execution of a waiver of the right of election in connection with a surviving spouse's application for Medicaid nursing home benefits. I refer the reader to the Winter 1998 issue for a discussion of the facts of this case.

On April 2, 1998, the New York Court of Appeals denied Appellant's motion for leave to appeal.[12] Accordingly, the decision of the Appellate Division, Second Department, stands. The ramifications of this decision are significant from a planning perspective. Based upon the *Dionisio* decision, two unwary spouses who execute mutual waivers of the right of election as part of an estate plan (a common planning technique for spouses in second marriages) may be surprised to learn that if one of them dies and the surviving spouse enters a nursing home, the execution of the waiver of the right of election will result in a penalty period commencing on the date of death of the deceased spouse, thereby rendering the surviving spouse ineligible for Medicaid nursing home benefits for a period of time. Since death is one of few remaining events that cannot be "planned," the execution of a waiver of a right of election should be done with caution. Unfortunately, the *Dionisio* decision, and the Court of Appeals' denial of Appellant's motion for leave to appeal, represents another case where the courts have adopted a restrictive view of the Medicaid statutes. This restrictive view also is applied by the Court of Appeals in the *Golf* case, discussed above.

Appellate Division, First Department, Affirms Supreme Court's Denial of Community Spouse's Motion to Dismiss an Action Brought by the Department of Social Services to Recover Benefits Paid on Behalf of the Institutionalized Spouse

On April 30, 1998, the Appellate Division, First Department, held in *Commissioner of the Department of Social Services of the City of New York v. Benjamin Spellman*[13] that New York State Social Services Law allows the New York City Department of Social Services (DSS) to recover from a community spouse Medicaid benefits paid for the care of his wife, to the extent he has resources in excess of the CSRA and where he has refused to make his income and resources available for her care. In its decision, the Appellate Division determined that the Supreme Court's denial of Mr. Spellman's motion to dismiss was proper. Mr. Spellman had argued, *inter alia*, that under the New York State statutory framework, DSS was only entitled to sue him for prospective support and not to recover the cost of past benefits paid. The Appellate Division rejected Mr. Spellman's argument and found that DSS may recover from Mr. Spellman pursuant to a statutory implied contract under Social Services Law section 366-c. I refer the reader to the Summer 1997 issue of the *Health Law Journal* for a more in-depth legal analysis and discussion of the lower court decision in this case.

The United States Attorney General Will Not Enforce Section 4734 of the Balanced Budget Act of 1997

In the Spring 1997 issue of the *Health Law Journal*, I discussed the recently enacted section 217 of the Health Insurance Portability and Accountability Act of 1996. As a result of that legislation, certain transfers of assets made on or after January 1, 1997, for the purpose of qualifying for Medicaid benefits and which resulted in a period of ineligibility (a period during which an individual does not qualify for

nursing home Medicaid benefits) triggered federal criminal liability punishable by up to one year in prison and/or a fine of up to $10,000. In the Summer 1997 issue of the *Health Law Journal*, I reported in this column that two separate bills had been introduced in the Senate and in the House which, if enacted into law, would shift the risk of criminal liability from senior citizens (the individual who transfers assets and subsequently applies for Medicaid) to attorneys and other professionals who counsel clients in this area. On August 5, 1997, President Clinton signed into law section 4734 of the Balanced Budget Act of 1997, which repealed the prior section 217 of the Health Insurance Portability and Accountability Act of 1996. Thus, as of August 5, 1997, no criminal liability attached to an individual who transferred assets to qualify for Medicaid. Section 4734 replaced section 217 and purported to make it a misdemeanor for a paid advisor to knowingly and willfully counsel or assist another to dispose of assets for the purpose of obtaining Medicaid, if the disposition resulted in the imposition of a penalty period. In the Winter 1998 issue of the *Health Law Journal*, I reported that the New York State Bar Association, in an unprecedented action, filed a complaint on December 4, 1997, in the United States District Court, Northern District of New York, challenging the constitutionality of section 4734. In addition, on January 27, 1998, the New York State Bar Association filed a motion for a preliminary injunction prohibiting the enforcement of section 4734.

In a letter dated March 11, 1998, addressed to the United States House of Representatives, U.S. Attorney General Janet Reno stated that "the Department of Justice will not defend the constitutionality of [section 4734] . . . because the counseling prohibition in that provision is plainly unconstitutional under the First Amendment." Ms. Reno adopted the New York State Bar Association's argument that section 4734 violates free speech protections afforded by the Fifth Amendment by precluding attorneys from giving advice to seniors about conduct which is otherwise lawful, stating that section 4734 "would prohibit attorneys and other professional advisors from 'counsel[ing]' their clients to engage in an estate-planning strategy that itself is lawful." In her March 13, 1998, answer to the lawsuit, and in her March 27, 1998, opposition to the New York State Bar Association's motion for a preliminary injunction, Janet Reno reiterated her intention not to enforce section 4734.

On April 7, 1998, Chief United States District Judge Thomas J. McAvoy granted the New York State Bar Association's motion for a preliminary injunction. This decision was significant, given the high standard which must be met for a preliminary injunction to be granted against the government. Generally, a preliminary injunction against a non-governmental party will be granted only if the moving party can show (1) irreparable harm; and either (2) likelihood of success on the merits or (3) sufficiently serious questions going to the merits to make them fair ground for litigation, and a balance of hardships tipping decidedly in favor of the movant. However, where a moving party seeks a preliminary injunction against a governmental agency, the moving party must satisfy the higher "likelihood of success on the merits" standard enumerated above, and the preliminary injunction will not be granted against a governmental agency if the moving party, in addition to showing irreparable harm, merely satisfies the "sufficiently serious questions" standard enumerated above.

In the instant case, the potential for self-censorship and the deprivation of First Amendment protections to free speech were deemed to constitute per se irreparable harm. With respect to the likelihood of success on the merits standard, given the U.S. Attorney General's position that she would not defend the constitutionality of section 4734 or enforce the statute, Judge McAvoy decided that the likelihood of success on the merits was sufficiently demonstrated to warrant the issuance of the preliminary injunction.

Notwithstanding Ms. Reno's assurances that she does not intend to defend the constitutionality of section 4734 or enforce its provisions, the New York State Bar Association is proceeding with the litigation out of concern that section 4734 is still the law on the books, and future U.S. Attorneys General may not concur with Ms. Reno's interpretation of this provision. I will keep members of the Health Law Section informed with respect to section 4734 and the New York State Bar Association lawsuit in future issues of the *Health Law Journal*.

Endnotes

1. N.Y.L.J., April 3, 1998, p. 26, col. 1, *rev'g* 634 N.Y.S.2d 581 (4th Dep't 1995).
2. N.Y.L.J., Nov. 24, 1997, p. 31, col. 2.
3. N.Y.L.J., May 5, 1998, p. 25, col. 3, *aff'g* N.Y.L.J., Feb. 10, 1997, p.1, col. 6.
4. "Community spouse" means a person who is the spouse of an institutionalized person and who is residing in the community. N.Y. Comp. Codes, R. & Regs. tit. 18, § 360-4.10(a)(2) (NYCRR).
5. In New York State, a community spouse's resource allowance may be anywhere from $74,820-$80,760, depending upon the total amount of marital assets. Social Services Law § 366-c(2)(d); 42 U.S.C. § 1396r-5(c)(1). Thus, if the couple has assets in excess of $161,520, the community spouse resource allowance is $80,760. If the couple has assets valued at less than $149,640, the community spouse resource allowance is $74,820. 96 ADM-11; 96 ADM-14. In other words, the community spouse may keep a minimum of $74,820 if the couple's combined countable resources are less than or equal to $149,640. If the couple's combined countable resources are greater than $149,640, the community spouse may retain one-half of the countable resources up to a maximum of $80,760.
6. "Institutionalized spouse" means a person: who is in a medical institution or nursing facility and is likely to remain in a medical institution or nursing facility for at least 30 consecutive days or is receiving home- and community-based services provided pursuant to a waiver under § 1915(c) of the federal Social Security Act (SSA) and is likely to receive such services for at least 30 consecutive days; and who is married to a spouse who is not in a medical institution or nursing facility or who is not likely to receive such home- and community-based services pursuant to a waiver under SSA § 1915(c) for 30 consecutive days. 18 NYCRR § 360-4.10(a)(7).
7. Please note that in the event the community spouse is not entitled to an enhanced resource allowance in the *Golf* situation, the community spouse may still keep additional resources above the CSRA by executing a "spousal refusal." This technique is permitted under federal and New York State law. However, in accordance with the *Spellman* case

(also discussed herein), the Department of Social Services may seek to recover from the community spouse's excess resources the cost of benefits paid on behalf of the institutionalized spouse.

8. 96 ADM-11.

9. Social Services Law § 366-c(8)(c); 18 NYCRR § 360-4.10(c)(7).

   Federal law similarly provides that

   > if either such spouse establishes that the community spouse resource allowance . . . is inadequate to raise the community spouse's income to the minimum monthly maintenance needs allowance, there shall be substituted, for the community spouse resource allowance under subsection (f)(2) of this section, an amount adequate to provide such a minimum monthly maintenance needs allowance. 42 U.S.C. § 1396r-5(e)(2)(C).

10. See, for example, *Gomprecht v. Sabol*, 86 N.Y.2d 47, 629 N.Y.S.2d 190 (1995), where the Court of Appeals held that the narrower "significant financial distress" standard must be applied in family court where the community spouse seeks a greater MMMNA, rather than the more liberal "lifestyle" standard.

11. 665 N.Y.S.2d 904 (2d Dep't 1997).

12. N.Y.L.J., April 2, 1998, p. 25, col. 3.

13. N.Y.L.J., May 5, 1998, p. 25, col. 3, *aff'g* N.Y.L.J., Feb. 10, 1997, p. 1, col. 6.

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'NET WORTH

by Margaret Moreland Murray*

Problem: It's hard enough keeping a law library up to date. How can practitioners get all the medical information they need? **Solution**: The Internet, of course!

We all know that there is a huge amount of consumer health information on the Internet. That is wonderful for public awareness purposes, but it is usually not the type of information needed by an attorney. Professional-level materials can also be found on the World Wide Web; it just takes a bit more digging to find them. The following medically oriented sites will all yield reliable reference information.

The Merck Manual of Diagnosis and Therapy

http://www.merck.com/pubs/mmanual/

This online version, like its identical printed counterpart, includes a browsable table of contents and index. Even better, however, is the fact that it is fully searchable by word. A search for "amniocentesis" yielded a main entry entitled "Prenatal Diagnostic Techniques" in section 14, Gynecology and Obstetrics, section 177, Genetic Evaluation and Counseling. There were also links to 29 other locations where "amniocentesis" was mentioned, such as "Single-Gene Defects," "Mental Retardation" and "Antepartum Risk." The main article was six paragraphs long and discussed the purpose of the procedure, timing, process, unusual amniotic fluids, risks to mother and fetus, and even the process for twin pregnancies.

Note that spelling is very important when doing a word search. I originally typed "amniocentisis" and got no hits at all!

Unfortunately, the site is not easy to navigate. When you type in the URL you are linked to a page where you can enter a word to search. To get to the Table of Contents you have to scroll down and click on "Continue." From there you can get to the alphabetic index, which does have links to all of its entries, but to do another word search you have to go back to the original page.

MedicineNet

http://www.MedicineNet.com/

The chief editor of this site is William Shiel, M.D., a Fellow of the American Colleges of Physicians and Rheumatology, who is in private practice at the Arthritis Center of Southern Orange County, California and an Associate Clinical Professor of Medicine at the University of California, Irvine. All of the other contributing writers and editors are also board-certified physicians with various specialties. There is a link on the home page, under "Who is MedicineNet?," with all the names and brief biographies.

From the home page there are various research paths you can take. The "Medical Dictionary" is an A-to-Z compilation of over 4,000 short definitions. Click on the initial letter and then scroll down to the specific word. Here "amniocentesis" is briefly defined: "Procedure used in prenatal diagnosis to obtain amniotic fluid which can be used for genetic and other diagnostic tests." "Amniotic fluid" is also defined. Occasionally, definitions contain additional—even whimsical—information. For example, the definition of "cesarean section" includes an explanation of the varied spellings, a description of the term's origin in the birth of Julius Caesar and a discussion of the allusions in *Macbeth* regarding the birth of Macduff!

For a much more complete discussion click on "Diseases & Treatments." Here the entry will include the following divisions: Main Article, Related Terms, Related Diseases & Treatments and Answers to Viewer Questions. The main article on amniocentesis is three pages long and includes links to Web sites with additional information. Two related terms are listed, for which definitions may (or may not) be found in the Medical Dictionary. Related Diseases & Treatments, in this case Achondroplasia and Turner's syndrome, have their own entries in this section. Answers to Viewer Questions contains replies from the writers and editors in response to questions posed through "Ask the Experts!" on the home page.

"Pharmacy/Drugs" includes entries under both prescription and over-the-counter drug names. Its divisions are similar to "Diseases & Treatments": Main Article, Related Diseases & Treatments, and Answers to Viewer Questions. There are also links under the headings Related Pharmacy and Related News Articles. The typical main article has the following sections: Drug Class, Generic, Prescription, Preparations, Storage, Prescribed For, Proper Use, Precautions and Side Effects.

The MedicineNet home page also has links to "Hot News!" and "Health Facts." At the beginning of September, "Hot News!" had articles on osteoporosis, Lyme disease, obesity, a new muscle disease, vertebroplasty and proposed managed health care changes. "Health Facts" has articles that present more of an overview. Recently it had articles on goose bumps, DNA testing, bones, cataract surgery and Cary Middlecoff, Dentist and Golfer. These articles are dated (always a good feature) and gathered in the Medical News Archives and the Health Fact Archives, both of which can be browsed by subject.

The On-Line Medical Dictionary
http://www.graylab.ac.uk/omd/index.com

This dictionary was created by Dr. Graham Dark and is distributed by CancerWeb. It contains over 46,000 definitions and is fully browsable by letter. There is also a growing collection of definitions by subject area. Its coverage is very broad, including "anything to do with medicine or science." Most entries are brief, but they contain many linked cross-references. For example, the entry for "amniocentesis" reads: "Sampling of the fluid in the amniotic sac. In humans this is carried out, between the 12th and 16th week of pregnancy, by inserting a needle through the abdominal wall into the uterus. By karyotyping the cells and determining the proteins present, it is possible to determine the sex of the foetus and whether it is suffering from certain congenital diseases such as Down's syndrome or spina bifida." All of the underlined terms are cross-referenced. Another feature adding to the site's usefulness is the date on each entry, indicating when it was created, updated or first date-stamped. Of course, there is also a disclaimer that there should be no inference that the definition was current on such date. An additional feature is a list of terms that were added or modified within the past 20 days.

Dictionary of Online Medical Resources
http://home.ipoline.com/~guoli/med/0intro.htm

Over the past two-and-a-half years Kwok Lee (Guo Li), M.D., Ph.D., has been creating this dictionary as well as an online Dictionary of Information for Patients and an online English-Chinese Dictionary of Medical Terms. "Medical Resources" now contains over 1,400 brief definitions, with some cross-references. The very useful, but frustrating, feature of this dictionary is the fact that many entries also have links to Internet resources for more detailed information. It is frustrating because some of the resources are "dead links"; this site is in need of more rigorous updating. However, the links that do work lead to some quite interesting materials, some of which would be difficult to locate elsewhere. "Alpha fetoprotein" has a link to a detailed position statement by the Wisconsin Association for Perinatal Care, as well as to patient-directed information from the Arnot Ogden Medical Center.

Multilingual Glossary of Technical and Popular Medical Terms in Nine European Languages
http://allserv.rug.ac.be/~rvdstich/eugloss/welcome.html

This glossary contains almost 2,000 words and is the result of a project by the European Commission, the Heymans Institute of Pharmacology at the University of Gent and the Mercator School's Department of Applied Linguistics. It is listed here only because it is unique; it is extremely difficult to use.

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