
CLIENT NEWSLETTER

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DPH Issues Final HIV Reporting Regulations

On January 23, 2007, the Public Health Council (“PHC”) of the Massachusetts Department of Public Health (“DPH”) approved and issued Emergency Amendments to 105 CMR 300.000: Reportable Diseases, Surveillance and Isolation and Quarantine Requirements. The Emergency Amendments require physicians and other health care providers in Massachusetts, including laboratories, to report to DPH the name of any patient who tests positive for HIV.

As previously reported by The Rogers Law Firm in a Client Advisory issued on November 21, 2006, physicians and other health care providers in Massachusetts are already required to disclose the names of AIDS patients to DPH. However, until now HIV cases were only reported using a code-based system. The purpose of the Emergency Amendments to the DPH regulations is to ensure access to federal funding. In December of 2006, the Ryan White HIV/AIDS Treatment Modernization Act of 2006 was signed into law by President Bush. The law mandates that states receiving Ryan White funding must implement an HIV reporting system acceptable to the Federal Centers for Disease Control and Prevention (“CDC”) by April 1, 2008, to be eligible for future funding under this law. CDC has indicated that it would only fund full name-based systems acceptable. According to DPH, in order for the data to be sufficiently mature to be counted for funding, Massachusetts must begin the reporting process as of January 1, 2007.

Although the regulations went into effect on January 1, 2007, physicians and other health care providers, including laboratories, will be permitted to amend previously-filed HIV code-based reports to “named reports” by the end of 2007.

Pursuant to the HIPAA Privacy Rule, a physician is permitted to disclose protected health information to a public health authority without the written authorization of the individual or without providing the individual with an opportunity to agree or object to such disclosure (45 C.F.R. 164.512(b)(1)(i)). DPH is a public health authority under the HIPAA Privacy Rule. Therefore, there is no liability exposure for appropriately reporting the names of HIV patients to DPH.

The Rogers Law Firm is available if you have any questions or concerns with respect to these Emergency Amendments.

President Bush Proposes Substantial Medicare and Medicaid Reductions

President Bush recently issued his Fiscal Year 2008 Budget Proposal calling for approximately \$101 billion in savings from Medicare and Medicaid over five years. The Budget Proposal calls for reducing Medicare spending growth from 6.5% to 5.6% over five years through a series of legislative and administrative proposals. These legislative and administrative proposals would provide a total savings of over \$75 billion. The proposed budget also calls for Medicaid cuts which would amount to over \$25 billion over a five year period.

The proposed budget cuts have received significant criticism from both the American Hospital Association and American Medical Association. In particular, it was noted that the proposed budget fails to address Medicare physician payment cuts which in 2008 will result in approximately 10% reductions in physician payments under Medicare.

President Bush's proposed budget also includes \$183 million in discretionary funding to combat fraud and abuse in the Medicare Part D Prescription Drug Benefit and Medicare Advantage Program.

IRS Proposes Good Governance Practices for 501(c)(3) Organizations

The United States Internal Revenue Service ("IRS") recently issued proposed governance guidelines for 501(c)(3) organizations entitled "Good Governance Practices for 501(c)(3) Organizations" ("Guidelines"). The Guidelines are part of the IRS' overall commitment to improving corporate governance for non-profit organizations. The Guidelines suggest that organizations review and consider the following areas to help ensure that directors understand their roles and responsibilities and actively promote good governance practices: Mission Statement; Code of Ethics; Due Diligence; Duty of Loyalty; Transparency; Fundraising Policy; Financial Audit; Compensation Practices; and Document Retention Policy. The following is a brief overview of the Guidelines with respect to each of these areas:

- Mission Statement:

The Guidelines state that "a well-written mission statement shows why the charity exists, what it hopes to accomplish, and what activities it will undertake, where, and for whom."

- Code of Ethics:

The board of a 501(c)(3) organization should consider adopting and regularly evaluating a Code of Ethics for the organization. The Guidelines suggest that the Code of Ethics should be a "principle means" to communicating to all personnel a strong culture

of legal compliance and ethical integrity. The Guidelines also suggest that organizations should adopt an effective policy for handling employee complaints and establish procedures for employees to report, in confidence, suspected financial impropriety or misuse of the charity's resources.

- Due Diligence:

The directors of a 501(c)(3) organization must exercise due diligence consistent with a duty of care that requires a director to act in good faith; with the care of an ordinarily prudent person in like position would exercise under similar circumstances; and in the manner the director reasonably believes to be in the organization's best interests. The Guidelines state that directors should see to it that policies and procedures are in place to help them meet their duty of care.

- Duty of Loyalty:

Directors of an organization owe it a duty of loyalty, which requires that each director act in the interest of the organization rather than in the personal interest of the director or some other person or organization. In this regard, organizations should have a Conflict of Interest Policy which requires annual disclosures, in writing, of any known financial interest that the individual, or the individual's family, has in any business entity that transacts business with the organization.

- Transparency:

The Guidelines state that the board of directors should adopt and monitor procedures to ensure that the organization's Form 990, Annual Reports, and Financial Statements are complete and accurate, are posted on the organization's public website, and are made available to the public upon request.

- Fundraising Policy:

An organization's board of directors should adopt and monitor policies to ensure that fundraising solicitations meet federal and state law requirements and solicitation materials are accurate, truthful and candid.

- Financial Audit:

The Guidelines state that an organization's board should ensure that financial resources are used to further charitable purposes by regularly receiving and reading up-to-date financial statements, including Form 990, auditors' letters and financial and audit committee reports. The Guidelines also state that if an organization uses an independent auditor to conduct an annual audit, the auditing firm should be changed periodically (e.g., every five years) to ensure a "fresh look" at the financial statements.

- Compensation Practices:

The Guidelines state that a successful 501(c)(3) organization pays no more than reasonable compensation for services rendered. In determining reasonable compensation,

the charity may wish to rely on the rebuttable presumption test of Section 4958 of the Internal Revenue Code and Treasury Regulation 53.598.6.

- Document Retention Policy:

The Guidelines state that an effective 501(c)(3) organization will adopt a written policy establishing standards for document integrity, retention and destruction. Document retention policies should include guidelines for handling electronic files and should cover back-up procedures, archiving of documents and regular check-ups of the reliability of the system.

It should be noted that the Guidelines are only “proposed” and the IRS has stated that they will listen to industry feedback. The Rogers Law Firm will continue to monitor any developments in this regard and will provide updates accordingly.

OIG Issues Advisory Opinion Regarding Free Acute Dialysis Treatment Services

The Office of Inspector General (“OIG”) of the United States Department of Health and Human Services (“HHS”) recently issued an Advisory Opinion regarding a hospital’s proposal to provide free acute dialysis treatment services to chronic dialysis patients unable to obtain dialysis in their community. The OIG concluded that although the proposed arrangement could potentially violate the Anti-Kickback Statute and/or the Civil Monetary Penalty Act, it would not impose sanctions against the hospital.

The hospital which requested the Advisory Opinion is an acute care hospital whose mission is to serve underserved populations. The hospital indicates that a high proportion of its patients are indigent. The hospital has a dialysis unit, which serves hospital inpatients and is operated by a non-profit management company. The hospital only offers dialysis services to inpatients and Emergency Department patients in an emergency condition. The hospital does not offer chronic dialysis services for outpatients. According to the Advisory Opinion, patients who need chronic dialysis treatments three times per week, but do not have access to an outpatient dialysis chair in the community, routinely present to the hospital’s Emergency Department or the hospital’s Outpatient Renal Clinic. According to the hospital, chronic dialysis patients may lack access to dialysis for a variety of reasons: no payment source for dialysis; lack of open dialysis chairs in the community; inability to sit in a dialysis chair for the four hour treatment; or behavioral or psychiatric issues that make the patient undesirable to receive dialysis in one of the privately-owned dialysis units in the area. As chronic dialysis patients are unable to obtain dialysis in the community, many of them forego treatment until their conditions become urgent, at which point they present to the hospital’s Emergency Department and are admitted as inpatients to receive emergency dialysis treatment. The Advisory Opinion states that the hospital has ten to fifteen chronic dialysis patients occupying inpatient beds who have been admitted under these circumstances. The hospital does not bill anyone for these admissions; rather, the hospital absorbs all costs associated with these services. The hospital stated that the current arrangement limits other patients’ access to the hospital’s inpatient unit, because chronic dialysis patients are occupying inpatient beds solely to receive weekly dialysis. This results in acute patients in the Emergency Department having to wait for an inpatient bed to become available, which in turn causes the Emergency Department to reach capacity, necessitating diversion of patients to other emergency facilities.

The hospital sought an Advisory Opinion from the OIG regarding a proposed arrangement to address this situation. The proposed arrangement provides that the hospital would admit chronic dialysis patient for dialysis treatment, and then immediately discharge them following treatment. The chronic dialysis patients would be admitted to the hospital and discharged three times per week. The hospital would not bill these patients or any third party payor for these admissions. The hospital would not advertise the availability of these services. Furthermore, as part of the proposed arrangement, the hospital's Renal Case Manager/Social Worker would assist any chronic dialysis patients who became eligible for Medicare or Medicaid in finding an outpatient dialysis chair in the community.

In its Advisory Opinion, the OIG stated that the proposed arrangement could potentially implicate both the Civil Monetary Penalty Act and the Anti-Kickback Statute. The Civil Monetary Penalty Act provides the imposition of civil monetary penalties against any person who gives something of value to a Medicare or Medicaid program beneficiary, that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, petitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or Medicaid. The OIG concluded that the proposed arrangement is unlikely to influence patients to select the hospital as its provider of items or services payable by Medicare or Medicaid. Specifically, the OIG concluded that the free dialysis treatments would not precipitate an ongoing relationship between Medicare or Medicaid patients and a service offered by the hospital, because the hospital does not offer outpatient dialysis services. Furthermore, the hospital will take affirmative steps to locate an available chair for patients requiring dialysis at a local outpatient dialysis facility. Also, the proposed arrangement will not be advertised; rather, patients presenting for services will more likely be influenced by extreme illness that drives them to the hospital's Emergency Department or an outpatient renal clinic or by local dialysis facilities that steer them to the hospital.

The Anti-Kickback Statute makes it a criminal offence to knowingly and willfully offer, pay, solicit or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. In its Advisory Opinion, the OIG concluded that the proposed arrangement poses a minimal risk of violating the Anti-Kickback Statute. First, the hospital would absorb all costs associated with providing dialysis services to chronic dialysis patients. Second, the proposed arrangement is expressly designed to discourage chronic dialysis patients from self-referring back to the hospital for dialysis by providing the assistance of the hospital's Renal Case Manager/Social Worker to help place them in local outpatient dialysis chairs as soon as possible. Third, the proposed arrangement is designed to efficiently treat chronic dialysis patients so that the inpatient beds that they currently occupy can be made available for other patients who require inpatient care and for whom the hospital likely can bill for services. Therefore, the hospital has a legitimate business purpose for participating in the proposed arrangement unrelated to the provision of services to chronic dialysis patients. Finally, the provision of free dialysis treatments to the chronic dialysis patients is consistent with the hospital's mission to serve underserved populations.

The OIG concluded that the proposed arrangement provides a minimal risk of federal health care program abuse, while providing "significant benefits" to an underserved patient population. Therefore, the OIG stated that it would not seek to impose administrative sanctions against the hospital under either the Civil Money Penalty Act or the Anti-Kickback Statute for the proposed arrangement.

Massachusetts Legislature Expands Definition of Medical Peer Review Committees

On January 3, 2007, Chapter 437 of the Massachusetts Acts of 2006 (“An Act Relative to Medical Peer Review Committees”) was signed into law. The Act expands the definition of “Medical Peer Review Committee” under section 1 of chapter 111 of the Massachusetts General Laws to include “a committee of a pharmacy, society or association that is authorized to evaluate the quality of pharmacy services or the competence of pharmacists and suggest improvements in pharmacy systems to enhance patient care; or a pharmacy peer review committee established by a person or entity that owns a licensed pharmacy or employs pharmacists that is authorized to evaluate the quality of pharmacy services or the competence of pharmacists and suggest improvements in pharmacy systems to enhance patient care.” The Act also amends section 203 of chapter 111 of the Massachusetts General Laws to provide that a licensed pharmacy may establish a pharmacy peer review committee to evaluate the quality of pharmacy services or the competence of pharmacists and suggest improvements in pharmacy systems to enhance patient care.

The Massachusetts Medical Peer Review Privilege Act (Massachusetts General Laws, c. 111, §204) provides that “proceedings, reports and records of a medical peer review committee shall be confidential and shall not be subject to subpoena or discovery.” Therefore, the Act will expand the medical peer review privilege to include pharmacy peer review committees.

NSTC to Develop Research Compliance Guidelines

The National Science and Technology Council (“NSTC”) is reportedly working with several federal agencies, including the Office of Inspector General and the Food and Drug Administration, to develop voluntary research compliance guidelines applicable to all recipients of federal research funds. The intent of NSTC is to issue the guidelines in draft form for public comment at some point this spring. It is believed that this will be a major development in the research industry. Although compliance with the guidelines will be voluntary, it is widely believed that adherence with these guidelines will become the new standard for research compliance.

The NSTC was established by Executive Order on November 23, 1993. The organization is the principle means within the Executive Branch of the United States Government to coordinate science and technology policy across the diverse entities that make up the federal research and development enterprise.

The Rogers Law Firm will continue to monitor any developments in this regard and will provide updates accordingly.

This Newsletter is published by The Rogers Law Firm to keep its clients informed of developments in health law. The Newsletter should not be construed or relied upon as legal advice or legal opinion on any specific facts or circumstances. If you have any questions or concerns regarding the articles contained in the Newsletter or would like legal advice or legal opinion concerning a specific matter, please do not hesitate to contact any of the attorneys at The Rogers Law Firm, at (617) 723-1100.