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NIH PUBLISHES FINAL GUIDELINES ON FEDERAL FUNDING FOR STEM CELL RESEARCH

On July 7, 2009, the National Institutes of Health ("NIH") published Final Guidelines for research involving human embryonic stem cells. The "National Institutes of Health Guidelines for Research Using Human Stem Cells" (the "Guidelines") pertain to the expenditure of NIH funds for research using human embryonic stem cells. The Guidelines were issued by NIH in response to the March 9th Executive Order from President Obama that lifted the ban on Federal funding for human embryonic stem cell research. The Guidelines allow funding for research using human embryonic stem cells that were created using in-vitro fertilization for reproductive purposes and were no longer needed for this purpose and that were donated by the individuals who sought reproductive treatment and who gave voluntary written consent for the human embryos to be used for research purposes. The Guidelines also specify that for embryonic stem cells to be eligible for Federal funding, they must meet certain other requirements, including the following:

(a) all options available in the health care facility where treatment was sought pertaining to the embryos no longer needed for reproductive purposes were explained to the individual who sought reproductive treatment;

(b) no payments, cash or in kind, were offered for donated embryos;

(c) policies and procedures were in place at the health care facility where the embryos were donated, that neither consenting nor refusing to donate embryos donated for research would affect the quality of care provided to potential donors; and

(d) there was a clear separation between the prospective donor's decision to create human embryos for reproductive purposes and a prospective donor's decision to donate human embryos for research purposes.

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The Guidelines also require that during the consent process, the donors were informed of the following: (i) that the embryos would be used to derive human embryonic stem cells for research; (ii) what would happen to the embryos in the derivation of the human embryonic stem cells derived from the embryos might be kept for many years; (iv) that the donation was made without any restriction or direction regarding the individuals who may receive medical benefit from the use of the human embryonic stem cells, such as who could adversely affect the health or welfare of a patient or patients, which adversely affects the physician's clinical privileges for more than thirty days, is reportable to the NPDB.

The Guidelines state that embryos donated before the effective date of the Guidelines (July 7, 2009) could seek review by NIH on whether the core principles and procedures used in the process for obtaining informed consent for donation of the specific embryo were such that the cell line should be eligible for Federal funding.

If you have any questions or concerns regarding the Guidelines, please do not hesitate to contact any of the attorneys in the Health Care Practice Group at The Rogers Law Firm.

NPDB CLARIFIES POSITION ON REPORTING OF PHYSICIAN CONDUCT

In a recent letter to representatives of the American Health Lawyers Association, the Director of the Division of Practitioner Data Banks (the "Director") within the United States Department of Health and Human Services ("HHS") clarified HHS's position on a health care entity's reporting of adverse credentialing decisions based upon a physician's competence or conduct to the National Practitioner Data Bank ("NPDB"). Specifically, the letter from the Director affirms the position that a professional review action, based on competence or professional conduct of an individual physician, which could adversely affect the health or welfare of a patient or patients, and which adversely affects the physician's clinical privileges for more than thirty days, is reportable to the NPDB.

The NPDB Regulations (45 CFR Part 60) provide that a health care entity must report to the NPDB the following actions:

(i) any professional review action that adversely affects the clinical privileges of a physician or dentist for a period longer than thirty days; and

(ii) acceptance of the surrender of clinical privileges or any restriction of such privileges by a physician or dentist -

(A) while the physician or dentist is under investigation by the health care entity relating to possible incompetence or improper professional conduct; or

(B) in return for not conducting such an investigation or proceeding.

A professional review action is defined as "an action or recommendation of a professional review body taken or made in the conduct of a professional review activity, which is based on the competence or professional conduct of an individual physician (which conduct affects or could adversely affect the health or welfare of a patient or patients) and which affects (or may affect) adversely the clinical privileges . . . of the physician."

Representatives of the American Health Lawyers Association requested clarification from HHS as to whether conduct or competence of a physician, which does not adversely affect patient health or welfare, is reportable to the NPDB. In the response from the Director, it was clarified that the standard for professional review actions is applied broadly. Specifically, the letter states that the definition of a professional review action "reaches conduct that not only adversely affects patients, but also actions that have the potential to adversely affect patients." Thus, if a physician's competence or conduct, which triggered an adverse credentialing decision, affects *or could* adversely affect a patient's health or welfare, the adverse credentialing decision is reportable to the NPDB if it is in effect for more than thirty days. The letter goes on to acknowledge, however, that an action which affects or could affect a patient's health or welfare is a factual determination which the health care entity taking the action is in the best position to determine.

The letter from the Director also indicated that the NPDB views intentional misrepresentations by a physician to the hospital body making determinations about the clinical competence of providers as having the potential to adversely affect the health or welfare of a patient. Thus, if a provider's misrepresentation of information to a hospital is the basis for an adverse action that affects clinical privileges for more than thirty days, it would be reportable to the NPDB.

The NPDB is expected to update its Guidebook and publish a new edition by the end of this year.

If you have any questions or concerns regarding reporting of professional review actions to the NPDB, please do not hesitate to contact any of the attorneys in the Health Care Practice Group at The Rogers Law Firm.

HIPAA SECURITY RULE DELEGATED TO OFFICE FOR CIVIL RIGHTS

Secretary Kathleen Sebelius of the United States Department of Health and Human Services ("HHS") recently announced that authority for the administration and enforcement of the Security Rule of the Health Insurance Portability and Accountability Act ("HIPAA") has been delegated to the Office for Civil Rights ("OCR"). Previously, the administration and enforcement of the Security Rule were the responsibility of the Centers for Medicare and Medicaid Services. According to Secretary Sebelius, the delegation for authority of the HIPAA Security Rule to OCR will eliminate duplication and

increase efficiencies in how HHS ensures that Americans' health information privacy is protected. OCR is already responsible for enforcement for the HIPAA Privacy Rule. The Security Rule provides a series of administrative, technical and physical security procedures for covered entities to use to assure the confidentiality of electronic protected health information.

The delegation of the Security Rule to OCR comes at a time when health care providers are seeking to comply with the substantial changes to the HIPAAPrivacy and Security Rules, which are set forth in Title XIII of the American Recovery and Reinvestment Act of 2009. As part of Title XIII of the Act, HHS was tasked with improved enforcement of the Privacy and Security Rules.

HHS FINDS MEDICAID STILL VULNERABLE TO AMBULANCE FRAUD AND ABUSE

The Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") recently issued a report to the Acting Administrator for the Centers for Medicare and Medicaid Services ("CMS") in which it concluded fraudulent billing of Medicaid Non-Emergency Medical Transportation continues to be a significant problem in the Medicaid Program with respect to ambulance services. The report, "Fraud and Abuse Safeguards for State Medicaid Nonemergency Medical Transportation Services" (the "Report"), does not provide any recommendations for steps to prevent fraud and abuse by ambulance providers, but it does provide information about safeguards that have been put into place by State Medicaid agencies to prevent this type of fraud and abuse.

Pursuant to Federal regulations, each State is required to ensure that Medicaid beneficiaries have necessary transportation to and from medical providers. The Deficit Reduction Act of 2005 gave States the option to "establish a non-emergency medical transportation brokerage program in order to more cost-effectively provide" transportation for Medicaid beneficiaries. The OIG indicated that increased reports of fraud and abuse in State non-emergency medical transportation programs, was the basis for its Report. In preparing the Report, the OIG collected data from all State Medicaid agencies regarding their non-emergency medical transportation program operations and the safeguards they had put in place to prevent fraud and abuse. All State Medicaid agencies reported multiple non-emergency medical transportation fraud and abuse safeguards, including screening providers, requiring prior approval of services and implementing methods to detect and prevent improper billing. Nevertheless, non-emergency medical transportation fraud and abuse continues to be a problem, with State Medicaid fraud control units reporting that they investigated 509 non-emergency medical transportation fraud cases from 2004 to 2006. According to these Medicaid fraud and control units, billing for services not rendered and unspecified over-billing were the most common non-emergency medical transportation fraud and abuse cases investigated.

The Report is available at http://www.oig.hhs.gov/oei/reports/oei-06-07-00320.pdf.

DEADLINE APPROACHING FOR CHANGES TO CLINICAL TRIAL ADVERSE EVENT REPORTING

Pursuant to the FDA Amendment Act of 2007 (the "Act"), as of September 27, 2009, "Responsible Parties" will be required to submit adverse event information when providing clinical study results to ClinicalTrials.gov. The Act requires that a "Responsible Party" (i.e., the study sponsor or designated principal investigator) register and report results of certain applicable clinical trials that were initiated or ongoing as of September 27, 2009. These applicable clinical trials generally include interventional studies of drugs, biological products or devices that are subject to FDA regulation. A clinical trial that is subject to FDA regulation is a trial that has one or more sites in the U.S. involving a drug, biologic or device that is manufactured in the U.S. or is conducted under an Investigational New Drug Application ("IND") or Investigational Device Exemption ("IDE").

Beginning September 27, 2009, adverse events information must be provided when either submitting results or modifying a prior entry in order to be accepted by ClinicalTrials.gov. Pursuant to the Act, the Responsible Party is required to submit "basic results" information no later than one year after the earlier of the estimated or actual completion date of the study. A delayed submission of a result is permitted under certain circumstances outlined in the Act. For example, a Responsible Party may submit a certification for a delayed submission of results if the applicable clinical trial is completed before the drug or device is initially approved, licensed or cleared by the FDA. In addition, the Director of NIH may provide an extension of the deadline for submission of results and information if the Responsible Party submits a written request for extension that provides a good cause for the extension and an estimate of the date on which results or information will be submitted.

If you have any questions or concerns regarding submission of adverse events information to ClinicalTrials.gov, please don't hesitate to contact any of the attorneys in the Health Care Practice Group at The Rogers Law Firm.

OIG: HOSPITAL MAY PROVIDE FREE BLOOD PRESSURE SCREENINGS

On August 10, 2009, the United States Office of Inspector General ("OIG") of the United States Department of Health and Human Services posted an Advisory Opinion regarding the provision of free blood pressure screenings to walk-in visitors at a hospital. Specifically, in Advisory Opinion 09-11 the OIG concluded that such an arrangement did not constitute grounds for the imposition of civil monetary penalties and did not violate the Anti-Kickback Statute.

The hospital which requested the Advisory Opinion is a small, county-owned critical access hospital. Pursuant to the arrangement, the hospital provides a free blood pressure check to any visitor who enters the hospital requesting this service during daylight hours. The blood pressure check is free and is provided in accordance with the hospital's specific guidelines and procedural checklist. The blood pressure check is conducted by a member of the hospital nursing staff who is on-duty and

available at the time the visitor presents. If a visitor's blood pressure reads outside of normal limits, the visitor is advised to see his or her own health care provider. The hospital does not bill the blood pressure check service to any Federal health care program or any other third-party payors.

In reviewing the arrangement, the OIG undertook an analysis as to whether it violated the Anti-Kickback Statute or would be subject to civil monetary penalties under Section 1128A(a)(5) of the Social Security Act. The Anti-Kickback Statute makes it a criminal offense 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. Section 1128A(a)(5) of the Social Security Act provides for the imposition of civil monetary penalties against any person who gives something of value to a Medicare or State health care program (Medicaid) beneficiary that the benefactor knows, or should know, is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program (including Medicaid).

The OIG concluded that the arrangement does not violate the Anti-Kickback Statute and is not subject to civil monetary penalties based upon the following reasons:

- the blood pressure check offered by the hospital under the arrangement is not conditioned on use of any goods or services from the hospital or any other particular practitioner or provider;

- the visitor receiving the blood pressure check is not directed to any particular healthcare practitioner or provider;

- the hospital does not offer the visitor any special discounts on follow-up services; and

- the staff responds to an abnormal blood pressure reading obtained during a free check by advising the visitor to see his or her own health care provider.

The OIG noted that the free blood pressure check does not promote the provision of non-preventative care reimbursed by Medicare or Medicaid to the hospital. Furthermore, in its Advisory Opinion the OIG pointed to its Preamble in the 2000 Final Rule on civil monetary penalties under Section 1128A(a)(5) of the Social Security Act, in which the OIG commented on a hospital's free diabetes screening as follows:

> The provision of a free non-covered screening test would not violate [the Civil Monetary Penalty Act] so long as the test is not tied to provision of services by the hospital. Thus, for example, the screening test would be permissible where the hospital provides an individual who tests positive for diabetes with general information or literature and a recommendation that the individual contact his or her personal physician. If, on the other hand, as part of the screening program, the hospital makes appointments for individuals with one of its physicians, offers individuals discounts for additional covered services, or otherwise promotes its particular diabetes programs, an inference may be drawn that the free screening test was an inducement to choose the hospital as a provider for other services.

Although the OIG concluded that the program does not violate the Anti-Kickback Statute and does not subject the hospital to civil monetary penalties, it is important to note that the OIG's opinion in this regard pertains only to the particular hospital which requested the Advisory Opinion. Nevertheless, it is clear from this Advisory Opinion that a hospital can provide free preventative care screenings to visitors provided there is no direct connection between the screening and other services provided by the hospital.

If you have any questions or concerns regarding this Advisory Opinion, please don't hesitate to contact any of the attorneys in the Health Care Practice Group at The Rogers Law Firm.

HHS ISSUES RULE REQUIRING INDIVIDUALS BE NOTIFIED OF BREACHES OF THEIR PROTECTED HEALTH INFORMATION

On August 19th, the Office for Civil Rights of the United States Department of Health and Human Services ("HHS") issued an interim final rule which requires notification of breaches of unsecured protected health information ("PHI"), as well as guidance specifying the technologies and methodologies that render protected health information unusable, unreadable, or indecipherable to unauthorized individuals. Section 13402 of the Health Information Technology for Economic and Clinical Health ("HITECH") Act, part of the American Recovery and Reinvestment Act of 2009 ("ARRA"), requires HHS to issue interim final regulations within 180 days to require covered entities under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and their business associates to provide notification in the case of breaches of unsecured PHI.

The interim final rule pertains to HIPAA covered entities and their business associates and sets forth the requirements for notification to affected individuals, the media, and the Secretary of HHS following a breach of unsecured PHI. The regulations require health care providers and other HIPAA covered entities to promptly notify affected individuals of a breach (without reasonable delay within 60 days). Furthermore, covered entities must notify the HHS Secretary and the media in cases where a breach affects more than 500 individuals. Breaches affecting fewer than 500 individuals need to be reported to the HHS Secretary on an annual basis. The regulations also require business associates of covered entities to notify the covered entity of breaches at or by the business associate.

Covered entities are already required to comply with the new Massachusetts Data Security Law (M.G.L. c. 93H), which in the event of a data security breach requires notification to the patient, Massachusetts Attorney General's Office, and Director of the Massachusetts Office of Consumer Affairs and Business Regulation.

The interim final rule will go into effect on September 19th. If you have any questions or concerns regarding the interim final rule, please do not hesitate to contact any of the attorneys in The Rogers Law Firm's Health Care Practice Group.

The Rogers Law Firm has been representing health care providers in Massachusetts for over 30 years, including integrated health care delivery systems, hospitals, physician groups, nursing homes, hospices and individual providers. In addition to having a specialty group dedicated to health care law, we recognize that managers in the health care industry, now more than ever, need to be able to project and control costs, which is why we have introduced ***Fixed Fee Assurance*** for health care providers and organizations. This means we can provide a fixed fee cost for most legal projects in advance as opposed to open-ended billable hours, allowing you to better budget and plan for your legal bill from the outset.

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