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In This Issue:

Senate Issues Draft Report on Non-Profit Hospital Reforms. . 1

IRS Releases Interim Report on Hospital Compliance Project . . 3

CMS Proposes to Eliminate E-Prescribing Computer-Generated Fax Exemption. 3

JCAHO Announces 2008 Patient Safety Goals. 4

CMS Proposes Revisions to Medicare Clinical Trial Policy .5

IRS Issues Additional Guidance on Health IT Subsidy Arrangements. 6

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Senate Committee Issues Draft Report on Non-Profit Hospital Reforms

On July 17, 2007, the Minority Staff of the U.S. Senate Committee on Finance issued a draft report on non-profit hospital reforms (the "Report"). The Report, which was directed by Sen. Chuck Grassley of Iowa, is intended to encourage discussion on how Congress can best assure that all non-profit hospitals are providing charitable care and medical assistance to those in need. The Report sets forth proposals for reform based on investigations by the Finance Committee.

The Report recommends that non-profit hospitals be classified under the Internal Revenue Code ("IRC") as either a 501(c)(3) or 501(c)(4) exempt organization. This would be a significant development as almost all hospitals in the United States are classified as 501(c)(3) exempt organizations. While 501(c)(3) and 501(c)(4) organizations are exempt from federal income tax, 501(c)(3) organizations receive the additional benefits of being able to issue tax-exempt bonds and receive contributions that are deductible under Section 170 of the IRC. Therefore, the idea behind classifying non-profit hospitals as either 501(c)(3) or 501(c)(4) organizations is that the requirements for 501(c)(3) status should be more stringent than the requirements for 501(c)(4) status. Specifically, the Report recommends the following standards for hospitals that seek exemption under Section 501(c)(3): (i) establishing a charity care policy and wide publication of that policy; (ii) quantitative standards for charity care; (iii) requirements for joint ventures between non-profit hospitals and for-profit entities; (iv) board composition and other governance requirements and executive compensation standards; (v) limiting charges billed to the uninsured; (vi) placing restrictions on conversions; (vii) curtailing unfair billing and collection practices; (viii) transparency and accountability requirements; and (ix) sanctions for failure to comply with applicable requirements for a 501(c)(3) or 501(c)(4) hospital.

IRS Circular 230 Disclosure: To ensure compliance with requirements imposed by the Internal Revenue Service, we inform you that any U.S. federal tax advice contained within this communication (including any attachments) was not intended or written to be used, and cannot be used, by any person for the purpose of (i) avoiding penalties under the Internal Revenue Code or (ii) promoting, marketing or recommending to another party any transaction or matter addressed herein.

As to hospitals that seek exemption under 501(c)(4), the Report recommends the following standards: (i) a quantitative amount of community benefits annually; (ii) limiting charges billed to the uninsured; (iii) governance reforms; (iv) restrictions on conversions; (v) curtailing unfair billing and collection practices; (vi) heightened transparency; and (vii) sanctions for failure to comply with applicable requirements.

Certainly, hospitals which seek to continue to be classified as 501(c)(3) organizations would have to conduct an analysis to determine compliance with the Report's recommendations. One of the more notable requirements is the minimum amount of charity care to be provided. Specifically, the Report recommends that no hospital can maintain 501(c)(3) status without dedicating a minimum of 5% of its annual patient operating expenses or revenues to charity care, whichever is greater, in accordance with its charity care policy. The basis behind this recommendation is that the Minority Staff of the Senate Finance Committee does not believe that offering a charity care policy is enough to justify exemption under 501(c)(3). Rather, charity care must be provided in a means which can be quantified.

The Report also addresses the issue of joint ventures between for-profit entities and non-profit hospitals. In particular, the Report recommends certain standards for such joint ventures for those non-profit hospitals seeking to maintain 501(c)(3) status. The purpose of those standards is to help ensure that the charitable purpose is furthered by the venture. As to the common ancillary joint venture (i.e., a portion of the non-profit hospital's assets are placed in the joint venture), the joint venture must have its own charity care policy. Furthermore, the 501(c)(3) hospital must control the joint venture's charity care policy and there must be at least one voting member on the Board who is from the 501(c)(3) hospital involved in the joint venture. The non-profit hospital must approve any decision that affects the charity care policy. All of the charity care provided at the joint venture level may be credited toward each non-profit hospital involved in the joint venture based on such hospital's proportionate share.

The issue of governance of non-profit hospitals is also addressed within the Report. In particular, the Report recommends that all 501(c)(3) and 501(c)(4) hospitals adopt provisions similar to those found in Section 501(q)(1)(D) of the IRC, such that: (1) the hospital is governed by a Board of Directors that is controlled by members who represent the broad interests of the public, such as public officials, persons having special knowledge or expertise in community healthcare, community leaders and especially advocates or representatives of those benefiting (or potentially benefiting) from charity care and discounted care for the medically indigent; and (2) not more than 25% of the voting power of the Board of Directors is vested in persons who are employed by the hospital or who will benefit financially, directly or indirectly, from the organization's activities (other than through the receipt of reasonable directors' fees). Furthermore, the Report recommends that physicians and management should not comprise more than 25% of the Board of Directors or any of its committees, except for those committees responsible for quality care or credentialing. The Report also recommends that all 501(c)(3) or 501(c)(4) hospitals have detailed conflict of interest policies that describe the scope of covered persons and arrangements (including all officers and directors), the procedures for addressing an actual or potential conflict of interest, the consequences of a violation and at least annual review of the policy and the potential conflicts reviewed thereunder.

It should be emphasized that the Report is in draft form. The Report sets forth a deadline of August 24th for comments on the proposed reforms. Although the Report is not legislation, it is likely that the Finance Committee will seek to transfer at least some, if not all, of the recommendations contained within the Report into legislation.

The Rogers Law Firm will continue to monitor the Report and will provide updates accordingly.

IRS Releases Interim Report on Hospital Compliance Project

The United States Internal Revenue Service ("IRS") recently released an interim report (the "interim report") on its Hospital Compliance Project ("Project"). The Project was initiated in 2006, for purposes of studying non-profit hospitals and community benefit. The IRS gathered responses of 487 hospitals to a comprehensive compliance questionnaire, as well as information reported on Forms 990 filed by those hospitals. The Project concerns the reporting of types and amounts of potential community benefit expenditures in various areas, including medical education and training, uncompensated care, medical research and community programs.

The most notable issue raised by the interim report is that there is considerable variation in how hospitals report uncompensated care. According to the interim report, ninety-seven percent of hospitals reported that they had a written uncompensated care policy, yet there was no uniform definition of what constitutes "uncompensated care". Fifty-six percent of the hospitals reported that they did not include bad-debt expense as uncompensated care, while the remaining forty-four percent included at least some bad-debt expense as uncompensated care.

Beyond uncompensated care, the interim report indicated that the next largest categories of expenditures reported as providing community benefit were medical education and training, research and community programs. In particular, more than seventy-five percent of hospitals report expenditures for producing publications and newsletters, medical screenings and public educational programs, and twenty-eight percent reported expenditures to study the health needs of the community.

Although the Project included an executive compensation component, that component is not addressed in the interim report because examinations in that area are still ongoing. The Rogers Law Firm will continue to monitor that portion of the Project and will provide an update once a report is released.

CMS Proposes to Eliminate E-Prescribing Computer-Generated Fax Exemption

A significant focus of the recently released proposed rule by the Centers for Medicare and Medicaid Services ("CMS") regarding the Medicare Physician Fee Schedule for 2008 was the 9.9% reduction in Medicare physician payment rates. However, also contained within the proposed rule is a provision that would eliminate the exemption for computer generated faxes from the e-prescribing standards.

The Medical Prescription Drug, Improvement, and Modernization Act of 2003 directed the Secretary of the United States Department of Health and Human Services to establish regulations that would permit certain arrangements to foster the adoption of e-prescribing technology. E-prescribing enables a physician to transmit a prescription electronically to the patient's pharmacy or ancillary provider. Such a process can improve patient safety by decreasing errors due to physician handwriting. Also, e-prescribing enables physicians and

pharmacists to obtain information from drug plans without the patient's eligibility and medication history. Although there is no requirement that prescribers or dispensers implement e-prescribing, those who do are required to comply with the e-prescribing standards of HHS. The standards included a SCRIPT standard for communications between physicians and pharmacies regarding prescription information. The rule provided that entities that transmit prescriptions via computer-generated faxes were exempt from using the SCRIPT standard.

According to CMS, it expected entities with computer-generated fax software to start using the SCRIPT standard over time. However, such a transition has not occurred. As a result, CMS is now proposing to eliminate the computer-generated fax exemption from the e-prescribing standards. CMS believes that by eliminating this exemption, e-prescribers and dispensers will be encouraged to move as quickly as possible to use the SCRIPT standard.

Although the elimination of the computer-generated fax exemption from e-prescribing standards is only a proposed rule, it is widely believed that the exemption will be removed in the final rule.

The Rogers Law Firm is available to assist providers with transitioning to the SCRIPT standard.

JCAHO Announces 2008 Patient Safety Goals

On June 25, 2007, the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") announced the 2008 National Patient Safety Goals. The goals and related requirements apply to all JCAHO accredited hospitals. The two new requirements for hospitals include the following: "reduce the likelihood of patient harm associated with the use of anticoagulation therapy"; and "the organization selects a suitable method that enables healthcare staff members to directly request additional assistance from a specially trained individual(s) when the patient's condition appears to be worsening." The new anticoagulant therapy requirement, which is set forth within JCAHO's goal to "improve the safety of using medications", addresses what JCAHO characterizes as a widely-acknowledged patient safety problem.

The 2008 National Patient Safety Goals can be found on the JCAHO website at jointcommission.org.

CMS Proposes Revisions to Medicare Clinical Trial Policy

The Centers for Medicare and Medicaid Services ("CMS") has issued a proposed Decision Memorandum (the "Memorandum") to address ambiguities concerning Medicare coverage in research studies and what items and services are reasonable and necessary for beneficiaries participating in clinical research studies. The Memorandum proposes revisions to the current Medicare Clinical Trial Policy ("CTP").

In September of 2000, the Healthcare Financing Administration (now CMS) implemented a CTP through the National Coverage Determination Process. The process limited the payment for items and services provided to Medicare beneficiaries in qualified trials "to routine costs." The policy defined "routine costs" as those items and services that would generally be covered for Medicare beneficiaries outside a trial. In July of 2006, CMS began a reconsideration of the 2000 National Coverage Determination Process. An advisory committee issued a proposed decision memorandum in April of 2007. The memorandum received several comments from hospitals and others suggesting that Medicare contractors have been paying claims involving patients in various types of clinical research outside the terms of the CTP. As a result of these comments, CMS decided to issue the Memorandum.

The Memorandum proposes several changes to the National Coverage Determination Process for the CTP. In particular, the Memorandum seeks to define clinical research as "any systematic investigation involving human participants which is designed to contribute to generalizable knowledge and which involves a clinical intervention, care delivery strategy or diagnostic technique designed to potentially improve predefined health outcomes."

The Memorandum also seeks to adopt the term "usual patient care" to define those items and services that are covered by Medicare in clinical research studies. "Usual patient care" includes routine clinical services and investigational clinical services in clinical research when the investigational clinical services would be covered outside of the clinical research and the clinical research meets the standards for a clinical research study outlined in the Memorandum. "Investigational clinical services" consists of those items and services which are being investigated as an objective within a study. "Routine clinical services" include items and services that: are covered for Medicare beneficiaries outside the clinical research study; are used for the direct patient management within the study; and do not meet the definition of investigational clinical services. Medicare will not cover usual patient care when such care is provided free to the Medicare beneficiary or when the study sponsor agreement with investigative sites or the informed consent documents provided to the patient specify that the care will be provided free to participants. CMS will cover usual patient care for beneficiaries enrolled in clinical research studies where the study sponsor/principal investigator has certified to CMS that the standards set forth in the Memorandum have been met. Those studies which have been certified by CMS will be posted at ClinicalTrials.gov. In order to be listed as a certified study, study sponsors or principal investigators may send a letter to CMS describing the scope and nature of the clinical research, and addressing the standards set forth in the Memorandum.

CMS is requesting public comments on the Memorandum. After considering the public comments, CMS will issue a final decision memorandum.

IRS Issues Additional Guidance on Health IT Subsidy Arrangements

The United States Internal Revenue Service ("IRS") recently issued additional guidance (the "Guidance") regarding hospitals' health information technology ("IT") subsidy arrangements with medical staff physicians. The Guidance, which is in the form of six questions and answers, follows the release of an IRS Field Memorandum this past May addressing circumstances in which tax-exempt hospitals may provide physicians with financial assistance to acquire and implement software that is used predominantly for creating, maintaining, transmitting or receiving electronic health records ("EHRs") for their patients. The Guidance and Field Memorandum are part of the ongoing effort by the IRS to clarify what is permissible for tax-exempt hospitals by way of health IT subsidy arrangements in response to the final regulations issued last year by the United States Department of Health and Human Services ("HHS") pertaining to the support of physician adoption of electronic prescribing ("e-prescribing") and EHR technology.

The following is an overview of the significant points raised in the Guidance:

- The IRS is providing a "safe harbor" for certain health IT subsidy arrangements between the hospital and its medical staff physicians. Specifically, hospitals will be permitted to provide health IT items and services to medical staff physicians at a discount so long as certain conditions are met, including: the hospital and the participating physicians must comply with the HHS EHR regulations on a continuing basis; the arrangement must permit a hospital to access all of the EHRs created by a physician to the extent provided by law; if a hospital decides to enter into health IT subsidy arrangements, it must ensure that the items and services are available to all of its medical staff physicians and at the same level of subsidy as provided to all of the hospital's medical staff physicians or the level of subsidy is varied "by applying criteria related to meeting the health care needs of the community."

- The terms "financial assistance" and "subsidy" do not include cash payments from hospitals to physicians. Rather, such terms refer to arrangements "in which the hospital provides the physicians with EHR-related software or information technology and training services and the physician contributes a portion of the cost."

- If a hospital meets all the conditions of the IRS safe harbor, the health IT subsidy to a "disqualified person" will not be treated as an excess benefit transaction under the IRS Intermediate Tax Sanctions.

- A medical staff physician who enters into a health IT subsidy arrangement with a hospital may deny the hospital access to EHRs if that access would violate federal and state privacy laws or the physician's contractual obligations to patients. The Guidance further provides that a hospital and a physician may agree on reasonable conditions on the hospital's access to EHRs.

- The Guidance states that a hospital may provide access to various groups of physicians at different times according to criteria related to meeting the health care needs of the community. The Guidance recommends that a hospital should establish a plan for providing such access.

The Guidance is important insofar as it clears up many of the questions which arose subsequent to the issuance of the Field Memorandum. In particular, the Guidance clarifies that the Field Memorandum represented a safe harbor and not a mandate from the IRS. The Guidance states that health IT subsidy arrangements that do not meet the parameters of the safe harbor will not necessarily create impermissible private benefit or inurement, but will rather be analyzed based on their particular facts and circumstances.

It is the recommendation of The Rogers Law Firm that any consideration to provide physicians with EHR technology first be discussed with our office so that we may appropriately structure an arrangement that meets the IRS safe harbor and HHS regulations.

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.