On the Horizon in
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Industry Hot Topics

New Stark Exceptions for Electronic Prescribing and Electronic Health Records

The Physician Self-Referral Law, also known as the Stark law, prohibits physicians from making referrals for designated health services (DHS) payable by Medicare to entities with which they (or an immediate family member) have a financial relationship. Generally, provision or receipt of free or reduced cost items or services to referral sources is prohibited under the Stark law, unless there is an applicable exception.

On August 1, 2006, the Department of Health and Human Services, Centers for Medicare and Medicaid Services, released final regulations excepting certain donations of items and services that promote the adoption of new information technology for electronic prescribing and electronic health records. These exceptions become effective on October 6, 2006, and at available at www.cms.hhs.gov.

The Stark E-Prescribing Exception

The Stark e-prescribing exception is intended to promote widespread adoption of e-prescribing by reducing the fraud and abuse concerns associated with donation of related items and services to physicians. As such, the rule authorizes non-monetary donations of items and services in the form of hardware, software, or information and training services that are necessary and used solely to receive and transmit electronic prescription information.

Under the new regulation, e-prescribing items and services must be provided as part of, or used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided. Additionally, the donation arrangement must cover all of the electronic prescribing items and services to be provided by the donor and must be set forth in a signed, written agreement specifying the items and services provided and the costs incurred by the donor.

Although the Stark e-prescribing exception arguably expands the ability to donate and receive electronic prescribing technology, it is not unlimited in scope. The exception is only applicable to donations provided by a hospital to a medical staff physician, by a group practice to a member physician, or by a prescription drug plan sponsor or Medicare Advantage organization to a prescribing physician.

Moreover, the exception will not apply where a donor has actual knowledge that a physician has already obtained equivalent items or services as those provided by the donor (or acts in reckless disregard or deliberate ignorance of such fact). Further, the exception will not apply where a donor takes action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems, or to limit or restrict a physician's ability to use the items or services for any patient without regard to payor status. Also, the exception will not apply where the physician or physician practice makes the receipt of the items or services a condition of doing business with the donor. In addition, the exception will not apply if the eligibility of a recipient for the items or services donated, or the amount or nature of such items or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties.

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The Stark Electronic Health Records Exception

The new regulations also create an exception for donations of electronic health records items and services. For this exception to apply, donations must consist of "interoperable" electronic health records software (not hardware) and directly related training services that are necessary to receive, transmit, and maintain electronic health records. "Interoperable" means the ability to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings, and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.

The electronic health records exception allows donations to physicians by hospitals and other DHS entities. However, to meet the requirements of the exception, a donation of electronic health records software must contain electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the physician's existing electronic prescribing system, meeting the applicable e-prescribing standards under Medicare Part D at the time the items and services are provided. In contrast, the items and services cannot include staffing of physician offices or be used for personal or other business unrelated to the physician's medical practice.

As with the Stark e-prescribing exception, each donation arrangement must cover all of the items and services to be provided by the donor and must be set forth in a signed, written agreement specifying the items and services provided and the costs incurred by the donor. Likewise, the donor may not take any action to limit or restrict the use, compatibility, or interoperability of donated items or services with other electronic prescribing or electronic health records systems and may not determine the eligibility of a recipient for the items or services donated, nor the amount or nature of such items or services, in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. As a general matter, this exception will not apply in many of the same circumstances that the e-prescribing exception will not apply (for example, when a donor has actual knowledge that a physician has already obtained equivalent items or services).

There are, however, notable differences between the Stark e-prescribing exception and the electronic health records exception. For example, the electronic health records exception only applies to donations made on or before December 31, 2013, and physicians receiving electronic health records software and training must pay 15% of the donor's cost for the items and services before receiving them. Furthermore, the Stark electronic health records exception expressly provides that the arrangement must not violate the Anti-Kickback Statute or any other federal or state mandate governing billing or claims submission, whereas the e-prescribing exception does not.

Anti-Kickback Safe Harbor Provisions

The Department of Health and Human Services, Office of Inspector General, has also issued similar regulations that set forth new safe harbor provisions protecting certain donations of items and services for electronic prescribing and electronic health records under the federal Anti-Kickback Statute. A copy of these safe harbor provisions is available at www.oig.hhs.gov.

Ohio Attorney General Issues Revised Rules for Tax Exempt Organizations

The Ohio Attorney General's second draft of proposed revisions to the administrative rules for charitable organizations, found at Chapter 109:1-1 of the Ohio Administrative Code, were published July 28, 2006. In general, the proposed rules subject charitable hospitals, health maintenance organizations (HMOs), insurance companies and nursing homes to the Attorney General's registration and reporting requirements for charitable organizations, and also clarify that faith-based organizations not closely controlled by churches must comply with the registration and reporting requirements as well. In addition, the proposed rules create a new nine-member "Charitable Advisory Council" to develop recommendations for model policies for charitable organizations and provide advice to the Attorney General on other issues affecting charities.

The second draft of the proposed rules was released on July 28, 2006 in response to an outpouring of negative feedback regarding extensive new policies pertaining to conflicts of interest, executive compensation, and fair billing and collection practices contained in the original proposed revisions to the rules. These controversial policies, as well as a proposal for large charitable organizations and charitable healthcare organizations to provide detailed annual "community benefit reports," have been removed from the current proposed rules and replaced by the provision creating the Charitable Advisory Council to make recommendations to the Attorney General in these areas. The Attorney General is seeking comments and feedback on the proposed rules through August 21, 2006, after which time the rules will be filed with the Joint Committee on Agency Rule Review (JCARR) for formal consideration.

New Registration Requirement for Certain Charitable Organizations

Charitable healthcare organizations exempt from federal taxation under 501(c)(3) of the Internal Revenue Code are expressly added to the list of entities required to register with the Attorney General.

Faith-based organizations not closely controlled by churches will now be required to register and comply with the annual reporting requirements under the rules. [See below discussion of exempt entities].

Reports

Revisions to this rule clarify that all charitable organizations required to file an annual report may satisfy the requirement by filing the Attorney General's annual report form. The form requires the organization to report its income, expenses, assets, liabilities, and net worth for the taxable year. In addition, to "assist the Attorney General in determining the proper administration of charitable trusts," the following questions **may** be included on the annual report:

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1) Has the organization made loans to executives, directors or employees?
2) Has the organization adopted a conflict of interest policy that requires the disclosure of any conflict by an executive or director and further requires the official minutes to reflect such disclosure?
3) Has the organization adopted a compensation and expense reimbursement policy that prohibits excessive compensation?
4) Has the hospital or nursing home adopted a fair billing policy that is consistent with the organization's mission of providing charity care?
5) Has the hospital or nursing home adopted a fair debt collection policy that follows charitable and humane principles?
6) Has the organization received certification from a state or national certification agency?

The requirement for submission of an annual report applies to any taxable year in which a charitable organization has gross receipts of more than $5,000 or gross assets of more than $15,000.

Charitable organizations that have gross receipts during any taxable year of less than $25,000, or are otherwise exempt from filing financial information with the IRS, ***are required*** to file the Attorney General's annual report form.

All other charitable organizations ***may*** choose to file the Attorney General's annual report form, or may choose one of two filing alternatives in lieu of the Attorney General's annual report form:

1) Organizations headquartered in Ohio that are required to file form 990, 990-PF, or 990-EZ with the IRS may file a form prescribed by the Attorney General certifying that the organization has filed such forms with the IRS;
2) All other organizations may file complete copies of all federal returns required to be filed by the organization with the IRS, together with all schedules, attachments, and reports due with the return or returns.

The Attorney General's on-line registration and filing system may be utilized for the submission of registration forms, annual reports and filing fees. Organizations seeking a determination of their status with respect to the registration and annual reporting requirements under the rules may submit a written request for determination to the Attorney General.

Any organization receiving a notice from the IRS that it is no longer exempt from taxation is required to notify the Attorney General's Charitable Law Section immediately upon receipt of the notice of revocation.

Charitable organizations registered with the Attorney General must file a final report and schedule of final distributions at the time of dissolution.

Charitable Advisory Council

The regulations establish a new "Charitable Advisory Council" to assist the Attorney General in developing recommended policies for charitable organizations. The council will consist of nine members to be appointed by the Attorney General, representing the interests of varying organizations in the charitable sector as follows:

- One member representing **grant-making charities**;
- One member representing **large charities** (more than $1 million in gross annual receipts);
- One member representing **medium-sized charities** (between $50,000 and $1 million in gross annual receipts);
- One member representing **small charities** ($50,000 or less in gross annual receipts);
- One member representing **charitable hospitals**;
- One member representing **charitable nursing homes**;
- One member representing **United Way organizations**; and
- Three members possessing general expertise in the **management** of charitable organizations.

The Charitable Advisory Council will advise and make recommendations to the Attorney General regarding the following matters:

- Training and educational needs of charitable organizations;
- Development of model policies related to governance and administration of charitable organizations in accordance with fiduciary principles;
- Identifying emerging issues and trends affecting charities, and
- Any other related issues at the Attorney General's request.

Peer Review Privilege

Ohio Appeals Court Upholds Constitionality of Ohio Credentialing and Peer Review Statutes

An Ohio Appellate Court recently reversed a trial court ruling that Ohio's credentialing and peer review statutes are unconstitutional. Filipovic v. Dash, 2006 WL 1521468 (Ohio App. 5 Dist. 2006.

In March 2004, Dragan Filipovic ("Filipovic") filed a medical negligence suit against Surendra N. Dash, M.D., ("Dash") and Mercy Medical Center ("Mercy"), claiming that Mercy negligently credentialed Dash. During discovery, Filipovic requested to examine Mercy's credentialing and peer review data related to Dash. Mercy objected to this request

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Peer Review Privilege

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based on the Appellate Court's decision in Huntsman v. Aultman Hospital, Ohio App.3d 196 (Ohio App. 5 Dist. 2005), which reviewed Sections 2305.251 and 2305.252 of the Ohio Revised Code. Section 2305.251 creates a presumption of non-negligent credentialing, while section 2305.252 shields peer reports from discovery. While ruling on the Filipovic's discovery request, the trial court surprisingly held that both of these statutes were unconstitutional and ordered Mercy to produce the files for inspection by the Court. The trial court reasoned that the statutes eliminated the common law tort of negligent credentialing previously recognized by the Ohio Supreme Court. It also stated that the statutes were contrary to the section of the Ohio Constitution, designating the court as the proper place to find redress from injuries.

On appeal, the Fifth District Court of Appeals reversed the trial court's ruling and held that the statutes are constitutional. The Court stated that the proper test for the validity of the statutes was whether they "had a reasonable relation to a proper legislative purpose without being arbitrary or discriminatory." The Court found that the statutes are reasonably related to the legitimate purpose of improving public health case. It ruled that neither statute provided hospitals with immunity for negligent credentialing or created an insurmountable burden for proving medical malpractice claims. The statutes, according to the Court, therefore, do not deny plaintiffs access to the courts and meet the due process requirements of the Ohio Constitution. In light of its decision on the constitutionality of the statutes, the Court overruled the trial court's order that Mercy needed to produce the peer review files for inspection.

Labor and Employment

Hospital Must Fire Nurses Who Don't Pay Union Dues Under Collective Bargaining Agreement

In a recent decision, the Eighth Circuit Court of Appeals required St. John's Mercy Medical Center ("St. John's") to fire seventy-three nurses and pay the overdue union dues and fees of the nurses in order to comply with an arbitration award. United Food and Commercial Workers' Union Local 655 v. St. John's Mercy Health Systems, Case No, 05-4316 (8th Cir. May 24, 2006).

The United Food and Commercial Workers' Union Local 655 ("the union") is the exclusive bargaining representative for the 1400 registered nurses who work at St. John's. St. John's and the union entered a collective bargaining agreement ("CBA") that required all registered nurses to become members of the union and pay dues as a condition of employment. If the nurses did not join the union or pay dues, the CBA required St. John's to fire the nurses at the union's request. The CBA also required disputes to be settled through arbitration.

When some of the nurses refused to join the union, the union sought arbitration under the CBA. At the arbitration, the union argued that St. John's was in violation of the CBA by not firing the nurses in question. St. John's argued that firing the nurses violated public policy because the hospital would be unable to meet patient needs. The arbitrator decided in favor of the union and ordered St. John's to fire the nurses, and to pay the union the late union dues. The National Labor Relations Board upheld the arbitrator's decision.

After the NLRB upheld the arbitrator's decision, the union filed a complaint in federal court to confirm the arbitration award. The district court decided that, although Missouri does have a public policy to promote quality healthcare, the arbitration award does not violate that policy because no statute contains specific standards for the number of nurses required to ensure quality healthcare. One important factor the Court considered was that the Medical Center had coped with a strike of more than 100 nurses in 2004 without violating public policy. On appeal, the Eighth Circuit affirmed, ordering St. John's to fire the nurses who had not paid their union dues, and to pay the late union dues, despite the fact that the parties had since then entered a new CBA that allowed nurses to opt out of joining the union.

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