

A Primer on the New Physician Self-Referral Exceptions and Anti-Kickback Safe Harbors for Electronic Prescribing and Electronic Health Records Technology

Introduction

On August 1, 2006, Health and Human Services (HHS) Secretary Mike Leavitt announced final regulations establishing rules intended to support physician adoption of electronic prescribing and electronic health records. The rules create two new exceptions in the Physician Self-referral Law, also known as the Stark law,¹ and two new safe harbors in the federal anti-kickback statute² that protect certain arrangements involving the donation of some forms of electronic health information technology and services to doctors and other designated healthcare providers. The rules, which were published in the Federal Register on August 8, 2006, will go into effect 60 days from the date of publication.

In part, the rules implement a provision in the Medicare Modernization Act (MMA) which directed the Secretary to adopt standards for electronic prescribing and further directed the Secretary, in consultation with the Attorney General, to create an exception to the Stark law and a new safe harbor under the anti-kickback statute to help promote widespread adoption of e-prescribing. The new rules, however, go beyond the mandate of Congress to create a second exception under the Stark law and a second anti-kickback safe harbor that are intended to support, more broadly, adoption of electronic health records items and services. The new exceptions in the Stark rule and the new anti-kickback safe harbors are viewed by many in the health care industry as necessary to eliminate a barrier to rapid adoption of health information technology.

Key to understanding the new rules is understanding the differences between the Stark law and the anti-kickback statute. The Stark law, which is enforced by the Centers for Medicare and Medicaid Services (CMS), only pertains to physicians and prohibits them from making referrals for certain designated health services (DHS) payable by

Medicare to an entity with which he or she (or a family member) has a financial relationship unless the arrangement meets an exception. An arrangement must meet all the requirements of an exception to be considered lawful under the Stark law. Designated health services are services payable in whole or in part by Medicare and include clinical laboratory services, physical and occupational therapy, speech-language pathology, radiology and certain other imaging services, radiation therapy services and supplies, parenteral and enteral nutrients, equipment and supplies, home health services, outpatient prescription drugs, and inpatient and outpatient hospital services.³

The anti-kickback statute, which is enforced by the Office of the Inspector General (OIG) is much broader. It establishes criminal penalties for individuals and entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under any Federal health care program. Certain business practices that may potentially induce referrals are not treated as criminal offenses, but only if they comply with "safe-harbor" provisions. Safe harbors are established by regulation. Unlike the exceptions established under the Stark law, compliance with anti-kickback "safe-harbors" is voluntary. Arrangements that meet all of the requirements of one of the safe harbors are not treated as criminal offenses under the anti-kickback statute. Arrangements that do not comply with a safe harbor may or may not violate the anti-kickback statute and must be evaluated on a case-by-case basis.

In promulgating the new Stark exceptions and the new anti-kickback safe harbors, CMS and the OIG strove to balance the desire to promote widespread adoption of health information technology against the significant fraud and abuse concerns that arise when free or discounted goods and services are provided to referral sources. CMS and the OIG also tried to ensure that the

new Stark exceptions and anti-kickback safe harbors were as clear and as consistent as possible.

Basic information about the new exceptions and safe harbors is provided in Section I. In Section II, additional information about the rules is provided in a Question and Answer format.

Section I – The Basics

A. The Stark Exceptions

CMS has created two new exceptions under the Stark rule: the e-prescribing exception and the electronic health records exception.

1. The Stark E-Prescribing Exception

The Stark e-prescribing exception is based upon Section 101 of the Medicare Modernization Act.⁴ For a donation to qualify as an exception under Stark, it must meet all the conditions explained below:

- a. **Form of Donation** – Based upon the statutory provisions of the MMA, the donation must be non-monetary consisting only 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. The prescription can be for any items that are normally obtained via a written prescription including drugs, medical supplies, durable medical equipment (DME), laboratory tests, etc. Wireless or broadband connectivity and interfaces designed to link the donor's existing electronic prescribing system to the physician's existing electronic prescribing system are permissible, as are electronic clinical support tools or a payor's formulary information. Billing, scheduling, administrative other general office software or bundled software that combines e-prescribing packages with office functions are not. Donations of items and services that duplicate what a physician already has also are not protected because such items and services are not considered necessary. However, upgrades of equipment or software that significantly enhance the functionality of an item or service would be protected.⁵
- b. **Protected Donors and Recipients** – Again, based upon the statutory provisions of the MMA and the Stark rule, the only protected donors and recipients are:
 - i. hospitals to physicians who are members of its medical staff;
 - ii. group practices to physicians who are members of the group;
 - iii. PDP sponsors or MA organizations to prescribing physicians.⁶
- c. **Criteria for Selecting Recipients** – Donors may not take into account, directly or indirectly, the volume or value of the physician's referrals or other business generated between the parties when determining which physicians are eligible to receive items and services or the amount or nature of the items or services received.⁷ Donors may select physician recipients based upon the total number of prescriptions written by that physician.⁸
- d. **Compliance with E-prescribing Standards** – The 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.⁹ CMS finalized the first set of these standards on November 7, 2005. Final standards must be in place by April 1, 2008 and will be effective one year later.
- e. **Donor Prohibitions** – The donor may not take any action or limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems¹⁰ or the physician's ability to use the items or services for any patient without regard to payor status.¹¹
- f. **Recipient Prohibitions** – Neither the physician nor their practices may make the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.¹²
- g. **Written Agreement** – The arrangement must be set forth in a signed written agreement that specifies the items and services being provided, the donors costs of the items and services and covers all of the electronic prescribing items and services to be provided by the donor.¹³
- h. **Good Faith** – The donor must not have actual knowledge of or act in reckless disregard or deliberate ignorance of the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.¹⁴

2. The Stark Electronic Health Records Exception

Using its statutory authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse, CMS created a second, broader exception for electronic health records items and services.¹⁵ While broader, it is also time limited. All donations must be made on or before December 31, 2013.¹⁶ CMS included this sunset provision to hasten adoption of health information technology and limit the potential for abuse. Unlike the Stark e-prescribing exception, only software or information technology and training services (and not hardware) are covered. As a further precaution against fraud, the rule requires recipients to contribute 15 percent of the donor's cost. To be eligible for this exception, all of the following conditions must be met:

- a. **Form of Donation** – The donation must consist of “interoperable” electronic health records software and directly related training services that are necessary and used predominately to receive, transmit, and maintain electronic health records of the entity's or physician's patients.¹⁷ 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.¹⁸ Software may be deemed interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the physician.¹⁹ In addition, any 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. Such systems must meet the applicable e-prescribing standards under Medicare Part D at the time the items and services are provided.²⁰ Finally, the items and services donated may not include staffing of physician offices and may not be used primarily to conduct personal business or business unrelated to the physician's medical practice.²¹
- b. **Protected Donors and Recipients** – Protected donors include all individuals or entities that provide designated health services (DHS). The list does not include health care entities that are not subject to the physician self-referral law including pharmaceutical manufacturers, regional health information organizations (RHIOs), entities in the research-based biopharmaceutical industry, or health information technology vendors. Protected recipients are physicians.²²
- c. **Criteria for Selecting Recipients** – As in the Stark e-prescribing exception, the rule provides that donors may not take into account, directly or indirectly, the volume or value of the physician's referrals or other business generated between the parties when determining which physicians are eligible to receive items and services or the amount or nature of the items or services received.²³ Unlike the Stark e-prescribing rule, however, the Stark electronic health records exceptions lists those considerations upon which the determination is based that are deemed to meet this requirement. These include:
 - i. the total number of prescriptions written by the physician.;
 - ii. the size of the physician's medical practice (*e.g.* total patients, total patient encounters, or total relative value units);
 - iii. the total number of hours that the physician practices medicine;
 - iv. the physician's overall use of automated technology in his or her medical practice;
 - v. whether the physician is a member of the donor's medical staff;
 - vi. the level of uncompensated care provided by the physician; or
 - vii. at reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.²⁴
- d. **Donor Prohibitions** – The donor may not take any action or limit or restrict the use, compatibility or interoperability of the items or services with other electronic prescribing or electronic health records systems²⁵ or the physician's ability to use the items or services for any patient without regard to payor status.²⁶
- e. **Recipient Prohibitions** – Neither the physician nor their practices may make the receipt of items or services, or the amount or nature of the

items or services, a condition of doing business with the donor.²⁷

- f. **Written Agreement** – The arrangement must be set forth in a signed written agreement that specifies the items and services being provided, the donor's costs of the items and services and covers all of the electronic prescribing items and services to be provided by the donor.²⁸
- g. **Good Faith** – The donor must not have actual knowledge of or act in reckless disregard or deliberate ignorance of the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.²⁹
- h. **Required Co-payments** – Before the receipt of the items and services, the physician must pay 15 percent of the donor's costs for the items and services and the donor may not finance the physician's payment.³⁰
- i. **Compliance with other Fraud and Abuse Laws** – The arrangement must comply with the Federal anti-kickback statute and all other Federal or State laws or regulations governing billing and claims submission.³¹

B. The Anti-kickback Safe Harbors

The OIG has promulgated two safe harbors under the federal anti-kickback statute. As with the Stark exceptions above, one provision addresses e-prescribing and the other addresses electronic health records.

1. The Safe Harbor For E-Prescribing

The safe-harbor for e-prescribing, like the Stark exception for e-prescribing is based upon Section 101 of the Medicare Modernization Act. For a payment practice to meet the safe-harbor, it must meet all the conditions explained below.

- a. **Form of Payment Practice** – Based upon the statutory provisions of the MMA, the payment practice must be non-monetary consisting only 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 for any items that would normally be conducted via a written prescription including drugs, medical supplies, durable medical equipment (DME), laboratory tests, etc. Wireless or broadband connectivity and interfaces designed to link the

donor's existing electronic prescribing system to the physician's existing electronic prescribing system are permissible, as are electronic clinical support tools or a payor's formulary information. Licenses, rights of use, intellectual property, and educational and support services all potentially fit in the safe harbor. Billing, scheduling, administrative, other general office software, or bundled software that combines e-prescribing packages with office functions do not.³² Donations of items and services that duplicate what a physician already has also are not protected because such items and services are not considered necessary.³³ However, upgrades of equipment or software would be protected.³⁴

- b. **Protected donors and recipients** – The only protected donors and recipients are:
 - i. hospitals to physicians who are members of its medical staff;
 - ii. group practices to physicians who are members of the group;
 - iii. PDP sponsors or MA organizations to network pharmacists and pharmacies and to prescribing health care professionals.³⁵

According to the OIG, the enumerated categories of donors and recipients reflect individuals and entities centrally involved in the ordering, processing, filing, or reimbursing of prescriptions. The OIG was not persuaded that additional donors (*e.g.* clinical laboratories) or recipients were necessary to achieve the purpose of the e-prescribing safe harbor.³⁶

- c. **Criteria for Recipient Selection** – Donors may not take into account, directly or indirectly, the volume or value of referrals or other business generated between the parties when determining which physicians are eligible to receive items and services or the amount or nature of the items or services received.³⁷ Donors may select physician recipients based upon the total number of prescriptions written by that physician.³⁸
- d. **Compliance with e-prescribing standards** – The 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 at the time the items and services are provided.³⁹ CMS finalized the first

set of these standards on November 7, 2005. Final standards must be in place by April 1, 2008 and will be effective one year later.

- e. **Donor Prohibitions** – The donor may not take any action or limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems⁴⁰ or the physician’s ability to use the items or services for any patient without regard to payor status.⁴¹
- f. **Recipient Prohibitions** – Neither the physician or their practices may make the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.⁴²
- g. **Written Agreement** – The arrangement must be set forth in a signed written agreement that specifies the items and services being provided, the donors costs of the items and services and covers all of the electronic prescribing items and services to be provided by the donor.⁴³
- h. **Good Faith** – The donor must not have actual knowledge of or act in reckless disregard or deliberate ignorance of the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.⁴⁴

2. The Safe Harbor For Electronic Health Records Items And Services

Using its statutory authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse, the OIG created a second, broader exception for electronic health records items and services.⁴⁵ The OIG safe harbor for electronic health records tracks many of the provisions of the Stark exception for electronic health records. For example, the safe harbor sunsets on December 31, 2013,⁴⁶ covers only software or information technology and training services (and not hardware) and requires recipients to contribute 15 percent of the donor’s cost.⁴⁷ To be eligible for this exception, all of the following conditions must be met:

- a. **Form of Donation** – The donation must consist of “interoperable” electronic health records software and directly related training services that are necessary and used predominately to receive, transmit, and maintain electronic health records of the entity’s or physician’s patients.⁴⁸ Software

may be deemed interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the physician.⁴⁹ In addition, any 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. Such systems must meet the applicable e-prescribing standards under Medicare Part D at the time the items and services are provided.⁵⁰ Finally, the items and services donated may not include staffing of physician offices and may not be used primarily to conduct personal business or business unrelated to the physician’s medical practice.⁵¹

- b. **Eligible Donors and Recipients** – Eligible donors include all individuals or entities that provide services covered by a Federal health care program and submit claims or requests for payment, either directly or through reassignment, to the Federal health care program; or a health plan.⁵² According to the OIG, this approach incorporates a brightline test focused on those individuals and entities that directly participate in the provision of health care to patients and are in the best position to advance the implementation of electronic health records adoption. The definition encompasses hospitals, group practices, physicians, nursing and other facilities, pharmacies, laboratories, oncology centers, community health centers, federally qualified health centers (FQHCs), dialysis facilities and a broad array of health plans. Also included are ancillary service providers such as durable medical equipment (DME) suppliers. However, based on the OIG’s enforcement experience with “unscrupulous” manufacturers, eligible donors do not include pharmaceutical, device or durable medical equipment manufacturers, or other manufacturers or vendors that indirectly furnish items and services used in the care of patients.⁵³ The final rule permits donation of protected remuneration to any individual or entity engaged in the delivery of health care services that are covered by a federal health care program.⁵⁴ Protected recipients include physicians, group practices, physician assistants, nurse practitioners, nurses, therapists, audiologists, pharmacists, nursing and other facilities, FQHCs and community health

centers, laboratories and other suppliers and pharmacies.⁵⁵

- c. **Criteria for Selecting Recipients** – Tracking the Stark exception for electronic records, the rule provides that donors may not take into account, directly or indirectly, the volume or value of the physician's referrals or other business generated between the parties when determining which physicians are eligible to receive items and services or the amount or nature of the items or services received.⁵⁶ The rule also contains a list of considerations which are deemed to meet this requirement. These include:
- i. the total number of prescriptions written by the physician;
 - ii. the size of the physician's medical practice (e.g. total patients, total patient encounters, or total relative value units);
 - iii. the total number of hours that the physician practices medicine;
 - iv. the physician's overall use of automated technology in his or her medical practice;
 - v. whether the physician is a member of the donor's medical staff;
 - vi. the level of uncompensated care provided by the physician; or
 - vii. in reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.⁵⁷
- d. **Donor Prohibitions** – The donor may not take any action or limit or restrict the use, compatibility or interoperability of the items or services with other electronic prescribing or electronic health records systems⁵⁸ or the physician's ability to use the items or services for any patient without regard to payor status.⁵⁹
- e. **Recipient Prohibitions** – Neither the physician nor their practices may make the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.⁶⁰
- f. **Written Agreement** – The arrangement must be set forth in a signed written agreement that specifies the items and services being provided, the

donor's costs of the items and services and covers all of the electronic prescribing items and services to be provided by the donor.⁶¹

- g. **Good Faith** – The donor must not have actual knowledge of or act in reckless disregard or deliberate ignorance of the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.⁶²
- h. **Required Co-payments** – Before the receipt of the items and services, the physician must pay 15 percent of the donor's costs for the items and services and the donor may not finance the physician's payment.⁶³
- i. **No Cost Shifting** – The donor does not shift costs of the items or services to any Federal health care program.⁶⁴

Section II – Questions and Answers

- Q. What are the penalties for violating the Stark law?
- A. For physicians, penalties include *civil* fines and penalties up to \$100,000 per violation and exclusion from federal health care programs. Individuals may also be denied payment or forced to refund payment for designated health care services provided in violation of the law.
- Q. What are the penalties for violating the federal anti-kickback statute?
- A. The federal anti-kickback statute provides *criminal* penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business that is reimbursable under any of the Federal health care programs. The offense is a felony and is punishable by fines up to \$25,000 and imprisonment for up to five years. In addition, violations of the anti-kickback statute may result in civil money penalties, program exclusion, and liability under the False Claims Act.
- Q. Do these regulations preempt state fraud and abuse laws?
- A. No. Under the MMA, federal electronic prescribing standards preempt State pharmacy law and regulation when the state law and regulation is contrary to the final standards or restricts the e-prescribing program and relates to the transmission of certain information. However, the federal government does not have authority to preempt state fraud and abuse laws. Before entering into any kind of arrangement to donate e-prescribing or medical record technology, it is impor-

tant to ensure that the arrangement is compliant not only with federal law, but with all applicable state laws.

Q. Why did CMS and the OIG limit donations of e-prescribing hardware, software, and training and support services to item and services that are used solely to transmit and receive electronic prescriptions? Isn't this likely to limit the usefulness of this exception?

A. While multi-functional technology such as a hand-held device that transmits prescription information, as well as send and receive email may be significantly more useful and cost effective, this provision comes directly from the statute and neither CMS nor the OIG had authority to change it. It should be noted that both the Stark exception and anti-kickback safe harbor for electronic medical records are broader. In addition, there are other exceptions to the Stark law and existing safe harbors that may be applicable. Finally, neither the Stark law or the anti-kickback statute are implicated in every arrangement involving the donation of non-monetary remuneration. For example, even the OIG has recognized that "fair market value arrangements that are arm's length and do not take into account in any manner the volume or value of Federal health care program business, or arrangements that do not have as one purpose the generation of business payable by a Federal health care program, should not raise concerns under the anti-kickback statute."⁶⁵

Q. Under both the Stark exception and the anti-kickback safe harbor for electronic medical records, recipients must contribute 15 percent of the donor's costs. How will this requirement affect safety-net providers such as FQHCs, other Medicaid providers and free clinics that serve the homeless and uninsured?

A. It is likely that safety-net providers that currently operate on thin margins may be more challenged than others to raise the matching funds needed to accept donations made possible by these final rules. However, such providers are not precluded from raising money from other sources. It will be important to monitor whether the requirement for a 15 percent co-payment has any disproportionate impact on the deployment of health information technology in health care settings serving the neediest patients.

– *Claudia Schlosberg*

¹ Social Security Act, §1128B(b), (42 U.S.C. 1320a-7b(b)).

² Social Security Act, § 1877.

³ 42 C.F.R. § 411.351

⁴ Medicare Modernization Act, Section 1860D-4(e)(6).

⁵ 42 C.F.R. §411.357(v); Physicians' Referral to Health Care Entities with Which They Have Financial Relationships, Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements, Preamble to the Final Rule, (hereinafter Preamble to Final Stark Rule") at 27-36.

⁶ 42 C.F.R. §411.357(v)(1).

⁷ 42 C.F.R. §411.357(v)(6); Preamble to the Final Stark Rule at 44.

⁸ Preamble to the Final Stark Rule at 44.

⁹ 42 C.F.R. §411.357(v)(2).

¹⁰ 42 C.F.R. §411.357(v)(3).

¹¹ 42 C.F.R. §411.357(v)(4).

¹² 42 C.F.R. §411.357(v)(5).

¹³ 42 C.F.R. §411.357(v)(7).

¹⁴ 42 C.F.R. §411.357(v)(8).

¹⁵ 42 C.F.R. §411.357(w).

¹⁶ 42 C.F.R. §411.357(w)(13)

¹⁷ 42 C.F.R. §411.357(w)

¹⁸ 42 C.F.R. §411.351

¹⁹ 42 C.F.R. §411.357(w)(2).

²⁰ 42 C.F.R. §411.357(w)(11).

²¹ 42 C.F.R. §411.357(w)(10)

²² 42 C.F.R. §411.357(w)(1).

²³ 42 C.F.R. §411.357(w)(6).

²⁴ 42 C.F.R. §411.357(w)(6)(i-vii).

²⁵ 42 C.F.R. §411.357(w)(3).

²⁶ 42 C.F.R. §411.357(w)(9).

²⁷ 42 C.F.R. §411.357(w)(5).

²⁸ 42 C.F.R. §411.357(w)(7).

²⁹ 42 C.F.R. §411.357(w)(8).

³⁰ 42 C.F.R. §411.357(w)(4).

³¹ 42 C.F.R. §411.357(w)(12)

³² 42 C.F.R. 1001.952(x), Medicare and State Health Programs: Fraud and Abuse; Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements under the Anti-Kickback Statute, (hereinafter "Preamble to Final Safe Harbor Rule") at 32-34.

³³ 42 C.F.R. 1001.952(x)(8).

³⁴ Preamble to the Final Safe Harbor Rule at 33.

- ³⁵ 42 C.F.R. §1001.952(x)91).
- ³⁶ Preamble to the Final Safe Harbor Rule at 36.
- ³⁷ 42 C.F.R. §1001.952(x)(6).
- ³⁸ Preamble to the Final Safe Harbor Rule at 44.
- ³⁹ 42 C.F.R. §.1001.952(x)(2).
- ⁴⁰ 42 C.F.R. §1001.952(x)(3).
- ⁴¹ 42 C.F.R. §1001.952(x)(4).
- ⁴² C.F.R. §1001.952(x)(5).
- ⁴³ 42 C.F.R. §1001.952(x)(7).
- ⁴⁴ 42 C.F.R. §1001.952(x)(8).
- ⁴⁵ 42 C.F.R. §1001.952(y).
- ⁴⁶ 42 C.F.R. §1001.952(y)(13)
- ⁴⁷ 42 C.F.R. §1001.952(y)(11).
- ⁴⁸ 42 C.F.R. §1001.952(y)(2)
- ⁴⁹ Id.
- ⁵⁰ 42 C.F.R. §1001.952(y)(10)
- ⁵¹ 42 C.F.R §1001.952(y)(9)
- ⁵² 42 C.F.R.§1001.952(y)(1)
- ⁵³ Preamble to the Final Safe Harbor Rule at 86-88
- ⁵⁴ 42 C.F.R. §1001.952(y)(1)
- ⁵⁵ Preamble to the Final Safe Harbor Rule at 95.
- ⁵⁶ 42 C.F.R. §1001.952(y)(5).
- ⁵⁷ Id.
- ⁵⁸ 42 C.F.R. §1001.952(y)(3).
- ⁵⁹ 42 C.F.R. §1001.952(y)(8).
- ⁶⁰ 42 C.F.R. §1001.952(y)(4).
- ⁶¹ 42 C.F.R. §1001.952(y)(6).
- ⁶² 42 C.F.R. §1001.952(y)(7).
- ⁶³ 42 C.F.R. §1001.952(y)(11).
- ⁶⁴ 42 C.F.R. §1001.952(y)(12).
- ⁶⁵ Preamble at 16.

For additional information or for assistance in structuring arrangements that may fall under these rules, please contact Claudia Schlosberg or any other member of Blank Rome's Health Law Practice Group.

Claudia Schlosberg, Partner
Blank Rome LLP
600 New Hampshire Avenue, N.W.
Washington, D.C. 20037
202.772.5985 (tel)
202.572.8403 (fax)
202.486.0822 (cell)
schlosberg@BlankRome.com

Health Law Practice Group

Howard A. Burde, Chair
215.569.5724
burde@BlankRome.com

Lawrence J. Beaser
215.569.5510
beaser@BlankRome.com

Katherine R. Friscia
215.569.5428
friscia@BlankRome.com

William E. Gramlich
215.569.5739
gramlich@BlankRome.com

Kathleen McDermott
202.772.5813
mcdermott-k@BlankRome.com

Claudia Schlosberg
202.772.5985
schlosberg@BlankRome.com

John D. Shire
215.569.5683
shire@BlankRome.com

Jessica M. Swartz
202.772.5871
swartz-j@BlankRome.com

Blank Rome's Health Law Practice Group

Blank Rome's Health Law Practice Group focuses on the core areas of Acute Care, Hospitals, and Health Systems; Compliance and Enforcement; Home and Community Based Care; Long Term Care; Health Insurance and Managed Care; and Public Health. The Health Law Practice Group serves clients nationally in more than 29 states, and internationally through affiliations in the United Kingdom, and the Far East.

To be added to or removed from any or all Blank Rome notices, please call 215.569.5500 ext. 4493 or email update@BlankRome.com