Submitter : Dr. JAMES SCULLY **Date:** 12/12/2005

Organization : AMERICAN PSYCHIATRIC ASSN.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

Issue

Background

[PLEASE NOTE: I TRIED MULTIPLE TIMES BEFORE 5:00 P.M. TO SUBMIT COMMENTS ONLINE AND HAD REPEATED ERROR WINDOWS COME UP FOR NO EXPLAINED REASON, BOTH WITH ATTACHED FILES AND PASTING INTO THIS FORM.] THANK YOU.

CMS-1303-P-56-Attach-1.DOC

American Psychiatric Association

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December 14, 2005

Mark McClellan, M.D. Ph.D., Administrator
Office of the Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1303-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Proposed Rule: "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements;" CMS-1303-P

Dear Administrator McClellan:

The American Psychiatric Association (APA), the national medical specialty society representing more than 37,000 psychiatric physicians, nationwide, appreciates the opportunity to submit these comments concerning the proposed rule, under 42 C.F.R. Part 411, published in the Federal Register on October 11, 2005, with the title, "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements."[1]

APA generally supports CMS's goal of creating protection from self-referral violations, under Section 1877 of the Social Security Act (the "Act"), for physicians who receive assistance with equipment and services to facilitate Medicare electronic prescribing and other electronic healthcare transactions. It is appropriate for the federal government to offset mandates and other pressures to participate in electronic healthcare transactions by giving providers the leeway to obtain assistance with items and services

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necessary for compliance. Otherwise, the financial burdens posed by these programmatic requirements may decrease providers' incentives to afford care to Medicare beneficiaries.

APA notes that the Office of the Inspector General (OIG) published on October 11, 2005, a proposed a safe harbor to afford legal protections to donors and recipients, with regard to e-prescribing items and services. This safe harbor protection is against prosecution under the anti-kickback statute Section 1128B of the Social Security Act (the "Act"), 42 U.S.C. 1320a-7b(b). APA is filing comments to OIG's proposed rule on this topic, as well as to CMS' proposed rule. Due to the nature of the topic, there is some overlap in the language from both agencies and in APA's comments to OIG and CMS. APA maintains that consistency across agencies is essential as to terms, requirements and standards used for the proposed safe harbor and the self-referral exception, insofar as is practically possible.

A. "Necessary and Used Solely"

Sec. 1860D-4(e)(6) of the Act mandates that, "The Secretary, in consultation with the Attorney General, shall promulgate regulations that provide for a safe harbor from sanctions under paragraphs (1) and (2) of section 1128B(b) and an exception to the prohibition under subsection (a)(1) of section 1877 with respect to the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and training services) *necessary and used solely to receive and transmit electronic* prescription information in accordance with the standards promulgated under this subsection.[2] (italics supplied for emphasis)

The phrase "necessary and used solely" within the context of the whole sentence in which it appears refers to the "hardware, software, or information technology and training services" "necessary and used solely *to receive and transmit electronic prescription information in accordance with the standards promulgated* under this subsection." That sentence clearly refers to the data interchange standards that CMS must establish for e-prescribing transactions, under the authority of that same statute.

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(A) in the case of a hospital, by the hospital to members of its medical staff;
(B) in the case of a group practice (as defined in section 1877(h)(4)), by the practice to prescribing health care professionals who are members of such practice; and
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CMS previously published a proposed rule on foundation standards for e-prescribing transactions, to which APA filed comments.[3]

Interpreted in context, the phrase "necessary and used solely" modifies the rest of that sentence. It means that the hardware, software and services must be "necessary" to perform e-prescribing transactions "solely" in accordance with CMS' established data interchange standards, instead of doing so using other, non-compliant data interchange standards. This interpretation is consistent with the purpose of the proposed self-referral exception, which is to allow donors to provide equipment and services that facilitate e-prescribing in compliance with regulations requiring specific data interchange standards. It does *not* mean CMS' interpretation that the only *function* the items or services can perform for purposes of the proposed rule, Sec. 411.357(v) are e-prescribing functions.[4] This interpretation is not consistent with legislative intent or the practical reality of computers and electronic transactions.

Legislators would have anticipated that computers, software and services would be capable of multiple functions that include e-prescribing data transactions. They would not intend to make a self-referral exception meaningless by its being overly restrictive to the point of requiring items/services to have only one capability. In addition, e-prescribing rules require transactions that are broader than just the prescription itself. These include electronic healthcare information on a patient that could reside in various software programs that communicate with or complement the prescribing software but are not necessarily in the same program.

APA maintains that this CMS interpretation does not take create incentives for provider participation in the e-prescribing program.

Physician Certification is Unduly Burdensome and Ineffective

The proposed certification requirement for physicians is based on CMS' narrow interpretation that "necessary" means "items or services that are technically or functionally equivalent." If they are not, the provider will fall outside the proposed self-referral exception's protections. In order to document a lack of technical or functional equivalence, CMS proposes to require a physician to provide certification of this both upon initial receipt of items or services and again, prior to receiving them, if they are not covered in the initial certification. This includes upgrades, as well. New or upgraded software, hardware, services, etc., are inevitable and can become available repeatedly within short timeframes. It is not possible to accurately forecast these and accurately certify for their eventual donation in the initial certification. CMS's proposed

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certification requirement will create an ongoing, needless burden for providers and an immense number of documents to handle.

Technical or functional equivalence is not an appropriate or workable standard. What this means is not even defined in the proposed rule. The certification requirement relating to this standard is, likewise, a problem. A comparative assessment of technical or functional equivalence between existing and new equipment or software requires more technical knowledge than many providers possess. As a practical matter, it is unclear how a prospective physician could perform a meaningful assessment of equivalence prior to receiving the equipment to be donated. Yet that is what CMS proposes. For these reasons, a physician's certification as to a lack of technical or functional equivalence would be without substance. It forces a provider to attest to that which: 1. is unlikely to be within his or her scope of expertise; and 2. cannot be meaningfully assessed as a practical matter, prior to receiving the items or services. A certificate that is primarily symbolic is not worth the time and financial expenditure it would entail.

On the other side, CMS proposes the requirement, under Sec. 411.357(v)(8) and (w)(6) that the donating entity must not have "actual knowledge" that the physician's items or services are "technically or functionally equivalent" to those the donor plans to donate.[5] Does CMS anticipate that the donor will also have to perform a comparative analysis to fall within this standard? This is impractical.

There is little practical sense in donors wasting money by providing the same equipment to physicians that donors know the physicians have. Some degree of communication in this regard can be expected between donors and physicians, especially within the same organizations, where cost-containment efforts would already limit redundant expenditures.

CMS' proposed approach is extremely unwieldy and burdensome for the provider, as well as posing an undue risk of non-compliance by donors. It also it requires costly, ongoing micro-monitoring by federal oversight bodies of every donor-physician transaction anticipated by this rule. These requirements are overly narrow for their intended purpose. They are virtually impossible to interpret, monitor and enforce. Thus, they will drain resources, while being unable to protect effectively against fraud and abuse. The goal of CMS is to get more providers to participate with electronic healthcare transactions, yet the structure of CMS' proposed rule does not effectuate this goal. It makes sense to provide the most closely tailored self-referral exception that will do the job.

Recommendation: APA strongly urges CMS to adopt APA's statutory interpretation and create within Sec. 411.357 a a provision that deems compliance with the statute, under certain circumstances of donation of items or services to a recipient. This approach is

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simpler and would still enable OIG and CMS to filter out egregious cases of non-compliance without placing an undue burden upon providers.

CMS should delete the physicians' certification requirements, per Sec. 411.357(v)(7)(iv) and (w)(5)(iv), from the proposed rule.[6] CMS should also delete proposed Sec. 411.357(v)(8) that refers to the "entity" not having knowledge of technical or functional equivalence.[7]

Instead of a provider's certification, the written agreement between donor and physician could affirm their intent to comply with the self-referral statute and relevant regulations. Specifically, both parties could sign a statement attesting that their business transactions do not take into account prohibited factors, such as the "volume or value of referrals or other business generated between the parties" or "the receipt of items or services a condition of doing business with the donor."[8]

B. "Substantial Use"

Computer systems and software are generally multi-functional. Also, many computers come with bundled software programs installed by the factory. More than one of those programs may relate to scheduling, patient contact information, billing databases, management of electronic healthcare records and functions related in some way to e-prescribing. It would be virtually impossible to monitor a provider's percentage of use of computer programs and hardware. Even if software could track this, the cost and time input for OIG or CMS to monitor the use of millions of computers would be excessive. It can be assumed that software programs designed for e-prescribing will be used for that purpose. Additional uses of software or equipment cannot feasibly be monitored. If a computer contains additional software beyond that used for e-prescribing, it would not be practical to strip out that software, especially if it is used for patient-related activities.

CMS anticipates creating an additional self-referral exception to deal with multi-functional items and services.[9] Similarly, OIG intends to adopt another, separate safe

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harbor, under Sec. 1128B(b)(3)(E) of the Act, that will accommodate a more realistic view of multi-functional technology. CMS and OIG propose to have in their future proposed rules a standard of "substantial use," which is subject to interpretation and difficulty in enforcement.[10, 11]

There should be consistency in standards between the new safe harbors and the self-referral exception. In addition, there is likely to be crossover in the hardware and software programs that will facilitate multiple uses in e-prescribing and other electronic health records transactions.

C. Value & Caps

There does not seem to be a clear way to determine a value of items or services that would trigger fraud and abuse. There are already safeguards in place to prevent donors and recipients from violating the anti-referral statute. Value itself is a slippery concept, since a number of reference points can be used to determine value, such as retail prices, wholesale prices, or discounted bulk-purchase prices. These may also change over time. For the same item, these reference points could be vastly different as cost to the donor.

The value of donations will be self-limiting to an extent. Donors are unlikely to spend more than necessary, especially those who provide items and services within their own organizations, such as hospitals and group practices.

There is no also point in creating a value cap on donations. Incorporating a value cap into regulations would require continual updates by regulatory revision, as inflation and other market factors render the original cap obsolete. The imposition of caps presupposes that compliance monitoring, which creates another layer of cost and time expenditure for federal agencies, donors and recipients.

Recommendation: APA urges CMS to refrain from requiring value assessments or caps for donated items or services, since these are unnecessary, unworkable and will create added administrative burdens on federal agencies, donors and physicians. Toward that end, CMS should delete any such references from the proposed rule, including in Sec. 411.357(v)(7(ii).

D. Hospitals/Medical Staff

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[10] CMS Proposed Rule: "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements;" CMS-1303-P [Federal Register: October 11, 2005 (Volume 70, No. 195)], at 59185.

[11] OIG Proposed Rule: "Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute;" OIG-405-P [Federal Register: October 11, 2005 (Volume 70, No. 195)], at 59019.

APA maintains that only prescribing medical staff (physicians) should be protected under the proposed self-referral exception. Hospitals should be encouraged through self-referral exceptions to provide their physicians with modern technology, especially for an essential function such as e-prescribing. Physicians are the ultimate arbiters of appropriate medical care and those to whom ultimate liability for legal compliance rests.

CMS states that, "(p)roposed Sec. 411.357(v)(1)(i) would protect donations of qualifying electronic prescribing technology provided by a hospital to physicians on its medical staff. We intend to protect donations only to physicians who routinely furnish services at the hospital."[12] If that is to be an assessment standard for compliance, then CMS' definition of "routinely" should be clarified. If a hospital provides e-prescribing systems, any physician on medical staff should be expected to use them. It is contrary to proper quality assurance measures to have side-by-side prescribing systems divided among medical staff who "routinely" practice there and those who practice less than "routinely." Systemic inconsistencies like that increase the risk of adverse errors in patients and non-compliance with legal requirements. Apart from hand-held devices, the main equipment is likely to be on site at the hospital, so it is practical for physicians working there to use the equipment at hand.

Recommendation: OIG's definition of "routinely" should be clarified, if that is to be an assessment standard for compliance.

E. Group Practices/Members

A group practice should be able to provide its independent contractors with access to the group's donated e-prescribing equipment and training. This furthers CMS' goal of widespread adoption of e-prescribing and enhances quality of patient care through consistency. Prescribing is a practice area especially fraught with adverse outcomes from medical errors. Therefore, consistency in the practice's risk management approach is more likely to result in reduced error rates and improved outcomes. For the same reasons described above for hospitals, it makes practical sense to avoid having physicians use different prescribing systems for the same group practice.

It is important that donated items or services become the legal property of the group practice. If the practice allows independent contractors to access these to do their jobs, it is not the same as giving ownership of donated items to the contractors.

Recommendation: APA urges CMS to allow a group practice's independent contractors to avail themselves of donated items or services under the ownership of the group

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practice. This will facilitate adoption of electronic healthcare transactions and promote consistency in patient care quality.

F. Selective Criteria for Recipients

CMS has expressed an interest in comments about proposed Sec. 411.357(x)(4), regarding donors' use of permissible criteria in order to selectively choose physicians to receive items and services. CMS proposes to distinguish between eligibility criteria that are "directly related to volume or value of referrals or other business generated between the parties," hence are prohibited, from those criteria that are indirectly related to these factors.[13] However, if donors are allowed to use even indirect markers for business value or volume, the intent and purpose of the statute to prevent such churning of business would appear to be violated. CMS' proposed criteria that it will automatically deem to be "not directly related." So deemed, CMS would not interpret these to be violations of the self-referral statute.[14]

Yet, contrary to the purpose of the statute, all of these criteria (apart from technology use) appear to be quite direct, reliable indicators for value and volume of business. In addition, CMS proposes that only one of the criteria has to be met, in order for the donor to be exempt from violation. The last criterion provides a wide berth of interpretation likely to favor donors. The permissible eligibility determination criteria, under Sec. 411.357(x)(4) are:

> "total number of prescriptions written by the recipient;
>
> "size of the recipient's medical practice (for example, total patients, total patient encounters, or relative value units);
>
> "number of hours that the recipient practices medicine;
>
> "the recipient's overall use of automated technology in his or her medical practice;

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"Proposed Sec. 411.357(x)(4) would enumerate several selection criteria that would be deemed not to be directly related to volume or value of referrals or other business generated between the parties. For example, selection criteria that are based upon the total number of prescriptions written by a physician would not be precluded, but the proposed regulation would prohibit criteria based upon the number or value of prescriptions written by the physician and dispensed or paid by the DHS entity, as well as criteria based on any other business generated between the parties. Also, the exception would not protect arrangements that seek to induce a physician to change loyalties from other providers or plans to the DHS entity."

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"whether the physician is a member of the hospital's medical staff, if the donor is a hospital; or

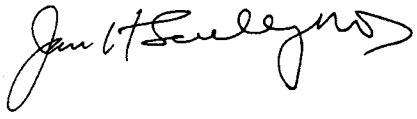
"The determination is made in any reasonable and verifiable manner that is not directly related to the volume or value of referrals or other business generated between the parties."[15]

Recommendation: APA maintains that it should not be permissible to use selection criteria, such as these, that are based either directly, or indirectly, upon value or volume of business that the physician generates for the donor's financial gain. The types of permissible eligibility criteria that APA envisions as appropriate would be far more neutral, i.e., years of seniority with the donor entity and some meaningful assessment of the physician's use of technology.

CONCLUSION AND RECOMMENDATIONS

APA strongly urges CMS to consider the proposed self-referral exception, in light of the clear legislative intent and CMS' goal to create an incentive for providers to participate in the Medicare e-prescribing, as well as to adopt electronic healthcare records transactions in general. Participation and compliance will be facilitated by regulations that are clearly understood and easy to apply to real life practice situations. Toward that end, APA makes the recommendations noted above and requests CMS to implement relevant changes in the proposed rule.

Thank you for your consideration of these comments.



James H. Scully Jr., M.D.
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CMS' proposed approach is extremely unwieldy and burdensome for the provider, as well as posing an undue risk of non-compliance by donors. It also it requires costly, ongoing micro-monitoring by federal oversight bodies of every donor-physician transaction anticipated by this rule. These requirements are overly narrow for their intended purpose. They are virtually impossible to interpret, monitor and enforce. Thus, they will drain resources, while being unable to protect effectively against fraud and abuse. The goal of CMS is to get more providers to participate with electronic healthcare transactions, yet the structure of CMS' proposed rule does not effectuate this goal. It makes sense to provide the most closely tailored self-referral exception that will do the job.

Recommendation: APA strongly urges CMS to adopt APA's statutory interpretation and create within Sec. 411.357 a a provision that deems compliance with the statute, under certain circumstances of donation of items or services to a recipient. This approach is

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[5] CMS Proposed Rule: "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements;" CMS-1303-P [Federal Register: October 11, 2005 (Volume 70, No. 195)], at 59197.

simpler and would still enable OIG and CMS to filter out egregious cases of non-compliance without placing an undue burden upon providers.

CMS should delete the physicians' certification requirements, per Sec. 411.357(v)(7)(iv) and (w)(5)(iv), from the proposed rule.[6] CMS should also delete proposed Sec. 411.357(v)(8) that refers to the "entity" not having knowledge of technical or functional equivalence.[7]

Instead of a provider's certification, the written agreement between donor and physician could affirm their intent to comply with the self-referral statute and relevant regulations. Specifically, both parties could sign a statement attesting that their business transactions do not take into account prohibited factors, such as the "volume or value of referrals or other business generated between the parties" or "the receipt of items or services a condition of doing business with the donor."[8]

B. "Substantial Use"

Computer systems and software are generally multi-functional. Also, many computers come with bundled software programs installed by the factory. More than one of those programs may relate to scheduling, patient contact information, billing databases, management of electronic healthcare records and functions related in some way to e-prescribing. It would be virtually impossible to monitor a provider's percentage of use of computer programs and hardware. Even if software could track this, the cost and time input for OIG or CMS to monitor the use of millions of computers would be excessive. It can be assumed that software programs designed for e-prescribing will be used for that purpose. Additional uses of software or equipment cannot feasibly be monitored. If a computer contains additional software beyond that used for e-prescribing, it would not be practical to strip out that software, especially if it is used for patient-related activities.

CMS anticipates creating an additional self-referral exception to deal with multi-functional items and services.[9] Similarly, OIG intends to adopt another, separate safe

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[6] CMS Proposed Rule: "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements;" CMS-1303-P [Federal Register: October 11, 2005 (Volume 70, No. 195)], at 59197.

[7] CMS Proposed Rule: "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements;" CMS-1303-P [Federal Register: October 11, 2005 (Volume 70, No. 195)], at 59197.

[8] CMS Proposed Rule: "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements;" CMS-1303-P [Federal Register: October 11, 2005 (Volume 70, No. 195)], at 59189; 59197.

[9] CMS Proposed Rule: "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements;" CMS-1303-P [Federal Register: October 11, 2005 (Volume 70, No. 195)], at 59185.

harbor, under Sec. 1128B(b)(3)(E) of the Act, that will accommodate a more realistic view of multi-functional technology. CMS and OIG propose to have in their future proposed rules a standard of "substantial use," which is subject to interpretation and difficulty in enforcement.[10, 11]

There should be consistency in standards between the new safe harbors and the self-referral exception. In addition, there is likely to be crossover in the hardware and software programs that will facilitate multiple uses in e-prescribing and other electronic health records transactions.

C. Value & Caps

There does not seem to be a clear way to determine a value of items or services that would trigger fraud and abuse. There are already safeguards in place to prevent donors and recipients from violating the anti-referral statute. Value itself is a slippery concept, since a number of reference points can be used to determine value, such as retail prices, wholesale prices, or discounted bulk-purchase prices. These may also change over time. For the same item, these reference points could be vastly different as cost to the donor.

The value of donations will be self-limiting to an extent. Donors are unlikely to spend more than necessary, especially those who provide items and services within their own organizations, such as hospitals and group practices.

There is no also point in creating a value cap on donations. Incorporating a value cap into regulations would require continual updates by regulatory revision, as inflation and other market factors render the original cap obsolete. The imposition of caps presupposes that compliance monitoring, which creates another layer of cost and time expenditure for federal agencies, donors and recipients.

Recommendation: APA urges CMS to refrain from requiring value assessments or caps for donated items or services, since these are unnecessary, unworkable and will create added administrative burdens on federal agencies, donors and physicians. Toward that end, CMS should delete any such references from the proposed rule, including in Sec. 411.357(v)(7(ii).

D. Hospitals/Medical Staff

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[10] CMS Proposed Rule: "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements;" CMS-1303-P [Federal Register: October 11, 2005 (Volume 70, No. 195)], at 59185.

[11] OIG Proposed Rule: "Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute;" OIG-405-P [Federal Register: October 11, 2005 (Volume 70, No. 195)], at 59019.

APA maintains that only prescribing medical staff (physicians) should be protected under the proposed self-referral exception. Hospitals should be encouraged through self-referral exceptions to provide their physicians with modern technology, especially for an essential function such as e-prescribing. Physicians are the ultimate arbiters of appropriate medical care and those to whom ultimate liability for legal compliance rests.

CMS states that, "(p)roposed Sec. 411.357(v)(1)(i) would protect donations of qualifying electronic prescribing technology provided by a hospital to physicians on its medical staff. We intend to protect donations only to physicians who routinely furnish services at the hospital."[12] If that is to be an assessment standard for compliance, then CMS' definition of "routinely" should be clarified. If a hospital provides e-prescribing systems, any physician on medical staff should be expected to use them. It is contrary to proper quality assurance measures to have side-by-side prescribing systems divided among medical staff who "routinely" practice there and those who practice less than "routinely." Systemic inconsistencies like that increase the risk of adverse errors in patients and non-compliance with legal requirements. Apart from hand-held devices, the main equipment is likely to be on site at the hospital, so it is practical for physicians working there to use the equipment at hand.

Recommendation: OIG's definition of "routinely" should be clarified, if that is to be an assessment standard for compliance.

E. Group Practices/Members

A group practice should be able to provide its independent contractors with access to the group's donated e-prescribing equipment and training. This furthers CMS' goal of widespread adoption of e-prescribing and enhances quality of patient care through consistency. Prescribing is a practice area especially fraught with adverse outcomes from medical errors. Therefore, consistency in the practice's risk management approach is more likely to result in reduced error rates and improved outcomes. For the same reasons described above for hospitals, it makes practical sense to avoid having physicians use different prescribing systems for the same group practice.

It is important that donated items or services become the legal property of the group practice. If the practice allows independent contractors to access these to do their jobs, it is not the same as giving ownership of donated items to the contractors.

Recommendation: APA urges CMS to allow a group practice's independent contractors to avail themselves of donated items or services under the ownership of the group

[12] CMS Proposed Rule: "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements;" CMS-1303-P [Federal Register: October 11, 2005 (Volume 70, No. 195)], at 59185.

practice. This will facilitate adoption of electronic healthcare transactions and promote consistency in patient care quality.

F. Selective Criteria for Recipients

CMS has expressed an interest in comments about proposed Sec. 411.357(x)(4), regarding donors' use of permissible criteria in order to selectively choose physicians to receive items and services. CMS proposes to distinguish between eligibility criteria that are "directly related to volume or value of referrals or other business generated between the parties," hence are prohibited, from those criteria that are indirectly related to these factors.[13] However, if donors are allowed to use even indirect markers for business value or volume, the intent and purpose of the statute to prevent such churning of business needs to be considered for consistency. CMS' proposed criteria that it will automatically deem to be "not directly related." So deemed, CMS would not interpret these to be violations of the self-referral statute.[14]

Recommendation: APA maintains that it should not be permissible to use selection criteria, unless they are consistent with the applicable statute.

CONCLUSION AND RECOMMENDATIONS

APA strongly urges CMS to consider the proposed self-referral exception, in light of the clear legislative intent and CMS' goal to create an incentive for providers to participate in the Medicare e-prescribing, as well as to adopt electronic healthcare records transactions in general. Participation and compliance will be facilitated by regulations that are clearly understood and easy to apply to real life practice situations. Toward that end, APA makes the recommendations noted above and requests CMS to implement relevant changes in the proposed rule.

Thank you for your consideration of these comments.

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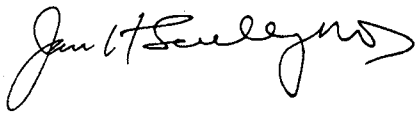
[13] CMS Proposed Rule: "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements;" CMS-1303-P [Federal Register: October 11, 2005 (Volume 70, No. 195)], at 59190; 59197-98:

"Proposed Sec. 411.357(x)(4) would enumerate several selection criteria that would be deemed not to be directly related to volume or value of referrals or other business generated between the parties. For example, selection criteria that are based upon the total number of prescriptions written by a physician would not be precluded, but the proposed regulation would prohibit criteria based upon the number or value of prescriptions written by the physician and dispensed or paid by the DHS entity, as well as criteria based on any other business generated between the parties. Also, the exception would not protect arrangements that seek to induce a physician to change loyalties from other providers or plans to the DHS entity."

[14] CMS Proposed Rule: "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements;" CMS-1303-P [Federal Register: October 11, 2005 (Volume 70, No. 195)], at 59197.



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Medical Director and C.E.O., American Psychiatric Association

Submitter : Dr. Robert Murphy **Date:** 12/13/2005

Organization : Memorial Hermann Healthcare System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1303-P-58-Attach-1.DOC

December 9, 2005

MEMORIAL HERMANN

Mark B. McClellan, M.D., Ph.D.
Adminstrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1303-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: CMS-1303-P "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Records Arrangements"

Dear Dr. McClellan:

On behalf of the Memorial Hermann Healthcare System (MHHS), the largest not-for-profit system in the state of Texas, and on behalf of our 15,000 employees and 5,000 medical staff members, we are supporting the consensus position regarding proposed rule articulated by the National Alliance for Health Information Technology (the "Alliance") with these exceptions and additional comments:

Electronic Prescribing Exception: § 411.357(v)

2. Designated Health Services (DHS) Entities Protected by the Exception

MHHS does not support the view of the Alliance that an Integrated Delivery System (IDS) would be ineligible as a donor under the proposed rule; we believe the proposed rule is not specific on this point.

With the growth of hospitalist services and reduction of inpatient services provided by many primary care providers, and an opportunity to rapidly advance EHR adoption, we believe a IDS with a network physician provider organization should be specifically noted as an additional entity protected by the exception.

As stated, the proposed rule "is intended to protect donations only to physicians who routinely furnish services at the hospital." This, however, does not cover the majority of

physicians who relate to an IDS. For example, as written, the regulation would allow donation of items and services to an infrequent but routine consultant (e.g., a rheumatologist or ophthalmologist), while excluding a busy primary care physician who uses a hospitalists service, and who provides essential follow-up care from the emergency department or post-admission. The exclusion of non-admitting physicians could significantly limit adoption in primary care physician offices.

Exceptions for Certain Arrangements Involving Electronic Health Records Items and Services: § 411.357(w) and § 411.357(x)

Covered Technology

We concur with the Alliance's proposal to replace the pre- and post-certification regulations with a single, more immediate and workable exemption. In addition:

We believe that e-prescribing is, in fact, an established functional component of computerized physician order entry (CPOE), which also includes the other noted items and services (supplies or labs). We recommend that CPOE be specifically added as a covered technology, with a requirement of enabling e-prescribing.

We believe the descriptive provisions of the proposed rule and the proposed rule are contradictory on the matter of physician certification that the received items or services are "[not] technically and functionally equivalent" (p. 59188, column three, line 12) or "not technically or functionally equivalent" (§ 411.357(w)(5)(iv)) to what the physician currently possesses. The distinction between "and" and "or" is significant. Many software systems contain the functional component of results review; by including the "or" statement, the equivalency test would be met and the physician excluded from the exemption. Defining technical equivalency faces even greater challenges on the other end, as many software systems have specific versions that, one could argue, are technically different, and therefore not equivalent. As the industry has struggled with terms such as standards, interoperability and the elements of certification, introducing generic regulatory language that would be widely open to interpretation, would be very problematic. We suggest this be stricken from the proposed rule.

Value of Protected Technology

In considering a cap on the value of protected technology, the proposed rule does not appear to include the critical ongoing customer support. As the amount and methodology is being debated, we would strongly suggest that ongoing customer support be specifically noted in the "items and services," and that the proportional cost allocation be included in the value cap.

We applaud the Administration efforts to improve health care by removing barriers to healthcare IT adoption, and appreciate the opportunity to comment on the proposed rule.

Please contact Dr. Robert Murphy at 713-448-6339, or email robert.murphy@memorialhermann.org for any questions regarding our comments.

Sincerely,

David F Bradshaw

David F. Bradshaw
Vice President, Marketing Communications & Chief Information Officer