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FY 2009 Inpatient Prospective Payment Final Rules Modifications to the Stark Law Regulations:

Does Your Organization Need to Restructure Any Financial Relationships with Physicians?

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On August 19, 2008, the Centers for Medicare and Medicaid Services ("CMS") issued the final Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates final rules ("FY 2009 IPPS Final Rules").[1] These rules, among other things, included a number of significant regulatory changes to the federal physician self-referral law, more commonly referred to as the "Stark Law".[2]

The Stark Law changes implemented by CMS in the FY 2009 IPPS Final Rules are significant, especially as many of the changes reverse previous, longstanding CMS interpretations of the Stark Law. Although many of the modifications included in the FY 2009 IPPS Final Rules became effective on October 1, 2008, certain of the provisions related to the Stark Law do not take effective until October 1, 2009. Meanwhile, many people in the industry are hoping that the change in Administration and CMS personnel responsible for Stark Law implementation, together with economic circumstances and/or pending litigation (discussed below), will result in a further delay or modification of the Stark Law changes in the new rules, obviating the need for any restructuring of arrangements prior to October 2009.[3] As is the case in general with the Stark Law, given the potentially onerous penalties for Stark Law violations, preparation is the key in this area.

This Client Alert addresses two of the changes included in the FY 2009 IPPS Final Rules that health care organizations should be aware of in determining whether a particular arrangement should be restructured. Each goes into effect on October 1, 2009. First, CMS expanded the definition of the term "entity". This results in a restriction on the ability of physician organizations to provide services "under arrangements". Second, CMS has limited the use of percentage and per click compensation formulae. Following a brief

background and overview of the Stark Law and the provisions included in the FY 2009 IPPS Final Rule, we address the following 4 questions:

- ***How do you know if your organization has any "under arrangements," percentage or per-click arrangements that should be restructured as a result of the revised Stark Law regulations?***
- ***Do the revised Stark Law regulations ban all "under arrangements" relationships between physicians (and physician-owned entities) and hospitals?***
- ***Do the revised Stark Law regulations prohibit all percentage and per-click payment arrangements with physicians?***
- ***What regulatory compliance factors should be considered when embarking on the restructuring or unwinding of a current arrangement?***

Background on the Stark Law and Its Regulatory History

In brief, the Stark Law (1) prohibits a physician from making referrals for certain designated health services ("DHS") payable by Medicare to an entity with which he or she (or an immediate family member) has a direct or indirect financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third-party payer) for those DHS rendered as a result of a prohibited referral.[4] The Stark Law establishes specific exceptions and grants the Secretary of the Department of Health and Human Services the authority to create regulatory exceptions for financial relationships that pose no risk of program or patient abuse.[5]

The Stark Law is a strict liability statute. This means that a financial relationship that does not meet a relevant exception is noncompliant, regardless of whether one or both of the parties to the arrangement were unaware of or did not intend the defect, or whether the arrangement has benign or even beneficial attributes.

Violations of the Stark Law are subject to onerous penalties.[6] Any person who submits or causes to be submitted a claim for a service that the person knows or should know is for a service that results from a prohibited self-referral, or does not make for each such service a required refund, can be assessed a civil monetary penalty ("CMP") of up to $15,000 for each such service plus two times the reimbursement claimed. Such person can be excluded from Medicare and Medicaid participation. Further, a CMP of up to $100,000 and exclusion can be imposed on persons who enter into circumvention schemes (such as a cross-referral arrangement).

During a six year period from 1998 to 2004, CMS issued three Stark Law rules (a proposed rule and two final sets of rules referred to as "Phase I" and "Phase II" final rules). Since July 12, 2007 to present – not quite a year and a half – CMS has issued five separate sets of proposed and final Stark Law rules, including the FY 2009 IPPS Final Rules, which have significantly changed the Stark Law regulations.[7]

Background on the Stark Law Regulations Included in the FY 2009 IPPS Final Rules

Definition of "Entity"

The first major revision to the Stark Law regulations is in the definition of the key term "entity." Currently, the term "entity" is defined as a person or entity that "furnishes DHS," defined as the person/entity "to which CMS makes payment for DHS." However, effective October 1, 2009, the term "entity" will be defined going forward as "the person or entity that has performed services that are billed as DHS or the person or entity that has presented a claim to Medicare for the DHS, including the person or entity to which the right to payment for the DHS has been reassigned…."[8] This modification means that the Stark Law will soon apply not only to the entity that submits a claim and receives Medicare payments for DHS, but also to an entity that "performs" DHS for which it does not directly bill the Medicare Program.

By way of example, the current Stark Law regulations do not extend directly to physician-owned companies acting as lessors of space and equipment or as providers of professional and non-professional personnel to hospitals "under arrangements." In these arrangements, the physician-owned companies are paid by the hospital to furnish services for which the hospital bills the Medicare Program. Under the current Stark Law regulations, the physicians could end up with direct or indirect *compensation* arrangements with the hospitals to which they supplied items or services (for which an exception would need to apply in order for the physicians to refer Medicare patients to those hospitals), but the company that the physicians directly own falls outside of the Stark Law, and the physicians' ordering of items or services from that physician-owned company are not Stark Law-covered referrals. Therefore, physician-owned companies have been able to provide services "under arrangements" or "perform" services through leased space, equipment and service arrangements with hospitals, provided that the indirect arrangement between the physicians and the hospitals are structured appropriately.

Under the FY 2009 IPPS Final Rules, effective October 1, 2009, the analysis has changed because the "entity" that "performs" the DHS (*e.g.*, the physician-owned company) is considered to be the Stark Law-covered entity for purposes of the compliance analysis, and the physicians' arrangements with that "entity" must qualify for Stark Law protection or the physicians will not be able lawfully to refer patients or services to that physician-owned company. Unfortunately, CMS declined to provide a specific definition of "perform" in the recent regulatory revisions. CMS did state, however, "[w]e do not consider an entity that leases or sells space or equipment used for the performance of the service, or furnishes supplies that are not separately billable but used in the performance of the medical service, or that provides management, billing services, or personnel to the entity performing the service, to perform DHS."[9]

This change in the definition of "entity" means that entities that were considered to be providing services that were not DHS now will be subject to the Stark Law because the services will be performed by the physicians and billed by the hospital as DHS. The challenge is that there are very few Stark Law exceptions that protect physician-

ownership in DHS entities (outside of whole hospital ownership, the in-office ancillary services exception or the rural provider exception), so many of these physician-owned companies will likely need to be reviewed and restructured.

The second major revision in the FY 2009 IPPS Final Rules is that CMS has adopted a number of limitations on the ability of health care entities to utilize percentage and per-click payment methodologies in the context of equipment and space lease arrangements. In previous final rules, CMS adopted a number of "special rules on compensation" and had provided that compensation would be considered to be "set in advance" if the aggregate compensation, which can include per-use and/or per-service methodologies, as well as specific percentage formulas, is set out in writing and in sufficient detail so that it can be objectively verified before the furnishing of items or services for which the compensation is to be paid.[10] In the past, CMS also provided that unit-based compensation (including time-based or per-unit compensation) is deemed not to take into account "the volume or value of referrals" if the per-unit or per-click based compensation is fair market value at the inception of the arrangement and does not vary during the course of the arrangement in any manner that takes into account referrals of DHS.[11]

However, in the FY 2009 IPPS Final Rules, CMS revised several exceptions (*i.e.*, the office space and equipment lease exceptions, as well as the fair market value and indirect compensation arrangements exceptions) to address the use of percentage-based compensation formulae and per-click arrangements in the context of equipment and space leases. Specifically, effective October 1, 2009, these revised Stark Law regulatory exceptions will prohibit compensation arrangements that use a formula based on either: "(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated [in the office space or by the use of the equipment]; or (B) Per-unit of services rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee."[12]

QUESTION 1: How Do You Know If Your Organization Has Any "Under Arrangements," Percentage or Per-Click Arrangements That Should Be Restructured As a Result of the Revised Stark Law Regulations?

To determine whether your organization has any arrangements that might be affected by the revised Stark Law regulations, your organization first should ensure that it has information on all of its current arrangements (either in the form of ownership or compensation arrangements or compensation) with physicians.

Some organizations already have compliance program systems in place to catalogue the various types of compensation arrangements they have with physicians, *e.g.*, equipment and space leases, services agreements, employment agreements, recruitment agreements. However, other organizations do not have adequate paper or electronic systems to identify compensation arrangements with physicians that may be affected by the revised Stark Law regulations. Therefore, it is important that organizations conduct a review of their cataloguing process for collecting physician financial arrangements (not only for purposes of the FY 2009 IPPS Final Rules, but

also as a result of soon to be released requirements that health care entities complete disclosure forms to CMS detailing their physician financial relationships).[13]

Ideally, the process should include cataloguing the paper and electronic agreements that are on file, as well as running an accounts payable report to determine whether any amounts are being paid by the organization to physicians or physician-owned companies that somehow may have missed the formal contracting process. The contracts catalogue should include a centralized location for storage of all currently effective physician arrangements, and a contracts expiration date assessment to ensure that current signed agreements are in place for all physician arrangements.

While it is usually a straight-forward exercise to run an accounts payable report against the list of physicians on a hospital's medical staff or physicians who routinely send patients to the organization, including all of its affiliates, it is often more difficult to identify physician-owned companies that have compensation arrangements with an organization where the physician's name is not in the company name. The following can be done to find those compensation arrangements with physician-owned companies that lack a physician's name:

- Look specifically for periodic payments or variable payments relating to operations that may appear to be based upon a per-click or percentage arrangement and then research the ownership of such entity.
- Someone should interview provider department heads, if any, to confirm whether any service lines within the organization are provided "under arrangements" with physicians. It may not be obvious from a physical inspection of the hospital premises that certain equipment or staff are not owned/employed directly by the hospital or other facility provider, but are leased from a third party that could be physician-owned. Hospitals and other providers with recent management turnover may be more likely to have arrangements with physicians that are not known to current management staff.

Depending on the findings, the organization may consider whether the compliance program needs to enhance its process for identifying new business partners that may be physician-owned companies, *e.g.*, a business partner questionnaire that is completed for every new and continuing compensation arrangement for medical or administrative services or equipment or space leasing.

QUESTION 2: Do the Revised Stark Law Regulations Ban All "Under Arrangements" Relationships Between Physicians (and Physician-Owned Entities) and Hospitals?

No, the revised Stark Law regulations do not ban all "under arrangements" relationships between physicians and hospitals. Nevertheless, many typical "under arrangements" structures should be reviewed and either dismantled or restructured.

As stated above, the change in the definition of "entity" means that entities that provide services that otherwise are currently not DHS will be subject to the Stark Law as of

October 1, 2009 because the services are billed by the hospital as DHS. The challenge is that there are very few Stark Law exceptions that protect physician ownership in DHS entities (outside of whole hospital ownership, the in-office ancillary services exception or the rural provider exception), so many of these "under arrangements" relationships between physician-owned companies and hospitals will be prohibited as of October 1, 2009.

Although "entity" covers "under arrangements" relationships, CMS did not extend the definition of "entity" to companies that lease or sell space or equipment used for the performance of DHS; or to companies that furnish supplies that are not separately billable, but used in the performance of the medical service; or to companies that provide management, billing services or personnel to the entity performing the DHS service.[14] As such, physician ownership in leasing companies, practice management companies, billing companies or staffing companies do not need to meet an ownership exception under the Stark Law – although if a DHS entity jointly owns such a company with referring physicians and the physicians refer to the DHS entity, the arrangement must still satisfy the Stark Law indirect compensation arrangement exception.

CMS' revision of the definition of "entity" is currently being challenged in the District Court of the District of Columbia in a case entitled "*Colorado Heart Institute v. Leavitt*."[15] On December 17, 2008, the plaintiffs in *Colorado Heart Institute* filed for summary judgment, arguing the following: [16]

- The court should find that CMS's definition of "entity furnishing DHS" is contrary to express Congressional intent, voids a statutory exception to the Stark Law, and is inconsistent with the Stark Law's statutory framework.
- Even if the court were to find that the Stark Law is ambiguous with respect to "under arrangements" relationships, the court should not give deference to CMS under *Chevron*[17] because CMS's new definition of an "entity" is a complete reversal of CMS's prior, long-standing rule-making, and even contradicts existing CMS federal regulations left unchanged by the revised Stark regulations in the FY 2009 IPPS Final Rules.
- CMS's new definition of "entity" is unreasonable, arbitrary and capricious because CMS failed to consider whether it should create an exception for service providers like the plaintiffs, failed to offer explanations for its decision to expand the definition of "entity" that were supported by the evidence before it, and failed to serve the objectives of the Stark Law.
- Therefore, as a matter of law, CMS's definition of "entity" is illegal.

We are monitoring this case because the outcome will affect whether this definition is revised and, as described above, the revised definition would impact all "under arrangements" agreements.

What compensation arrangements with "under arrangements" structures remain potentially permitted under the revised Stark Law regulations?

- Physicians whose ordering of services are not "referrals" under the Stark Law should be able to continue to participate in "under arrangements" structures even under the revised Stark Law regulations going into effect October 1, 2009. Therefore, when the services are provided pursuant to a "consultation"[18] requested by another physician, radiologists for diagnostic radiology services, radiation oncologists for radiation therapy services, and pathologists for clinical diagnostic laboratory tests and pathological examination services should remain exempt from the new prohibition and continue to be able to participate in "under arrangements" structures.
- DHS entities providing services pursuant to the rural provider exception also remain potentially permitted. As such, physicians with ownership in a DHS entity that furnishes substantially all (*i.e.*, not less than 75%) of the DHS that it furnishes to residents of a rural area may continue under these revised Stark Law regulations.[19]
- Cardiac catheterization arrangements may remain potentially permitted based on the pending litigation.[20]

QUESTION 3: Do the Revised Stark Law Regulations Prohibit All Percentage and Per-Click Payment Arrangements With Physicians?

No. The revised Stark Law regulations in the FY 2009 IPPS Final Rules only prohibit percentage and per-click compensation methodologies that involve the use or lease of space or equipment. Arrangements for services do not appear affected by these regulatory changes – so physicians can still perform professional services for a DHS entity, *e.g.*, on-call services or medical director services, pursuant to a percentage or per-click compensation methodology and continue to refer Medicare patients to that DHS entity, as long as the compensation arrangement meets a Stark Law compensation exception.

The prohibition on per-click or percentage payments for space or equipment used in the treatment of a Medicare patient referred to the lessee applies regardless of whether the physician himself or herself is the lessor or whether the lessor is a DHS entity in which the referring physician has an ownership or investment interest.[21] Further, CMS prohibited per-click and percentage arrangements with regard to direct or indirect compensation arrangements. As such, after the effective date of these revised Stark Law regulations, a physician may not have ownership in a leasing company that leases diagnostic equipment on a per-click or percentage basis to a hospital to which the physician refers Medicare patients.

CMS expressed concern that lease arrangements that provide for per-click payments to a physician lessor for services provided to Medicare patients referred to the DHS entity lessee by the physician lessor create the incentive for overutilization, because the more referrals the physician lessor makes the more revenue he or she earns through the lease arrangement.[22] CMS also expressed concerns that such arrangements de-incentivize physicians from referring to entities that may employ a different and possibly more efficacious treatment modality. In addition, CMS stated that such compensation arrangements may foster anti-competitive behavior because DHS entities may enter into agreements out of fear of losing the physicians' patient referrals.[23]

The per-click or percentage compensation prohibition also will apply when the lessor is a DHS entity that refers Medicare patients to a physician lessee or a physician organization lessee. CMS stated that because physicians, themselves, may bill for DHS, CMS has the same concerns with respect to per-click lease arrangements in which a DHS entity is the lessor and receives a per-click payment from a physician lessee for space or equipment used by the physician in the provision of services to Medicare patients who were referred by the DHS entity-lessor to the physician lessee. Presumably, CMS' concerns noted above for physician lessors would apply equally to DHS entity lessors when the physicians are billing the DHS.

As of October 1, 2009, what lease arrangements are allowed?

- Block time leases for space or equipment continue to be acceptable, as long as the leases meet the equipment and space lease exceptions, including the requirements that the agreement be set out in writing, signed by the parties and set out the specific equipment or premises; fair market value; commercially reasonable, even if no referrals; and do not take into account the volume or value of referrals or other business generated between the parties.[24] If the leases are direct compensation arrangements, *e.g.*, if the physician owns the equipment directly and not through a leasing company, the leasing agreement also must have a term of at least 1 year and must be set in advance, *i.e.*, not vary during the year term. CMS did express its concern over leases with small blocks of time (*e.g.*, 1 time per week for 4 hours) or very extended time periods, which it believes may indicate that the lessee is leasing space or equipment that it cannot use in order to compensate the lessor for referrals.[25] Further, CMS prohibited "on-demand" time-based arrangements.[26]
- Flat fee leases for equipment or space also are acceptable. A "flat fee" leasing arrangement is interpreted by CMS as "an agreement in which the rental charges over a period of time are fixed and are thus unaffected by the usage of the equipment (or, in other words, a time-based lease)."[27]
- As with "under arrangements" scenarios, physicians whose ordering of services are not "referrals" under the Stark Law, and thus do not require an exception, also should be able to participate in per-click or percentage leasing arrangements even under the revised Stark Law regulations. Consequently, when the services are provided pursuant to a "consultation"[28] requested by another physician, radiologists for diagnostic radiology services, radiation oncologists for radiation therapy services, and pathologists for clinical diagnostic laboratory tests and pathological examination services should remain exempt from the new prohibition and able to participate in per-click or percentage leasing arrangements.

QUESTION 4: What Regulatory Compliance Factors Should Be Considered When Embarking on the Restructuring or Unwinding of a Current Arrangement?

As stated above, the revised Stark Law regulations affecting "under arrangements" relationships and per-click and percentage leasing arrangements become effective October 1, 2009. Even if your physician agreements are well documented and accessible, many of these arrangements may take some time to review, renegotiate

and restructure to meet a Stark Law exception. If your physician agreements are not well documented and accessible, this restructuring process will take much longer. Therefore, health care organizations should begin reviewing these arrangements immediately.

To this end, CMS permits mid-term revisions of compensation arrangements. This allows parties to renegotiate agreements, rather than merely terminating them.[29] Mid-term revision of a compensation arrangement is permissible if:

(1) All the requirements of an applicable Stark Law exception are satisfied;

(2) The amended rental charges or other compensation is determined before the amendment is implemented (so back-dating of agreements is not allowed);

(3) The formula for the amended rental charges or other compensation does not take into account the volume or value of referrals or other business generated by the referring physician; and

(4) The amended rental charges or other compensation remains in place for at least a year from the date of the amendment.[30]

CMS says that its more restrictive interpretation of percentage and per-click space and equipment lease compensation provides greater latitude with respect to its interpretation of the one-year contract requirement, including contract amendments. Therefore, to the extent you have arrangements with physicians that are mid-term, you can amend those currently Stark Law compliant arrangements prior to the effective date of the revised Stark Law regulations even if the current arrangement has been in place for less than a year.

Also, please be sure to review your current agreements for provisions that apply in the event of a material change in law or need to restructure. If an arrangement ultimately needs to be unwound, relevant requirements regarding how to value and organize the unwinding of an arrangement already may have been negotiated by the parties and reflected in the arrangement's written documents. If the documents fail to address how to unwind an arrangement, then the parties may need to negotiate a structured winding up of their arrangement in which case, the parties should remember that compliance principles under the Stark Law and federal Anti-kickback Statute (e.g., fair market value) will apply to any unwinding of an arrangement. Consequently, the documentation of fair market value for any buying or selling of interests is important.

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Endnotes

1 73 Fed. Reg. 48,434 (Aug. 19, 2008).

2 *See* Social Security Act §1877, 42 U.S.C. § 1395nn; 42 C.F.R. §411.350 et seq.

3 *See* Memorandum regarding Regulatory Review from Rahm Emanuel, Assistant to the President and Chief of Staff, to Heads of Executive Departments and Agencies (Jan. 20, 2009) (written on behalf of President Obama and requesting that the agency heads "[c]onsider extending for 60 days the effective date of regulations that have been published in the *Federal Register* but not yet taken effect, subject to exceptions [when the regulations affect critical health, safety, environmental, financial or national security functions], for the purpose of reviewing questions of law and policy raised by those regulations. Where such an extension is made for this purpose, [agency heads] should immediately reopen the notice-and-comment period for 30 days to allow interested parties to provide comments about issues of law and policy raised by those rules.").

4 42 U.S.C. § 1395nn; 42 C.F.R. § 411.353(a), (b).

5 42 U.S.C. § 1395nn(b)-(e); 42 C.F.R. §§ 411.352-411.357. In addition to applying to the Medicare program, certain aspects of the Stark Law apply to the states' Medicaid plans. Specifically, the Social Security Act denies federal financial participation payment under a Medicaid plan to a state for services that would have been prohibited by Medicare under the Stark Law if Medicare covered the services to the same extent as under the state's Medicaid plan.

6 42 U.S.C. § 1395nn(g); 42 C.F.R. §§ 1003.102-1003.105.

Endnotes, cont.

[7] EBG has issued a number of previous Special Alerts concerning the Stark Law regulations including: EBG special Alert: *The "Agony" and the "Ecstasy" of Stark II Continues: CMS Postpones Effective Date of Stark Law Rule on Percentage Compensation Arrangements* (Dec. 2001); EBG Special Alert: *The "Agony" and the "Ecstasy" Continues with Issuance of Final Phase III Stark Regulations* (Oct. 2007); EBG Client Alerts: *Where "The Agony and the Ecstasy" Meets "Back to the Future": Proposed Modifications to the Stark Law Regulations Included in FY 2009 Hospital Inpatient Prospective Payment Rule* (May 31, 2008).

[8] *See* 73 Fed. Reg. at 48,751 (revising 42 C.F.R. § 411.351) (effective Oct. 1, 2009).

[9] *Id*. at 48,726.

[10] 42 C.F.R. § 411.354(d)(1).

[11] *Id*. § 411.354(d)(2).

[12] 73 Fed. Reg. at 48,752-53 (revising 42 C.F.R. §§ 411.357(a)(5), 411.357(b)(4), 411.357(*l*)(3); and 411.357(p)(1)); *id* at 57,541 (Correction of final rules); *see also* 73 Fed. Reg. at 48,709 – 48,721.

[13] *See* Epstein Becker Green Client Alert entitled, "Proposed CMS Survey Form Requiring Extensive Disclosure by Hospitals of Hospital/Physician Relationships is Under Review by OMB—Comment Period Currently Open" at http://www.ebglaw.com/showclientalert.aspx?Show=9624.

[14] 73 Fed. Reg. at 48,726.

[15] *See* Colorado Heart Institute, LLC v. Levitt, Civil Act. No.: 1:08-cv-01626-RMC (D.D.C. pending).

[16] *Colorado Heart Institute* Plaintiffs' Motion for Summary Judgment at 21.

[17] Chevron U.S.A. Inc. v. Natural Resources Defense Council, 467 U.S. 837 (1984).

[18] Criteria to identify a consultation are the following:
(1) A consultation is provided by a physician whose opinion/advice regarding evaluation and/or management of a specific medical problem is requested by another physician.
(2) The request and need for the consultation is documented in the patient's medical record.
(3) After the consultation is provided, the consulting physician prepares a written report of his or her findings, which is provided to the physician who requested the consultation.
(4) With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatment over a period of time will be considered to be furnished pursuant to a consultation, provided the radiation oncologist communicates with the referring physician on a regular basis about the patient's course of treatment and progress.

42 C.F.R. § 411.351 (definition of "Consultation").

[19] *See id*. § 411.356(c)(1). "Rural area" would include those areas that are not a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive office of Management and Budget. *Id.* (citing 42 C.F.R. § 412.62(f)(1)(ii)).

[20] *See supra* note 15-17 and accompanying text.

[21] *See* 73 Fed. Reg. at 48,714.

[22] *Id.* at 48,715.

[23] *Id.*

[24] *Id.* at 48,719.

[25] *Id.* at 48,720.

[26] *Id.*

[27] *Id.* at 48,719.

[28] *See supra* note 18.

[29] 73 Fed. Reg. at 48,696-97.

[30] *Id.* at 48,697.