

MEDICARE

Stark Update

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Practicing Physicians Advisory Council

RECENT DEVELOPMENTS IN PHYSICIAN SELF-REFERRAL

I. PHASE III

- Final Rule Published on September 5, 2007 (72 FR 51012)
- Generally Effective December 4, 2007
- Culmination of a Rulemaking began in 1998

NPRM on January 9, 1998; Phase I on January 14, 2001 and Phase II on March 26, 2004

Phase III --Continued

- Phase III comprehensively addressed the physician self-referral provisions
- Did not add new exceptions
- Provided additional clarity to existing exceptions
- Relaxed some restrictions in existing exceptions
 - Physician Recruitment (411.357(e))
 - Physician Retention (411.357(t))
 - Non-monetary Compensation (411.357(k))
 - Intra-family Referrals (411.355(j))
 - Fair Market Value (411.357(l))
 - Compliance Training (411.357(o))
 - Professional Courtesy (411.357(s))

Phase III -- Continued

- Expanded “Stand in the Shoes” Doctrine
 - Physician stands in shoes of a “physician organization”
 - “physician organization” is defined as a physician (including the physician’s PC), a physician practice, and a “group practice” that meets the requirements of 411.352
 - Effect of stand in the shoes is physicians in a physician organization will be deemed to have the same compensation relationship that the physician organization has with a DHS entity
 - Where stand in the shoes comes into play, arrangements that previously were considered to be indirect, or were considered to be nothing, will now have to be analyzed to determine if the compensation relationship between a physician in a physician organization and the entity to which the physician refers DHS meets a direct compensation exception

Phase III -- Continued

- Stand in the shoes has special effective date—
 - Arrangements that were in existence prior to the publication date of Phase III (Sept. 5, 2007) and met the definition of an indirect compensation arrangement and satisfied the indirect compensation exception do not have to comply with stand in the shoes until the current term of the arrangement expires
- Stand in the shoes posed problems for Academic Medical Centers and integrated section 501(c)(3) health care systems
- On November 15, 2007, we issued a final rule, extending the effective date for AMCs and integrated section 501(c)(3) health care systems, with respect to certain arrangements, for 1 year

II. Physician Fee Proposals

- In the CY 2008 proposed PFS rule, we proposed changes on the following issues:
 - Anti-markup provisions for TCs and PCs of diagnostic tests
 - Burden of Proof
 - Exception for obstetrical malpractice insurance subsidies
 - Per click leases
 - Period of disallowance
 - Ownership or investment in retirement plans
 - Set in advance and percentage-based comp arrangements
 - Stand in the shoes
 - Alternative route for compliance
 - Under arrangements

Physician Fee Proposals-- Continued

- We also sought comments on whether to make changes to the in-office ancillary services exception at §411.355(b)
- Finalized proposal on the anti-markup provisions
 - Anti-markup will apply to TC and PC of diagnostic tests if billing supplier ordered the test and if the TC and PC were either purchased or performed outside of the billing supplier's office
- Did not finalize other physician self-referral proposals but are actively working on them

III. DFRR (Disclosure of Financial Relationships Report)

- Section 5006 of the DRA required the Secretary to study certain issues relating to physician-owned specialty hospitals
- Among the issues we were required to study were whether physician-owners had disproportionate returns on investment, and whether investments of physician-owners were bona fide
- In order to get information for the study we sent a survey to all 130 physician-owned specialty hospitals and 320 “competitor” hospitals

DFRR --Continued

- Survey was voluntary because it asked questions that were within the scope of Section 5006 but outside the scope of physician self-referral (and therefore outside our authority to demand under §411.361)
- 290 Hospitals did not respond to the survey
- In the Enforcement section of the Strategic and Implementing Plan portion of the Final Report to Congress, we said that we would explore an annual disclosure process to capture information related to financial relationships between hospitals and physicians
- We indicated that we were interested in information concerning both ownership/investment and compensation relationships, from all types of hospitals, not just physician-owned specialty hospitals

DFRR -- Continued

- On May 17, 2007, CMS published CMS-10236 setting forth the proposed Disclosure of Financial Relationships Report (DFRR) and seeking comment on the ICR, as required by the Paperwork Reduction Act of 1995
- CMS received comments from the AHA, FAH, Tennessee Hospital Association, Texas Hospital Association and National Surgical Hospitals.

DFRR -- Continued

- On September 14th, following review of the comments, CMS published a revised version of the DFRR package in the Federal Register
- Public had 30 days to comment to OMB
- OMB has 30 days to review, and an additional 30 days to approve/deny the PRA package (the review period starts after the notice is published in the FR, HHS sends the package to OMB, and OMB logs it into its system)

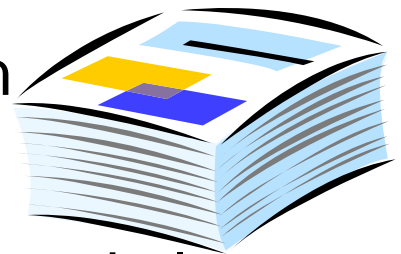
DFRR-- Continued

Comments to OMB:

- Challenge CMS's authority to collect information as proposed
- Argue CMS has not complied with the Paperwork Reduction Act (PRA)
- Believe DRA directs CMS to capture only information related to physician-owned specialty hospitals

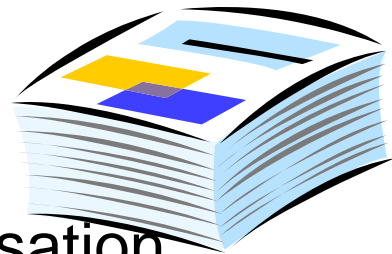
REVISED DFRR PACKAGE

- The revised DFRR consists of a cover page with certification statement, general instructions, and eight (8) worksheets. The Excel worksheets are:
 - Worksheet 1 – Hospital Characteristics
 - Worksheet 2 -- Direct Ownership in Hospital
 - Worksheet 3 -- Indirect Ownership in Hospital
 - Worksheet 4 – Payments Made to Hospital by Direct Owners



DFRR Worksheets (Continued)

- Worksheet 5 – Payments Made to Hospital by Indirect Owners
- Worksheet 6 – Investment Reconciliation
- Worksheet 7 – Compensation Arrangements (Rentals, Personal Service Arrangements, and Recruitment)
- Worksheet 8 – Other types of Compensation Arrangements



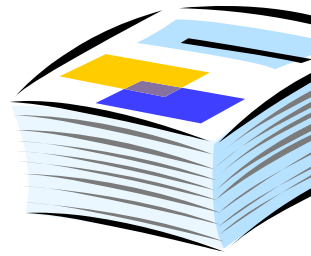
Cover Note and Instructions

- Cover Note is addressed to CEOs, CFO or others in a comparable position
- Cover note includes a certification statement that must be signed prior to submission of the completed DFRR
- Attachment 1 consists of general instructions, key terms and a detailed list of instructions for each separate worksheet
- Confidentiality Statement



Process for Responding to DFRR

- CMS will post a list of the hospitals on cms.hhs.gov website.
- CMS will email the DFRR to the hospitals (except for the small number for which it does not have an e-mail address, in which case we will mail a hard copy).
- The hospital must send a hardcopy of the DFRR to CMS within 60 days of the date that appears on the e-mail transmission or cover letter (unless CMS grants an extension).



Process for Responding to DFRR

- CMS provides an e-mail address for questions:
DFRR-Questions@cms.hhs.gov

DFRR-- Continued

Penalties for Non-Compliance

- There are potential penalties of up to ***\$10,000 a day*** for not responding timely.



DFRR-- Continued

- CMS Review of DFRR
- CMS will review the completed DFRR through a contractor
- The contractor will analyze the DFRR. If necessary, the contractor will contact the hospital to request additional information
- Where it believes that a hospital may have one or more noncompliant financial relationships, the contractor will forward information to CMS for review.

DFRR -- Continued

Review of DFRR

- Where CMS believes it appropriate, it will direct the DFRR contractor to forward the information to the Program safeguard contractor (PSC) that has jurisdiction over the hospital involved, which will forward the information to the appropriate OIG field office

DFRR-- Continued

Future – Annual Disclosure?

- CMS will review the results of the information obtained through the DFRR and determine whether it believes a regular disclosure process for hospital/physician financial relationships is warranted
 - If CMS believes a regular disclosure process is appropriate, it will issue a NPRM, most likely in a stand-alone rule
 - The NPRM would contain a proposed information collection instrument

For More Information

Visit: cms.hhs.gov

OR

Send your questions to:

[DFRR-
Questions@cms.hhs.gov](mailto:DFRR-Questions@cms.hhs.gov)

Key Websites

Contact Information

Name/Title/E-Mail/Phone