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Gainsharing Comment Period Extended

As anticipated in the Holiday 2008 issue of Health Capital Topics, the 2009 Medicare Physician Fee Schedule Final Rule (MPFSR), issued on November 19, 2008, extended the comment period for the proposed exception to Starks Law related to allowing for certain types of incentive payments or shared savings programs. The Centers for Medicare and Medicaid (CMS) was of the belief that inadequate information had been collected from stakeholder comments; by reopening the comment period of 90 days, CMS hopes to procure sufficient information to "*finalize an exception that will allow the full array of beneficial, nonabusive incentive payment and shared savings programs*" [1]

The American Hospital Association (AHA), Federation of American Hospitals (FAH), and Association of American Medical Colleges (AAMC), responded to this extension by submitting two letters: one to CMS and the other to the Inspector General's Office (OIG). In their letter to CMS, the associations express appreciation for the efforts made towards an exception but follow with their critiques and detailed suggestions for a more effective regulatory proposal. With regards to the design of the exception, the represented associations emphasize that "*the level of specificity and detail in the proposed regulation results in a very narrow exception*." They continued to explain that an exception exhibiting such a constricting degree of detail would limit its applicability in the health care community, inconvenience hospitals with systems of comparable quality to the processes outlined in the exception, and discourage alternate but equally sufficient methods of compliance. They proceed to propose that the exception outlines only the essential or material requirements to reasonably disprove fraud and abuse, establish that hospitals are responsible for achieving goals by any sufficient means, and provide examples of potential compliance methods with emphasis to the fact that these suggestions are non-exclusive. Similar concerns are exhibited with regards to the content of the exception; claiming that rather than focusing "*on the broader construct for an exception and establish(ing) the essential obligations*," the regulation has become an inflexible process for quality improvement rather that frowns upon innovative methods of improved care. Specific suggestions are outlined in the detailed comments attached to the letter. [2]

Despite its issuance of the 1999 Special Advisory Bulletin on gainsharing arrangements and the accompanying civil monetary penalties set forth in the Social Security Act[3] for legally impermissible payments related to hospital payments to physicians in exchange for reduced services to Medicare or Medicaid beneficiaries under the physician's care[4], the OIG has approved gainsharing programs since 2001.[5] Most recently, a December 2008 OIG advisory opinion approved a gainsharing arrangement between a hospital and four cardiology groups, stating that the relationship provided cost savings not based on volume or value of referrals.[6]

In light of the OIG's recent history of approvals, the AHA, FAH, and AAMC coalition wrote a second letter to the OIG[7] urging that the Inspector General Dan Levinson to pull the 1999 Advisory Bulletin, as the opinions of the OIG had clearly changed. They argue that with the favorable review of fourteen gainsharing arrangements, the presence of "*appropriate safeguards can prevent quality and efficiency programs from becoming conduits for fraud and abuse.*" Further, they argue that the 1999 Advisory Bulletin does not distinguish between the reduction of medically *unnecessary* treatments and the reduction of medically *necessary* treatments. Because of what the associations feel are these apparent inconsistencies between the 1999 Advisory Bulletin and the recent passage of several gainsharing arrangements, the associations suggest that the OIG and CMS coordinate their efforts to implement an enforcement policy that would give providers "*coordinated guidance that would facilitate the development of these programs.*"[8]

[1] "Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions: Final Rule and Revisions, Summary" 42 CFR Parts 422 and 423, January 12, 2009, p. 2
[2] "Letter to CMS," AHA, AAMC, FAH, February 17,.2009, http://www.aamc.org/advocacy/library/teachhosp/corres/2009/21709.pdf (Accessed 4/20/09)
[3] Section 11281(A)(b)(1) of the Social Security Act.
[4] Gainsharing arrangements and CMPs for hospital payments to physicians to reduce or limit services to beneficiaries," Office of the Inspector General, July 1999, http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm
[5] "Letter to OIG," AHA, AAMC, FAH, February 17, 2009, http://www.aha.org/aha/letter/2009/090217-cl-OIG-113-N.pdf (accessed 4/21/09)
[6] OIG Advisory Opinion No. 08-21 , 2008.
[7] "Letter to OIG," AHA, AAMC, FAH, February 17, 2009, http://www.aha.org/aha/letter/2009/090217-cl-OIG-113-N.pdf (accessed 4/21/09)
[8] "Letter to OIG," AHA, AAMC, FAH, February 17, 2009, http://www.aha.org/aha/letter/2009/090217-cl-OIG-113-N.pdf (accessed 4/21/09)

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