

*January 22, 2008*

Two new Advisory Opinions posted last week by the Office of Inspector General (OIG) provide added evidence that certain provider gainsharing arrangements between hospitals and providers can pass OIG scrutiny under the Federal anti-kickback statute and the Civil Monetary Penalties ("CMP") law when carefully structured, properly administered, and supported by detailed objective data and ongoing monitoring of clinical quality.

"Gainsharing" commonly refers to arrangements where a hospital implements cost-saving measures that require physician cooperation in implementation and splits the actual amounts saved with the physicians. Common examples of gainsharing are standardizing products used during surgeries or procedures and changing procedures to reduce waste. While hospitals long have viewed gainsharing arrangements as potentially valuable tools in their ability to secure physician cooperation with various cost containment and quality management initiatives of their facilities, concerns about legal exposures under the Anti-kickback, CMP, and other laws have deterred many hospitals from implementing these arrangements.

On January 14, 2008, the OIG issued two Advisory Opinions that give qualified approval to two separate gainsharing arrangements proposed by a hospital. In Advisory Opinions # 07-21 and 07-22 respectively, a hospital implemented five specific cost-savings measures with a hospital-based anesthesiology group and 25 cost-savings measures with a cardiac surgery group. Both physician groups were the sole providers of these services to the hospital.

In granting its qualified approval of the two proposed arrangements, the OIG initially noted its continuing concern that gainsharing arrangements could trigger the Anti-kickback statute and the CMP law by allowing health care providers to "cherry pick" healthy patients, steer sicker patients to other hospitals, stint on patient care services and items, and disguise payments in exchange for referrals. However, the OIG also acknowledged that properly structured cost-savings arrangements could have legitimate medical and business purposes.

Specifically, the CMP law allows imposition of a penalty of up to \$2,000 per patient where a hospital knowingly makes a payment to a physician to limit or reduce the services or items provided to a Medicare or Medicaid beneficiary under the physician's direct care. Under the Anti-kickback law, it is a criminal offense to offer, pay, solicit, or receive remuneration to induce or reward the referral of patients whose healthcare is paid for by Federal healthcare programs. The OIG determined that the arrangement could not fit into the potentially applicable personal services and management contracts safe harbor under the Anti-kickback, as the compensation was calculated on a percentage basis and thus not set in advance.

With these general comments, the OIG then decided that although the two gainsharing arrangements described implicate the Anti-kickback statute and the CMP law, it would not impose sanctions. The OIG found that the particular safeguards developed by the hospital would be sufficient to prevent any improper relationship or payment. For example, the hospital developed the cost-savings recommendations based on objective historic data, grouping the recommendations into product standardization, "use as needed", product substitution, and delaying opening disposables until actually needed groups. The specific measures and the anticipated savings were also clearly and separately identified.

The proposed cost-saving measures were then compared with national best practices and clinical quality data and indicators and determined to not impact actual patient care. In addition, the hospital established certain baseline quality measures. Cost-savings measures that went below the established floors resulted in no payment to the physician groups. In addition, the hospital monitored the volume of cases and the patient severity, age and payer. The savings were calculated over all patients, regardless of the payer.

Finally, both the hospital and the physician groups were required to provide a written disclosure of the cost-savings arrangements to patients. The hospital also limited the term of the arrangement to one year and required the physician groups to sign a detailed contract. The physician groups distributed profits to each physician on a per capita basis, eliminating any incentive for an individual physician to generate a disproportionate cost-savings share.

The OIG did take the unusual step of sending the specific cost-savings measures to an independent medical expert for review. The independent medical expert concluded that the specific measures should not adversely affect patient care.

In light of all of these safeguards, the OIG concluded that it would not impose sanctions on the specific arrangements described in the Advisory Opinions.

In summary, while the Advisory Opinions make clear that the OIG continues to view the Anti-Kickback and/or CMP statutes as

prohibiting many gainsharing arrangements, the gainsharing Advisory Opinions issued on January 14, 2007 document the willingness by the OIG to allow hospitals and physicians to cooperate in improving the financials of providing patient care, while avoiding the legal penalties that are possible provided that the gainsharing arrangements incorporate appropriate structural and operational safeguards. The latest Advisory Opinions make clear, however, that only those gainsharing arrangements that are appropriately motivated, carefully structured, supported by detailed objective data and ongoing monitoring of clinical quality, and operated appropriately will pass OIG scrutiny. Additionally, the design and implementation of proposed gainsharing also can be expected to require careful negotiation of various other potential civil and criminal exposures beyond the CMP and Anti-kickback rules that are the subject of the Advisory Opinions. Accordingly, health care providers contemplating involvement in any proposed gainsharing arrangements should seek the assistance of qualified legal counsel before participating in any proposed gainsharing arrangement.

To read Advisory Opinion # 07-21 go to <http://oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-21A.pdf>.

To read Advisory Opinion # 07-22 go to <http://oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-22A.pdf>.

For additional information about gainsharing arrangements or other health care concerns, please contact Cynthia Marcotte Stamer, at [cynthiastamer@solutionslawyer.net](mailto:cynthiastamer@solutionslawyer.net), (972) 419-7188 or Heidi Kocher at [hkocherjd@solutionslawyer.net](mailto:hkocherjd@solutionslawyer.net), (972) 419-7107.

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### ***About Cynthia Marcotte Stamer & Heidi Kocher***

Cynthia Marcotte Stamer, P.C., a member of the law firm of Glast, Phillips & Murray, P.C. has extensive experience advising, and representing health care providers and other health industry clients about health care operations, reimbursement, regulatory and public policy, risk management, human resources, peer review and credentialing, technology, privacy, and other concerns. Her clients include hospitals, physicians, clinics, IPAs, PHOs, skilled nursing facilities, assisted living and home health, rehabilitation, imaging and other diagnostic services providers, DME, physician practice management companies and other management services organizations, health care technology, and other health industry clients. Board Certified in Labor & Employment Law by the Texas Board of Legal Specialization, Ms. Stamer combines her extensive experience with health industry regulatory and operational matters with her knowledge of the regulatory and practical requirements for managing internal and external workforce to help clients identify and use practical strategies for Recognized in the International Who's Who of Professionals and bearing the Martindale Hubble AV-Rating, Ms. Stamer is a highly regarded legal advisor and consultant, author and speaker, who regularly conducts management and other training on health care reimbursement and other health industry operational, regulatory, and public policy matters.

Chair of the American Bar Association (ABA) Health Law Section Managed Care & Insurance Interest Group and known for her practical, direct problem-solving approach, Ms. Stamer also applies her extensive industry experience in numerous professional and industry leadership roles. In addition to her ABA Health Law Section involvement, Ms. Stamer serves on the editorial advisory boards of and is a contributing author for the Bureau of National Affairs and other publications, served as the Compliance Committee Chair and a member of the Board of the National Kidney Foundation of North Texas Board of Directors, serves on the continuing education and conference planning committees of the ABA Joint Committee On Employee Benefits (JCEB), the HFMA Lone Star Chapter, TAHFA, the IRS TEGE Advisory Council, and numerous other health industry groups. She also is the past-president of the Alliance for Health Care Excellence, and founder of its Health Care Heroes and Patient Empowerment Programs. She also is active in numerous other industry organizations including the American Health Lawyers Association, the Medical Group Management Association, the Alliance for Healthcare Excellence, the Dallas Bar Association Health Law Section,

Ms. Stamer is a widely published author and highly sought-after speaker nationally and internationally sought out for her strategic knowledge and insights on operational and technical health care risk management and operational concerns. A columnist for MD News and recurring author for various other health industry publications, Ms. Stamer's insights have been quoted by the Wall Street Journal, the Bureau of National Affairs (BNA), HIPAA Comply, Private Payer News, Modern Health Care, Managed Healthcare Executive, Health Leaders, Caring for The Elderly Magazine, For The Record, the Dallas Morning News, Spencer Publications, the Dallas Business Journal, the Houston Business Journal, and a various other national and local publications. Ms Stamer is the author of 100s of publications on health industry matters including numerous highly regarded works published by the American Bar Association, Aspen Publishers, BNA, the American Health Lawyers Association, and Government Institutes, Inc. and others.

Heidi Kocher has over 10 years experience in healthcare law, having represented many kinds of healthcare providers, from small DME companies to large national health care organizations. Prior to returning to private practice, Ms. Kocher was in-house at one of the largest national hospital companies. Her wide-ranging experience includes advising corporate and individual clients on the myriad federal and state fraud and abuse laws, such as Stark, the Anti-kickback statute, and False Claims Act, structuring mergers, acquisitions, joint ventures, employment agreements, and other deals, developing compliance programs and plans, interfacing with fiscal intermediaries, carriers, and other payers, resolving reimbursement issues, conducting investigations, assisting with preparing for and responding to JCAHO surveys, obtaining advisory opinions from the OIG, and representing providers in relation to federal and state agencies. She has worked with hospitals, physicians, mid-level practitioners, pharmacies, DME companies, LTACs, SNFs, home health and hospice agencies, inpatient rehab facilities, clinical laboratories, as well as allied health practitioners. She is active in the Health Care Compliance Association, and has written numerous articles and provided training on various healthcare law topics.

For more information about Cynthia Marcotte Stamer, P.C., Ms. Stamer and Ms. Kocher, a listing of selected publications and other health industry links, information about workshops and other training and other health industry information and resources, see [CynthiaStamer.com](http://CynthiaStamer.com) or contact Ms. Stamer or Ms. Kocher.

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