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"Can You Handle the Truth?"

"The Stark Law: A User's Guide to Achieving Compliance"

Gina M. Cavalier, Christopher G. Janney, Albert W. Shay, Gadi Weinreich and Howard J. Young, 2005, 313 pages and CD, HCPro, \$199.00

Review by Norman M. Goldfarb

"The Stark Law: A User's Guide to Achieving Compliance" demonstrates that lawyers can make the complex simple, rather than the more usual, opposite result. If your travel plans include a trip into the labyrinth land of Stark, this book is your best hope for finding your way back out.

As demonstrated by the table of contents, the Stark Law consists of broad prohibitions and numerous exceptions:

- Background
- Definitions
- Designated Health Services
- Referrals
- Financial relationships
- All-purpose exceptions
- Ownership interest exceptions
- Direct compensation arrangement exceptions
- Indirect compensation arrangement exceptions
- Physician recruitment and retention exceptions
- Sanctions, collateral consequences, and reporting requirements
- Advisory opinions

This book has been selected for
[The First Clinical Research Bookshelf](#)
Essential reading for clinical research professionals

There is a lot of material in the book. To minimize the risk of a cranial explosion, read it with a specific scenario in mind. For example, imagine this scenario:

Dr. Smith practices medicine in Everytown, U.S.A. He is a partner at Valley Health Clinic, PA (VHC), a physician-owned group practice. He is on the medical staff of Everytown Community Hospital (ECH), but is not an employee or independent contractor of ECH. He regularly refers his patients to ECH for inpatient stays and outpatient procedures.

Acme Pharmaceuticals, Inc. (API) invites Dr. Smith to participate in a clinical trial, and Dr. Smith accepts the invitation. The protocol requires a PET scan for study subjects. Dr. Smith lacks the necessary equipment, so he sends the subjects to the hospital's outpatient imaging center for the scans.

ECH knows it cannot charge Medicare for the scans because the imaging is not standard of care. Although ECH's chargemaster (price list) sets the charge for an outpatient PET scan at \$1,000, the average managed care company reimburses ECH \$750 per scan and the Medicare fiscal intermediary pays \$500. Recognizing that Dr. Smith is a valued member of the staff and is conducting important scientific

research, ECH charges Dr. Smith (actually, VHC) \$500 per scan. The line item in the study budget is \$750, offsetting other costs that API is unwilling to compensate.

Over the next year, Dr. Smith successfully completes the study, enrolling ten subjects.

Prior to undertaking the clinical trial, Dr. Smith and the other physician-owners of VHC referred their Medicare patients to ECH for inpatient and outpatient services without triggering the Stark Law's referral or billing prohibitions. However, the study has probably changed that happy condition, arguably creating an indirect compensation arrangement among the physician-owners of VHC (including Dr. Smith) and ECH. If Medicare deems the charge of \$500 per scan to be below fair market value, no exceptions are available either to the doctors or the hospital. The fact that everyone was proceeding with the best intentions does not alter the situation. Good intentions and ignorance of the law are not excuses (nor defenses) under the Stark Law. It is also irrelevant that VHC's referral patterns to ECH were unaffected by the study.

Was \$500 per scan below fair market value? It was the same price that Medicare paid, but below the price paid by managed care providers and "retail" customers. It was also below the price API paid Dr. Smith. If Medicare finds that there has been a Stark Law infraction, Dr. Smith, VHC and ECH will have their day in court to argue their case.

If they lose their case, consequences potentially include:

- Refunds of all reimbursements for all Medicare patients referred by Dr. Smith and the other physician-owners of VHC to ECH
- Civil money penalties of up to \$15,000 per service (all of them, not just the study imaging procedures)
- An additional assessment of three times the amount billed to Medicare
- Exclusion from participation in Federal healthcare programs, including Medicare

The U.S. Department of Human Health Services (HHS), Office of the Inspector General (OIG) has latitude to overlook Stark Law infractions that do not affect the law's public policy objectives. To the authors' knowledge, OIG has not, to date, enforced the Stark Law in the above scenario, but that could change at a moment's notice, especially in response to whistleblower actions, which could be highly remunerative. Imagine that scenario and the chaos that would ensue.

The book is available at <http://www.hcpro.com>

Acknowledgement

The reviewer extends his gratitude to Gadi Weinreich, a co-author of the book, for helping with the above scenario and analysis. The scenario is common, but the analysis is not legal advice.

Reviewer

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