

WWW.EBGLAW.COM

Resurgens Plaza
945 East Paces Ferry Road
Suite 2700
ATLANTA, GA 30326
(404) 923-9000

150 North Michigan Avenue
Suite 420
CHICAGO, IL 60601-7553
(312) 499-1400

Lincoln Plaza
500 N. Akard
Suite 2700
DALLAS, TX 75201-3320
(214) 397-4300

Wells Fargo Plaza
1000 Louisiana, Suite 5400
HOUSTON, TX 77002-5013
(713) 750-3100

1875 Century Park East
Suite 500
LOS ANGELES, CA 90067-2506
(310) 556-8861

Miami Center
201 South Biscayne Boulevard
10th Floor
MIAMI, FL 33131
(305) 373-4088

250 Park Avenue
NEW YORK, NY 10177-1211
(212) 351-4500

Two Gateway Center
12th Floor
NEWARK, NJ 07102-5003
(201) 642-1900

One California Street
26th Floor
SAN FRANCISCO, CA 94111-5427
(415) 398-3500

One Landmark Square
Suite 1800
STAMFORD, CT 06901-2681
(203) 348-3737

1227 25TH Street, N.W.
Suite 700
WASHINGTON, D.C. 20037
(202) 861-0900

The Epstein Becker & Green, P.C., **Special Alert** is published by the National Health Care & Life Sciences Practice to inform health care organizations and providers of new legal developments which may affect the delivery and financing of their health care services.

Information published in the **Special Alert** is not intended to be, nor should it be considered, legal advice. Readers should consult an attorney to discuss specific situations in further detail.

Lynn Shapiro Snyder, Esq.
Editor

Published by
Health Care & Life Sciences
Practice
of

EPSTEIN BECKER &
GREEN, P.C.



THOUGHT LEADERS IN
HEALTH LAW®
WWW.EBGLAW.COM

SPECIAL ALERT

The Center for Medicare and Medicaid Services ("CMS") Proposes to Make Nuclear Medicine and PET Scans Subject to Stark Prohibition

On August 8, 2005, the Centers for Medicare and Medicaid Services ("CMS") published its proposed revisions to the Medicare Part B Fee Schedule for 2006. 70 Fed. Reg. 45,764 (Aug. 8, 2005). Included in the proposed revisions is an expansion of the scope of the physician self-referral provisions of Section 1877 of the Social Security Act, commonly known as the Stark Law, to include nuclear medicine services, including positron emission tomography ("PET") scans. If this regulatory change is published as a final rule, it may significantly affect numerous arrangements under which physicians currently furnish nuclear medicine services to Medicare beneficiaries.

Briefly, the Stark Law prohibits payment of Medicare or Medicaid claims submitted by a physician or on that physician's behalf if (1) the physician has made a referral; (2) the referral was made to an entity for the purpose of furnishing a Designated Health Service as defined in the Stark Law; (3) the physician or a member of the physician's immediate family has a "financial relationship" with the entity to which the patient is referred, which may be either an ownership interest or a compensation arrangement; and (4) the financial relationship does not fall into one of the exceptions set out in the Stark Law.¹ If a referral is made by a physician for a Designated Health Service and that physician has a financial relationship with the entity receiving the referral that is not permitted under the Stark Law, then a range of administrative sanctions are available to the Secretary. The possible penalties under the Stark Law include (1) denial of payment and an obligation to refund payments made as a result of a tainted referral; (2) civil monetary penalties of up to \$15,000 for each service that a person "knows or should know" violates the Stark Law, (3) civil monetary penalties of up to \$100,000 for schemes to circumvent the Stark Law, (4) possible exclusion from the Medicare and Medicaid programs, or, (5) liability under the False Claims Act.

Since 1993, radiology services and radiation therapy services have been Designated Health Services subject to the Stark Law. However, the status of nuclear medicine and PET scans under the Stark Law has been unsettled. When CMS published the last set of regulations to implement the Stark Law in 2004, it declined to include either nuclear medicine or PET in the definitions of radiology services and radiation therapy services. However, CMS also stated that "we are mindful of the issue . . . and are continuing to consider the application of section 1877 of the Act to nuclear medicine procedures." 69 Fed. Reg. at 16104 (2004).

¹ Several states have their own versions of physician self-referral laws. Although CMS's proposal would not change these laws, its actions can influence the actions of state legislators and regulators.

The Epstein Becker & Green, P.C., **Special Alert** is published by the National Health Care & Life Sciences Practice to inform health care organizations and providers of new legal developments which may affect the delivery and financing of their health care services.

Information published in the **Special Alert** is not intended to be, nor should it be considered, legal advice. Readers should consult an attorney to discuss specific situations in further detail.

Lynn Shapiro Snyder, Esq.
Editor

Published by
Health Care & Life Sciences
Practice
of

**EPSTEIN BECKER &
GREEN, P.C.**



THOUGHT LEADERS IN
HEALTH LAW®
WWW.EBGLAW.COM

CMS's proposed change in the regulatory definitions would include both diagnostic and therapeutic applications of nuclear medicine and PET technology in the definition of a Designated Health Service. As with other Designated Health Services, CMS has provided a list of selected CPT and HCPCS codes that would be subject to the Stark Law. CMS explained that when it first evaluated these services in 2001, it believed that these services were not widely considered to be either radiology services or radiation therapy services. However, CMS was persuaded that since 2001 there has been a shift in the location of nuclear medicine procedures from the hospital setting to physicians' offices; in particular, CMS referred to its own decision to expand Medicare coverage for PET scans and the recent finding by the Medicare Payment Advisory Commission ("MedPAC") that the volume of nuclear medicine services had grown more rapidly than other physician services or imaging services.

The proposed change would not disrupt all arrangements under which nuclear medicine services are furnished. CMS explained that physicians who own or invest in entities that furnish nuclear medicine services would not violate the Stark Law if the services satisfy the in-office ancillary services exception. Similarly, ownership or investment in an entity that furnishes nuclear medicine services to beneficiaries in a rural area would not violate the Stark Law. If CMS's proposal becomes final, then those physicians affected by the change may have to either cease all Medicare and Medicaid referrals to the nuclear medicine entity, or divest themselves of their ownership interests. Nevertheless, CMS is soliciting comments from interested parties. CMS has specifically requested comments as to "whether, or how, to minimize the impact on physicians who are currently parties to arrangements that involve nuclear medicine services and supplies (that is, by specifying a delayed effective date or by grandfathering certain arrangements)." 70 Fed. Reg. at 45,856. Those parties with such arrangements should consider what effect, if any, that CMS's proposal may have on compliance with applicable state laws.

Interested parties should submit comments to CMS no later than October 7, 2005. Although the revisions to the Part B fee schedule must be published in time to be implemented on January 1, 2006, there is no guarantee that this proposed revision to the Stark Law regulations will be published at that time.

* * *

If you would like additional information regarding this topic, please contact [Robert E. Wanerman](mailto:Robert.E.Wanerman@ebglaw.com) at 202/861-1885 or rwanerman@ebglaw.com, [Jana Kolarik Anderson](mailto:Jana.KolarikAnderson@ebglaw.com) at 202/861-1804 or jkolarik@ebglaw.com, or [Jason Caron](mailto:Jason.Caron@ebglaw.com) at 202/861-4190 email jcaron@ebglaw.com in the firm's Washington, D.C. office, or the Epstein Becker & Green attorney who regularly handles your legal matters. For further information about Epstein Becker & Green's Health Care & Life Sciences Practice, or to see back issues of Special Alerts, please visit our website at www.ebglaw.com.

The Epstein Becker & Green, P.C., **Special Alert** is published by the National Health Care & Life Sciences Practice to inform health care organizations and providers of new legal developments which may affect the delivery and financing of their health care services.

Information published in the **Special Alert** is not intended to be, nor should it be considered, legal advice. Readers should consult an attorney to discuss specific situations in further detail.

Lynn Shapiro Snyder, Esq.
 Editor

Published by
 Health Care & Life Sciences
 Practice
 of

**EPSTEIN BECKER &
 GREEN, P.C.**



THOUGHT LEADERS IN
 HEALTH LAW®
 WWW.EBGLAW.COM

If you would like to be added to our mailing list, please complete the form below and return it to:

Amy Simmons
 Marketing & Recruitment Manager
 Health Care & Life Sciences Practice
 Epstein Becker & Green, P.C.
 1227 25th St., NW, Suite 700
 Washington, D.C. 20037

phone (202) 861-1811 -- fax (202) 296-2882

asimmons@ebglaw.com

Name: _____ Title: _____

Company/Firm/Organization: _____

Street address: _____

City: _____ State: _____ Zip Code: _____

Phone number: _____ Fax number: _____

Internet E-mail address: _____

**HEALTH CARE & LIFE SCIENCES PRACTICE
 ATTORNEYS OF THE FIRM**

ATLANTA

Michael Barry, Robert Berg, Christy Durden
 Phyllis Granade, Amy Haywood, Kimberly Naegele
 Rebekah Plowman, Kristen Pollock, Carol Saul, Kristin
 O'Connell Upton and Alan Wynne

CHICAGO

Amy Dow, Steve Drake, Heather Fesko
 Catherine Katilius, Diane Romza-Kutz

DALLAS

Gayla Crain

HOUSTON

Eraka Childs, Steve Cochell
 Michelle Moore and Marty Wickliff

LOS ANGELES

Dale Bonner and Susan Graham

NEW YORK

Jeffrey Becker, Cathy Cachero, Jerrold Ehrlich
 Philip Gassel, Jay Gerzog, John Gleason
 Wendy Goldstein, Robert Groban, Carrie Kissick
 Purvi Maniar, Ari Markenson, Mark Moskovitz
 Christopher Panczner, Brian Platton, Leigh Rubinstein
 David Simon, Steven Swirsky and Jonathan Trafimow

NEWARK

Richard Davis, Joan Disler, Lynne DeLisi
 Mathew Farkas, James Flynn, Hervé Gouraige
 Sucharita Iyengar, Philip Mitchell, Maxine Neuhauser
 Kerry Parker and Jana Taylor

SAN FRANCISCO

William Helvestine, Michael Horan
 Tim O'Connor, Jamie Platto and Lawrence Rose

WASHINGTON, D.C.

Daniel Abrahams, Jill Alvarez, Gianna Arnold
 Kirsten Backstrom, Clifford Barnes, Uri Bilek
 Michael Bissegger, George Breen, Teresa Brooks
 Lee Calligaro, Jason Caron, Jason Christ
 Kendra Dimond, John Eriksen, Steven Epstein
 James Falk, Jr., James Falk, Sr., Rebecca Fayed
 Gregory Fortsch, Jackie Frazer, Stuart Gerson
 Alexis Gilroy, Julianna Gonen, Daniel Gospin
 Leah Guidry, Niteesha Gupte, Marci Handler
 Douglas Hastings, Robert Hudock, Taylor Jones
 Teresa Kelton, Jana Kolarik, William Kopit
 Jennifer Luong, Mark Lutes, David Matyas
 John Murdock, Elizabeth Murphy, Clayton Nix
 Sarah Oliker, Sandra Park, Corey Perman
 Corinne Pouliquen, Helen Quick, John Rah
 Lauren Ranone, Carolyn Ratner, Robert Reif
 Christopher Robinson, Tisha Schestopol, Anuj Shah
 Lynn Shapiro Snyder, Rachel Spitz, Jessica Swartz
 David Tatge, Daly Temchine
 Linda Tomaselli (admitted in MA & NH only)
 Carrie Valiant, Dale Van DeMark, Patricia Wagner
 Robert Wanerman, Connie Wilkinson and
 Hilary Weckstein