

UPDATES FROM BARATZ & ASSOCIATES, P. A. FOR THE HEALTHCARE INDUSTRY

April 2009
Issue 6

SIGNIFICANT CHANGES TO OIG SELF-DISCLOSURE PROTOCOL

While attending a Stark update conference at the American Health Lawyer Association in Baltimore, Maryland on March 24, 2009, the Office of Inspector General (OIG) of the Department of Health and Human Services publicly released an open letter to health care providers with some significant changes to its long-standing provider self-disclosure protocol. First, the OIG will no longer accept self disclosures that involve only a Stark violation. This in effect reduces the options that providers have while dealing with technical violations of Stark that may occur. An example of this would be if a contract was not signed by one of the parties in a physician / hospital relationship violating a requirement of a Stark exception. This violation, if not discovered timely, could result in significant provider claims that may have been submitted becoming refundable to the Government as the contract was not in compliance with a Stark exception. This technical mistake, even if accidental, could result in a very significant liability back to the Federal Government.

Previously this issue could be handled through the OIG self-disclosure Protocol with some potential for mitigation of the possible liability. Now this method is not available. There must also be a "colorable" anti-kickback violation for the OIG to consider a Stark violation under the self-disclosure protocol. Secondly, the OIG is establishing a \$50,000 minimum for all self-disclosure settlements. The OIG noted that \$50,000 is the minimum civil monetary penalty that may be imposed for an anti-kickback violation.

These changes are a reversal of the position taken in an open letter from April 2008 in which the OIG encouraged providers to utilize the self-disclosure protocol for Stark violations. The reason given at the conference for this change was centered around the limited resources to handle all issues at the OIG level and that this was intended to focus OIGs resources on kickbacks intended to induce or reward a physician's referrals. The letter did caution, that while OIG is narrowing the self-disclosure protocols scope for resource purposes, that providers should not "draw any inferences about the Government's approach to enforcement of the physician self-referral law".

There are still other alternatives available for self-disclosure in the health care arena for potential violations that legal counsel can assist their clients with.

The open letter is attached for your review.

Ambulatory Surgery Center Issue Finally Resolved in New Jersey

Governor Jon Corzine (NJ) signed bill S-797/A-1933 authorizing physicians to refer patients to ambulatory surgery centers (ASC) that they own. Surgery centers have long been acceptable for self-referral by physicians using the specific anti-kickback exception for ASCs, as it was felt that they were not likely to cause fraud and abuse and that they were more cost effective for certain types of procedures performed in an ambulatory outpatient setting. In New Jersey, the piggy-backing of the federal "Stark laws" under the "Cody Law" created a potential conflict issue that came to light in the 2007 Bergen County trial, Garcia v. Health Net, Ber-C-37-06, where Superior Court Judge Robert Contillo ruled that doctors who sent their own patients to the Wayne Surgical Center violated a 1992 law against self-referral. While the Judge said the violations did not rise to a level of fraud that would allow insurers to deny claims, he implied thousands of doctors were acting illegally and could be subject to discipline.

The new law retroactively states that the referral prohibition to a health care service that the referring physician has a financial interest in does not apply to "a health care service provided at an ambulatory surgical facility licensed by the Department of Health and Senior Services to provide ambulatory surgery, if the physician who provided the referral also performs the surgery and the physician's remuneration as an owner of or investor in the facility is not related to the volume of patients the physician refers to the facility". This in effect puts the state and federal law on the same footing and spares 120 New Jersey surgical centers from a very significant problem.

A-1933 is attached for your review.

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Friendly Reminder: RAC's Are Coming Soon

As a follow up to a previous newsletter, this is a reminder that RACs are coming. For Part B providers, the 2009 record request limits are:

- 10 Medical records per 45 day period for solo practitioners;
- 20 Medical records per 45 day period for two to five provider offices;
- 30 Medical records per 45 day period for groups of six to fifteen providers;
- 50 Medical records per 45 day period for groups of sixteen or more providers;

Making sure you are prepared for selection is the best approach.

**An Open Letter to Health Care Providers****March 24, 2009**

This Open Letter refines the OIG's Self-Disclosure Protocol (SDP) to build upon the initiative announced in my April 24, 2006, Open Letter. The 2006 Open Letter promoted the use of the SDP to resolve matters giving rise to civil monetary penalty (CMP) liability under both the anti-kickback statute and the physician self-referral ("Stark") law. As part of our ongoing efforts to evaluate and prioritize our work, these refinements aim to focus our resources on kickbacks intended to induce or reward a physician's referrals. Kickbacks pose a serious risk to the integrity of the health care system, and deterring kickbacks remains a high priority for OIG.

To more effectively fulfill our mission and allocate our resources, we are narrowing the SDP's scope regarding the physician self-referral law. OIG will no longer accept disclosure of a matter that involves only liability under the physician self-referral law in the absence of a colorable anti-kickback statute violation. We will continue to accept providers into the SDP when the disclosed conduct involves colorable violations of the anti-kickback statute, whether or not it also involves colorable violations of the physician self-referral law. Although we are narrowing the scope of the SDP for resources purposes, we urge providers not to draw any inferences about the Government's approach to enforcement of the physician self-referral law.

To better allocate provider and OIG resources in addressing kickback issues through the SDP, we are also establishing a minimum settlement amount. For kickback-related submissions accepted into the SDP following the date of this letter, we will require a minimum \$50,000 settlement amount to resolve the matter. This minimum settlement amount is consistent with OIG's statutory authority to impose a penalty of up to \$50,000 for each kickback and an assessment of up to three times the total remuneration. See 42 U.S.C. § 1320a-7a(a)(7). We will continue to analyze the facts and circumstances of each disclosure to determine the appropriate settlement amount consistent with our practice, stated in the 2006 Open Letter, of generally resolving the matter near the lower end of the damages continuum, i.e., a multiplier of the value of the financial benefit conferred.

These refinements to OIG's SDP are part of our ongoing efforts to develop the SDP as an efficient and fair mechanism for providers to work with OIG collaboratively. Further information about our SDP can be found at: <http://oig.hhs.gov/fraud/selfdisclosure.asp>. I look forward to continuing our joint efforts to promote compliance and protect the Federal health care programs and their beneficiaries.

Sincerely,

Daniel R. Levinson
Inspector General

ASSEMBLY, No. 1933

STATE OF NEW JERSEY

213th LEGISLATURE

INTRODUCED JANUARY 28, 2008

Sponsored by:

Assemblyman HERB CONAWAY, JR.

District 7 (Burlington and Camden)

Assemblyman NELSON T. ALBANO

District 1 (Cape May, Atlantic and Cumberland)

Assemblyman MATTHEW W. MILAM

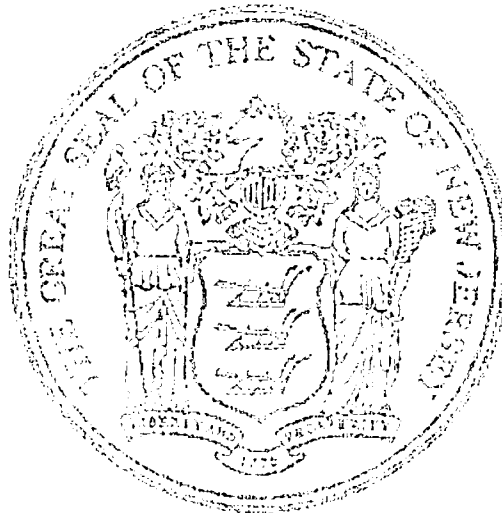
District 1 (Cape May, Atlantic and Cumberland)

SYNOPSIS

Permits physicians to refer patients to certain ambulatory care facilities in which they have financial interest.

CURRENT VERSION OF TEXT

As introduced.



(Sponsorship Updated As Of: 3/4/2008)

A1933 CONAWAY, ALBANO

2

1 AN ACT concerning certain health care service referrals, and
2 amending P.L.1989, c.19.

3

4 **BE IT ENACTED** by the Senate and General Assembly of the State
5 of New Jersey:

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7 1. Section 2 of P.L.1989, c.19 (C.45:9-22.5) is amended to read
8 as follows:

9 2. a. A practitioner shall not refer a patient or direct an
10 employee of the practitioner to refer a patient to a health care
11 service in which the practitioner, or the practitioner's immediate
12 family, or the practitioner in combination with practitioner's
13 immediate family has a significant beneficial interest; except that,
14 in the case of a practitioner, a practitioner's immediate family or a
15 practitioner in combination with the practitioner's immediate family
16 who had the significant beneficial interest prior to the effective date
17 of P.L.1991, c.187 (C.26:2H-18.24 et al.), the practitioner may
18 continue to refer a patient or direct an employee to do so if that
19 practitioner discloses the significant beneficial interest to the
20 patient.

21 b. If a practitioner is permitted to refer a patient to a health care
22 service pursuant to subsection a. of this section, the practitioner
23 shall provide the patient with a written disclosure form, prepared
24 pursuant to section 3 of P.L.1989, c.19 (C.45:9-22.6), and post a
25 copy of this disclosure form in a conspicuous public place in the
26 practitioner's office.

27 c. The restrictions on referral of patients established in this
28 section shall not apply to:

29 (1) a health care service that is provided at the practitioner's
30 medical office and for which the patient is billed directly by the
31 practitioner; **[and]**

32 (2) radiation therapy pursuant to an oncological protocol,
33 lithotripsy and renal dialysis; **and**

34 (3) a health care service provided at an ambulatory surgical
35 facility licensed by the Department of Health and Senior Services
36 on the effective date of P.L. . c. (C.)(pending before the
37 Legislature as this bill) to provide ambulatory surgery, if the
38 physician who provided the referral also performs the surgery and
39 the physician's remuneration as an owner of or investor in the
40 facility is not related to the volume of patients the physician refers
41 to the facility.

42 (cf: P.L.1991,c.187, s.47)

43

44 2. This act shall take effect immediately.

EXPLANATION – Matter enclosed in bold-faced brackets **[thus]** in the above bill is
not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.

STATEMENT

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This bill amends section 2 of P.L.1989, c.19 (N.J.S.A.45:9-22.5), which currently prohibits physicians and other health care practitioners from referring patients to health care services in which the practitioner or the practitioner's immediate family has a significant beneficial interest.

This bill would exempt from the prohibition surgery provided at an ambulatory care facility that is licensed by the Department of Health and Senior Services on the effective date of the bill to provide ambulatory surgery if:

- the physician who made the referral also performs the surgery; and
- the physician's remuneration as an owner/investor of the facility is not related to the volume of patients the physician refers to the facility.