Four Things You Need to Know About the OMIG's Mandatory Compliance Program

By Gregory J. Naclerio[*]

Starting in the New Year, it is anticipated the OMIG will start to vigorously enforce its mandate that certain Medicaid providers adopt and implement an "effective compliance program." Having a so-called paper compliance plan that merely sits on a shelf and gathers dust will not pass muster and non-complaint providers will be sanctioned.

The OMIG Bureau of Compliance, headed by Assistant Medicaid Inspector Matthew Babcock, will take the lead and review a provider's compliance program as part of OIG's "routine" audits and investigation but more importantly the Bureau will also conduct focused "Compliance Program Effectiveness Reviews."

By the close of 2010, mandated providers will have submitted two "Mandatory Provider Compliance Certifications" (Attached A) in which a senior executive certified that the provider has adopted, implemented and maintains an effective compliance program that meets the requirements of state law and regulations. Thus, a provider who filed the certification and fails to meet its obligation can not only be sanctioned by OMIG but also face the criminal charge of offering a false instrument for filing in the second degree, a class A misdemeanor.[1]

This article will seek to apprise the provider community of what OMIG demands of your compliance program and how you can pass an OMIG compliance audit without adverse consequences.

1. **<u>Are you Required to Have a Compliance Program</u>?**

Pursuant to New York State Law[2] you must have an "effective compliance program" as of December 31, 2009 if you are:

a. Operating under a license issued under Public Health Law Articles 28 or 36 or under Mental Hygiene Law Articles 16 or 31; or

b. Ordering, providing, billing or claiming $500,000 from Medicaid in a 12 month period.

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Pursuant to the Federal Deficit Reduction Act of 2005 (DRA)[3], an entity that receives at least $5 million from Medicaid is required, as a condition of participation in the Medicaid Program, to:

a. have "detailed provisions" regarding the entities policies and procedures for detecting and preventing fraud, waste and abuse.

b. provide "employees (including management) and any contractor or agent of the entity information about the Federal False Claims Act, federal administrative remedies for false claims/statements, state laws pertaining to civil or criminal penalties for false claims/statements and whistleblower protection under such laws; and

c. include the above information in any employee handbook.

Practice Tip:

- If you are subject to the DRA you must meet all three requirements of its compliance program or you risk losing your Medicaid funding. Having a DRA Compliance Program is a "condition of participation" in the Medicaid Program and if a provider fails to meet such conditions Medicaid can demand return of funds they will deem an "overpayment."
- If you are not subject to the DRA requirements, following the more stringent DRA Rules will tend to show OMIG that you take compliance seriously and should go a long way to establish your plan as being "effective."

2. **What Areas Does a Compliance Program need to address?**

A Compliance Program should address risk areas in the following areas:

1. Billing
2. Payments
3. Medical necessity and quality of care
4. Governance
5. Mandatory reporting
6. Credentialing; and
7. Other risk areas that should be identified by the provider.

Practice Tip:

- As can be seen, OMIG's concept for an "effective compliance program" goes far beyond billing issues. For example, if you are an SNF, your program needs to address quality of

care issues, credentialing of staff (Medical Director, RN's, LPN's) and also address certain special risk issues such as possible kickback violations.

3. **What are the elements of a Compliance Program?**

The elements of a compliance program are set forth in N.Y.S. Social Services Law §363-d as supplemented by regulations at 18 NYCRR Part 521. The highlights of what is required follows but you are cautioned to read the statute and regulations in their entirety.

"A required provider's Compliance Program" must include the following:

a. **written policies and procedures that describe compliance expectations as embodied in a code of conduct or code of ethics, implement the operation of the compliance program, provide guidance to employees and others on dealing with potential compliance issues, identify how to communicate compliance issues to appropriate compliance personnel and describe how potential compliance programs are investigated and resolved:**

Practice Tip:

Many providers get hung up on drafting a Code of Conduct or Code of Ethics (the "Code"). Remember, the most respected Code came down from Mt. Sinai on two stone tablets! You should be able to draft a Code in one or two pages. The Code should not contain specifics, only general aspirations to "do the right thing."

The more cumbersome task is in drafting of the "Policies and Procedures" to implement the program, training employees and the process of how to report and investigate compliance problems. Depending on the provider, the policies and procedures need not rival *War and Peace* but should set forth what the compliance plan seeks to do and how it intends to do it.

b. **Designate an employee vested with responsibility for the day-to-day operation of the compliance program; such employee's duties may solely relate to compliance or may be combined with other duties so long as compliance responsibilities are satisfactorily carried out; such employee shall report directly to the entity's chief executive or other senior administrator designated by the chief executive and shall periodically report directly to the governing body on the activities of the compliance program**.

Practice Tip:

- A specific employee has to be designated by management (as the Compliance Officer) to oversee the company's compliance program. It is suggested that this individual not be general counsel or the chief financial officer, as these individuals are identified too closely with management.[4] The Compliance Officer must have delineated reporting lines directly to the company's CEO or other senior manager designated by the CEO. The intent here is to make sure the CEO is involved in compliance matters. Additionally, the Compliance Officer should meet at least quarterly with the Governing Board to address the activities of the compliance program. It is preferable to have such meetings with the Board in executive session (i.e., without management being present) to avoid the perception that management is unduly influencing the Compliance Officer's presentation. For a compliance program to work or be "effective" - from the OMIG perspective – the Compliance Officer needs a mandate to perform his or her tasks from the highest levels of the organization.

c. **Training and education of all affected employees and persons associated with the provider, including executives and governing body members, on compliance issues, expectations and the compliance program operation; such training shall occur periodically and shall be made a part of the orientation for a new employee, appointee or associate, executive and governing body member**.

Practice Tip:

- The DRA and the OMIG's compliance rules differ on who shall receive "training and education." While OMIG requires training for "employees and persons associated with the provider," DRA goes further and requires training of "employees of the entity (including management) and any contractor or agent of the entity." The question then arises, "Do I need to train the cleaning service or landscaper?" The answer is "no." Rather, training should be given to all employees, independent contractor or agent that engages in billing, finances or patient care activities.[5]

- Training of the required individuals, including the governing authority, should be done yearly and be made part of the orientation of any new employee. These training sessions should be documented (i.e., copy of training syllabus, a sign-in sheet or acknowledgment of attendance) and maintained by the Compliance Officer.

- The training program should address the providers Code, how the compliance program operates and the providers specific risk areas (See, question 2, above). While OMIG does not require what statutes should be addressed, DRA-required providers must include reference to following in their training module:
    - The Federal False Claims Act
    - Federal Administrative remedies for false claims and statements.
    - State laws pertaining to civil and criminal penalties for false claims and statements, and
    - Whistleblower protections under such laws.

Also, depending on the provider, reference to the Federal Antikickback statute[6] and/or the Stark Law[7] may be appropriate.

- The intent of such training is not to make legal scholars of the attendees but to outline in general terms how the compliance program works and provide an overview of applicable laws. The program should be presented in plain English and the thrust of the presentation should control its length. For most employees, depending on the size of the provider, it should be accomplished in 45-50 minutes. Executives and governing board members should be trained for about double that time.
- As many providers have round-the-clock staff, the presentation may be videotaped for playing on other shifts. Also, barring any significant change in the compliance program or the law, the presentation can be used for subsequent years.

d. **Communication lines to the responsible compliance position, as described in paragraph (2) of this subdivision, that are accessible to all employees, persons associated with the provider, executives and governing body members, to allow compliance issues to be reported; such communication lines shall include a method for anonymous and confidential food faith reporting of potential compliance issues as they are identified**.

Practice Tip:

- While the "policy" to have a line of communication established between the Compliance Officer and other employees, agents, etc. of the entity is set forth in criteria "a," this element of a Compliance Program requires that a procedure be established for such a

communication. The communication to the Compliance Officer must allow for "anonymous and confidential" reporting of potential compliance issues. This is almost always provided by a "Compliance Hot Line" that is available 24/7. Depending on the organization, the hotline could be on the Compliance Officer's desk during business hours and then placed on voice mail for off hours, or in certain instances, be operated 24/7 by an outside vendor.

- The recent report by the American Association of Fraud Examiners[8] states that 40.2% of all occupational frauds were initially detected by "Tips." This figure is all the more astonishing when compared to the fact that external and internal audits only detected 4.3% and 13.9%, respectively. Hence, the value of a hotline or similar method of communication is invaluable to the operation of an effective program.

- Anonymous tips via a hotline, while a good source to start an investigation, does not permit follow-up as the inquiry continues. Thus, if a hotline is manned, the Compliance Officer can give the caller a "confidential designation" (for example, confidential caller #1) and arrange for a follow-up contact after the initial investigation is under way and questions arise. The confidential caller designation keeps the line of communication open with the source and can provide feedback to the caller. Other methods the provider believes will engender confidentiality can also be instituted.

e. **Disciplinary policies to encourage good faith participation in the compliance program by all affected individuals, including policies that articulate expectations for reporting compliance issues and assist in their resolution and outline sanctions for:**

i. Failing to report suspected problems;
ii. Participating in non-compliant behavior; or
iii. **Encouraging, directing, facilitating or permitting either actively or passively non-compliant behavior;**

Such disciplinary policies shall be fairly and firmly enforced.

Practice Tip:

- Providers are encouraged to include in their disciplinary rules that all employees are expected to follow the Code and compliance plan. Disciplinary action must also be taken against not only those who violate the code but those who encouraged or facilitated (actively or passively) in the noncompliant conduct or failed to report suspected behavior. Additionally,

those individuals who, by virtue of their position in the organization, should have known but failed to detect such conduct should be disciplined.

- In short, the Compliance Program should have "teeth" to penalize those who directly engage in proscribed conduct as well as those who turn a blind eye.

f. **A system for routine identification of compliance risk areas specific to the provider type, for self-evaluation of such risk areas, including but not limited to internal audits and as appropriate external audits, and for evaluation of potential or actual non-compliance as a result of such self-evaluations and audits, credentialing of providers and person associated with providers, mandatory reporting, governance, and quality of care of medical assistance program beneficiaries.**

Practice Tip:

- A compliance plan must have systems or procedures in place which are designed to identify compliance risk areas. These procedures will differ by types of providers but should show that the provider is being "proactive" (responding to hotline tips is "reactive"). An effective compliance plan should test its own systems, do self-evaluations and conduct audits of high risk areas. This self-policing concept is a key component of a compliance Program and systems must be put in place to make sure it is being done.

g. **A system for responding to compliance issues as they are raised; for investigating potential compliance problems; as identified in the course of self-evaluations and audits; correcting such problems promptly and thoroughly and implementing procedures, policies and systems as necessary to reduce the potential for recurrence; identifying and reporting compliance issues to the department or the Office of Medicaid Inspector General; and refunding overpayments.**

Practice Tips:

- This is the heart of a compliance program. Now that the provider has a compliance issue placed before them, how does the provider react? Initially, the compliance issue should be recorded in a Compliance Log and an investigative response to the complaint needs to be considered. The Compliance Officer, depending on the issue, may seek guidance

from the general counsel or the provider's outside counsel. Once the plan for the investigation is decided upon, the Compliance Officer (or, if it is a major allegation, the Compliance Officer with outside counsel) should conduct the investigation. The investigation should result in the allegation being "found" or "not substantiated." This finding should be documented in the Compliance Log.

- In the event the investigation does not reveal wrongdoing but rather potential areas of concern, action should be taken to correct any system weaknesses detected. As always, the Compliance Officer must document such action.

- In the event an overpayment is found, the compliance program should respond by following the OMIG's Self-Disclosure Guidance of March 12, 2009.[9]

- Providers should not fear being "targeted by OMIG" if they make a self-disclosure. Rather, doing so shows OMIG that your compliance plan works. Those compliance programs that <u>never</u> get a hotline tip or <u>never</u> find system weakness or <u>never</u> need to self-disclose are the programs OMIG will deem "not effective."

h. **A policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, self-evaluations, audits and remedial actions, and reporting to appropriate officials as provided in sections seven hundred forty and seven hundred forty-one of the labor law**.

<u>Practice Tip</u>:

- The Compliance Program should clearly state that intimidation or retaliation will not be permitted against individuals who in good faith report potential compliance issues. It is also the compliance officer's job to investigate allegations of intimidation/retaliation and to report such instances up the chain of command. Nevertheless, discipline can be imposed on those who report in bad faith and seek to use the compliance program for self-interested motives.

4. **<u>Will your compliance plan be audited by OMIG</u>?**

- Based upon statements from OMIG and the recently issued OMIG Compliance Alert concerning the "Provider Self Assessment Tool," to determine the "effectiveness of Medicaid Providers Compliance Programs," (Attachment B) you can be assured in 2011, the OMIG will start to vigorously audit.

- An audit of your Compliance Program will be part of OMIG's, "routine audits, routine investigations or routine Compliance Program effectiveness reviews." Clearly, OMIG intends to visit providers for the sole purpose on conducting a review of the provider's compliance program. Since, for the mandated providers, a compliance program is considered a "condition of participation" it is fair to say that OMIG will take vigorous efforts to show the provider community that it is serious about enforcing this provision of law. A strong response can be expected from OMIG for those providers who fail to have an "effective" compliance program. OMIG has given providers significant advance warning to establish and operate such a program. Those that do not will be called to task.

CONCLUSION.

In his webinar of November 12, 2010, the head of OMIG gave the provider community his definition of the word "effective" in terms of a compliance program. According to Mr. Sheehan, "effective" means.

1. the organization exercises due diligence to prevent and detect inappropriate conduct by the Medicaid provider;
2. the organization promotes an organizational culture that encourages ethical conduct and is committed to compliance with the law; and
3. the compliance program is reasonable designed, implemented, and enforced so that the program is generally effective in preventing and detecting improper conduct.

If your Compliance Program does not meet these and the requirements set forth above, It's not too late to comply. The choice is yours.

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[1] Penal Law § 175.30
[2] Social Services Law 363-d, 18 NYCRR Part 521
[3] 42 USC § 1396a (a) (68).
[4] See, OIG, Compliance Program Guidance for hospitals, Feb. 23, 1998, footnote 35.
[5] See, footnote 3, supra
[6] Federal Antikickback Statute, 42 USC §1320-a 7(b)
[7] Limit on certain physician referrals (the "Stark Law") 42 USC §1395nn
[8] American Association of Certified Fraud Examiners, 2010 Report to the Nation, 2010 p. 16 (See, www.acfe.com).
[9] See, omig.ny.gov, "Compliance" tab.

EXHIBIT A

Form: NYS OMIG CCSSL2010-1 (Revised: 12/01/2010)

Certification of Compliance with the Social Services Law § 363-d and 18 NYCRR Part 521

This form permits Medicaid providers to certify that their compliance program is effective as required by NYS Social Services Law Section 363-d and 18 NYCRR Part 521.

This form **CANNOT** be used to certify that Medicaid providers meet the requirements of the Federal Deficit Reduction Act of 2005 (DRA) which establishes requirements about the False Claims Act. To determine if you must certify under the DRA, please see the material on the Federal Deficit Reduction Act by going to www.omig.ny.gov, clicking on the Compliance tab on the home page and clicking on the Certification sub tab and looking for the Federal Deficit Reduction Act material.

Corporation/Provider Information

Federal Employer Identification Number (FEIN) (SSN IF 1099): Re-Enter FEIN or SSN:

Corporation/Provider Name: , hereinafter "Provider"

Address1: Address2:

City: State: Alabama Zip Code:

Compliance Officer Information

First Name: Middle Initial: Last Name: Suffix: Title:

Phone Number: Email Address: Re-Enter Email Address:

Person Certifying

First Name: Middle Initial: Last Name: Suffix: Title:

Phone Number: Email Address: Re-Enter Email Address:

Certification

☐ Provider certifies that the provider and its affiliates have adopted, implemented and maintain an effective compliance program that meets the requirements of NYS Social Services Law §363-d and 18 NYCRR Part 521.

A provider who does not have an effective compliance program should not complete this form.

If you determine that your compliance program is not effective, you should not certify, but you must communicate to OMIG the following:

1. Identify the provider:

- the name of the provider
- the provider's Federal Identification Number ("FEIN") that the provider uses to bill Medicaid
- all Provider Numbers that provide services to Medicaid beneficiaries under the FEIN
- the name, telephone number and e-mail address of the person providing the communication to OMIG

2. The subject line on your e-mail should indicate your name and "Unable to Certify"

3. The body of your e-mail should indicate:

- the reasons why your compliance program is not effective

- the steps you are taking to make your compliance program effective
- when you expect that you will be able to certify that your compliance program is effective.

Your communication that you are unable to certify that your compliance program is not effective should be sent via e-mail to: compliance@omig.ny.gov.

Captcha

Please enter the numbers in the order as they appear. NOTE: There are no spaces inbetween the numbers.

Reload Image

Submit Certification

When you click the Submit button, a Confirmation Page will appear. Please print a copy of the Confirmation Page for your records.

Submit Cancel

EXHIBIT B

New York State Office of Medicaid Inspector General

Compliance Alert

2010 - 02

Effectiveness of Medicaid Provider's Compliance Program

Provider Self Assessment Tool - 2010

New York State Social Services Law Section 363-d and the corresponding regulations at 18 NYCRR Part 521 require certain providers in the medical assistance program (Medicaid) to have an effective compliance program. The Office of Medicaid Inspector General (OMIG) has the responsibility under Section 363-d to determine if compliance programs meet these requirements.

New York State Social Services Law Section 363-d also requires the OMIG to create and make guidance available on its website to reflect the requirements of mandatory provider compliance programs. OMIG uses Compliance Alerts as one method to provide guidance to Medicaid providers in order to meet the guidance requirements of Section 363-d. Compliance Alert 2010-01 describes the purpose behind OMIG's publication of Compliance Alerts.

Purpose of this Compliance Alert

OMIG believes that it is a best practice for Medicaid providers to perform, at a very basic level, an annual self-assessment of the effectiveness of their compliance programs. Compliance officers, chief executives and governing boards should use self-assessment, along with other measurements, to objectively assess the strengths and weaknesses of their compliance programs.

A Medicaid provider's self assessment will be one measure available to OMIG when reviewing the effectiveness of a provider's compliance program. OMIG may ask Medicaid providers for evidence of their self assessment as part of routine audits, routine investigations or routine Compliance Program effectiveness reviews. The pages that follow in this Compliance Alert present a very basic Provider Self Assessment Tool – 2010 that could be used by providers in their self assessment. If providers opt to use their own tool, the following pages outline the information that OMIG would expect to be included on the providers' tools.

OMIG recommends that the compliance officer review the questions under each of the eight essential elements of an effective compliance program and objectively determine if the provider's compliance program supports each element. (It is expected that the compliance officer will consult with other members of the Medicaid provider's staff, management or governing board, as appropriate.) The tool could be used for each entity that separately bills Medicaid. Once the Provider Self Assessment Tool is completed, OMIG recommends that the compliance officer share the responses on the tool with the provider's senior management and governing board.

A provider's response to the tool's questions are a first step to indicate whether the provider has established a structure that meets the eight elements of an effective compliance program as required by Section 363-d and Part 521. Structure alone does not determine the effectiveness of a compliance program, but it creates the framework for an effective compliance program. How the compliance program works and the outcomes produced must also be assessed.

It must be noted that the following tool is a generic tool that can be used for any type of provider that bills for Medicaid-covered services. Providers should take into account their size, complexity, and the sophistication of their compliance program. Some of the terms used on the tool may not apply to specific providers in their operating context. In reviewing the questions posed on the tool, OMIG has included questions that are tied directly to requirements set out in SSL 363-d and Part 521. Those questions include an asterisk in the box containing the question's number. OMIG has included some questions that relate to the United States Federal Sentencing Guidelines that are effective on November 1, 2010, the Patient Protection and Affordable Care Act of 2010 (PPACA), and New York's Fraud Enforcement and Recovery Act of 2010 (Chapter 379 of the Laws of 2010). Those questions are identified by a double asterisk in the box containing the question's number. The remaining questions are designed, in part, to encourage the Medicaid provider, its governing board, senior management and compliance officer to consider factors beyond just the requirements of the statute or regulations and reflect issues that OMIG recently has addressed in other forums.

Directions for use of the Self Assessment Tool

If the answer is "yes" to a question on the attached tool, complete the "Yes" box and provide a description of what supports that response in the "Evidence of Compliance" column. The Evidence of Compliance description will provide a cross reference to the provider as to where the evidence supporting the "Yes" response can be located. For example, if the provider responds, "Yes," that its compliance expectations are included in a written code of conduct or code of ethics (see 1.1 on the attached tool), the provider should state what documents, policies and procedures exist that set out the code of conduct or code of ethics and specify whether it is a code of conduct, code of ethics, or both.

If the answer is "no" to a question, complete the "No" box and consider what action (if any) should be taken to address the "no" response or document the rationale for the "no" response. Because OMIG intends this tool to be used by many provider types of various sizes and complexity, a "no" response may be an appropriate response.

An explanation column is provided for the provider's use to provide any additional information that the provider may wish to include to demonstrate how the provider is ensuring compliance.

In preparing this Compliance Alert, comments were solicited from various Medicaid provider constituencies. The OMIG appreciates and recognizes the contributions of those who provided comments. Those ideas, suggestions, and constructive criticism were invaluable in the development of this Compliance Alert. Not all ideas, suggestions, and constructive criticisms were incorporated into the final version, nor should the final product be considered to be a consensus document. Ultimately, this Compliance Alert is the work product of OMIG and is provided in accordance with the requirements of Social Services Law Section 363-d.

If there are questions regarding this Compliance Alert or any Medicaid compliance related issue, you are requested to forward your question to the Office of Medicaid Inspector General's Bureau of Compliance at compliance@omig.ny.gov. Please include in the subject line of your e-mail, "Compliance Alert."

Providers are encouraged to monitor OMIG's Web site, www.omig.ny.gov, for additional compliance information and any changes to this Alert or information contained herein.

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