

## OMIG COMPLIANCE PROGRAM

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Effective July 1, 2009, New York State (NYS) requires Medicaid providers with \$500,000 or more in annual Medicaid billings to have an effective compliance program. Such compliance plans must be in place no later than October 1, 2009. In addition, providers will be required to certify annually that they have established an effective compliance program in accordance with statute.

### ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM

The eight basic requirements of an effective compliance program are: written policies and procedures, appointment of a compliance officer, periodic training, communication lines that allow compliance issues to be reported, disciplinary policies to encourage good faith participation in the compliance program and sanctions for non-compliant behavior, a system for routine identification of compliance risk areas, a system for responding to compliance issues and a policy of non-intimidation and non-retaliation for good faith participation in the compliance program.

In a recent address to a statewide association, the NYS Medicaid Inspector General, James Sheehan, indicated that systematic billing errors, retention of known overpayments or credit balances, and quality of care issues could be considered evidence of an ineffective compliance program. According to the Office of the Medicaid Inspector General (OMIG), an effective compliance program requires:

- Disclosure of overpayments received, when identified;
- Risk assessment, audit, data analysis and remedial measures;
- Response to issues reported through hotlines and employee disclosures.

### PROVIDER ACTION

The OMIG intends to review compliance programs during the course of their audits and investigations. As a result, it is important for providers to either establish an effective compliance program or to review the effectiveness of existing compliance programs. Compliance programs should not only identify potential areas of fraud and/or abuse, but should also identify systemic errors and inadequate policies and procedures. Under the current statute, compliance programs should address:

- Billings and payments;
- Medical necessity and quality of care;
- Governance;
- Mandatory reporting;
- Credentialing; and
- Other risk areas that should be identified by the provider.

One of the most important tools of an effective compliance plan is a comprehensive internal and external audit program which would include clinical record audits (for documentation and medical necessity), as well as financial and billing audits.

The following is a compliance summary which describes some of the background and details of these requirements. Providers whose current compliance plans may not meet the requirements described herein are urged to update their compliance programs accordingly.

## OVERVIEW: OMIG COMPLIANCE PROGRAM REQUIREMENTS

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Effective October 1, 2009, New York State providers that bill Medicaid more than \$500,000 annually are required to have an “effective” compliance program in place.

### BACKGROUND

A compliance program is a system which is designed to detect and prevent violations of law by the agents, employees, officers and directors of a business. Although highly recommended, compliance plans were voluntary for health care providers until 2005. Prior to 2005, the only occasion under which a compliance program was mandated was when the government imposed them as part of Corporate Integrity Agreements associated with the resolution of an allegation of fraud or abuse.

To assist providers in establishing and maintaining voluntary compliance programs, the Federal Office of the Inspector General (OIG) issued a series of compliance guidelines aimed at specific sectors of the health care industry. The guidance documents and the dates of their publication in the Federal Register are:

Compliance Program Guidance for Hospitals	February 23, 1998
Compliance Program Guidance for Home Health Agencies	August 7, 1998
Compliance Program Guidance for Clinical Laboratories	August 24, 1998
Compliance Program Guidance for Third-Party Medical Billing	December 18, 1998
Compliance Program Guidance for the Durable Medical Equipment Prosthetics, Orthotics, and Supply Industry	July 6, 1999
Compliance Program Guidance for Hospices	October 5, 1999
Compliance Program Guidance for Medicare+Choice Organizations	November 15, 1999
Compliance Program Guidance for Nursing Facilities	March 16, 2000
Compliance Program Guidance for Ambulance Suppliers	September 25, 2000
Compliance Program Guidance for Individual and Small Group Physician Practices	October 5, 2000
Compliance Program Guidance for Pharmaceutical Manufacturers	March 24, 2003

### 2005 FEDERAL DEFICIT REDUCTION ACT (DRA)

In 2005, the Federal Deficit Reduction Act (DRA) instituted a requirement for health care entities which receive or make \$5.0 million or more in Medicaid payments during a Federal fiscal year to establish written policies and procedures informing and educating their employees, contractors and agents about Federal and State false claim acts and whistleblower protections. Under these requirements, a covered health care entity must establish and disseminate detailed written policies to all employees (including management), contractors or agents of the health care entity regarding Federal and State False Claims Acts, whistleblower protections, and the health care entity’s policies and procedures for detecting and preventing waste, fraud and abuse. Although health care entities were not required to produce an employee handbook, entities were required to update existing handbook materials to incorporate information regarding these compliance laws, policies and whistle blower protections.

Oversight of this requirement for affected New York Medicaid providers is primarily the responsibility of the Office of the Medicaid Inspector General (OMIG). Each applicable health care entity is required to submit a certification that it maintains the written policies, that any employee handbook includes materials required under the above mandates and that they have been properly adopted and published by the health care entity and disseminated among employees, contractors and agents. These certifications are required to be filed with the OMIG before January 1 of each year.

## **OVERVIEW: OMIG COMPLIANCE PROGRAM REQUIREMENTS**

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### **NEW YORK STATE MANDATORY PROVIDER COMPLIANCE PROGRAMS**

Chapter 442 of the Laws of 2006, which established the New York State Office of the Medicaid Inspector General (OMIG) also created a new Social Services Law § 363-d which requires that Medicaid providers develop and implement compliance programs aimed at detecting fraud, waste, and abuse in the Medicaid program. These must be in place no later than October 1, 2009.

In developing provider compliance program regulations, the OMIG exercised its authority to impose additional requirements for compliance plans beyond the basic statutory requirements associated with Medicaid billing and payments. As a result, under Part 521, Title 18 of NYCRR, the compliance plan must be applicable to:

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

Certain Medicaid providers are automatically covered such as those subject to the provisions of Articles 28 and 36 of the Public Health Law as well as Articles 16 and 31 of the Mental Hygiene Law. Beyond that, the law applies to those Medicaid providers of care, services and supplies for which the Medicaid program “constitutes a substantial portion of their business operations.” The “substantial portion” is defined in the law as \$500,000 or more in Medicaid business (receiving, billing or ordering). This is estimated to cover 10% of New York State’s Medicaid providers, but 95% of the State’s Medicaid claims.

### **STRUCTURE OF A COMPLIANCE PLAN**

Part 521, Title 18 NYCRR, states that a required provider’s compliance program shall include the following elements:

1. 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 problems are investigated and resolved.
2. Designate an employee vested with responsibility for the day-to-day operation of the compliance program; such employee shall report directly to the entity's chief executive or other senior administrator and shall periodically report directly to the governing body on the activities of the compliance program.
3. Periodic 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.
4. Communication lines to the responsible compliance position 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 good faith reporting of potential compliance issues as they are identified.

## OVERVIEW: OMIG COMPLIANCE PROGRAM REQUIREMENTS

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5. 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:
  - a) failing to report suspected problems
  - b) participating in non-compliant behavior
  - c) encouraging, directing, facilitating or permitting non-compliant behavior

Such disciplinary policies shall be fairly and firmly enforced.

6. A system for routine identification of compliance risk areas specific to the provider type, for self-evaluation of such risk areas, including 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.
7. A system for responding to compliance issues as they are raised; for investigating potential compliance problems; responding to 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 OMIG or the DOH (or other agency as appropriate); and refunding overpayments.
8. 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 NYS labor law.

### ENFORCEMENT AND SANCTIONS

The OMIG and the DOH have the authority to determine at any time if a Medicaid provider that is subject to the new law has a satisfactory compliance program.

Failure by a provider to implement a satisfactory compliance program within ninety days after the effective date of the regulations (October 1, 2009) will subject the provider to any sanctions or penalties permitted by Federal or State laws and regulations, including, but not limited to, the revocation of the provider's agreement to participate in the Medicaid program.

### ADDITIONAL RESOURCES

Finally, the OMIG has indicated the intention to create guidelines that reflect the requirements of this new law including one or more model compliance program(s) as an example for providers. In the meantime, the Federal compliance guidelines listed above are available to all providers.

If you would like assistance in this area, please contact:

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