



MANDATORY COMPLIANCE PROGRAM RULES ARE IN EFFECT; FALSE CLAIMS ACT AMENDMENTS REQUIRE DRA POLICY REVISIONS

Two recent changes -- one in New York State regulation and the other in Federal law -- will require certain health care providers to take action.

NEW YORK STATE REGULATIONS: MANDATORY COMPLIANCE PROGRAM RULES

The New York State Office of Medicaid Inspector General ("OMIG") has formally adopted implementing regulations for Social Services Law § 363-d, a statute that has been on the books since 2007 and which makes compliance programs mandatory for certain Medicaid providers. In fact, having an effective compliance program is now a prerequisite to payment by the Medicaid program. Effective July 1st, the new regulations:

- § further define which Medicaid providers must implement effective compliance programs;
- § list specific risk areas that the compliance program must address;
- § require providers to certify to the OMIG upon enrollment in Medicaid (and annually every December thereafter) that they have established effective compliance programs that meet the requirements of the statute and regulations;
- § allow the New York State Department of Health ("DOH") and the OMIG to evaluate the effectiveness of provider compliance programs; and
- § set September 29, 2009 as the date by which all providers subject to the regulations must have compliance programs in place or risk sanctions, up to and including termination of their Medicaid Provider Agreement.

Which Providers Are Affected

Both the Social Services Law and the new regulations outline the health care providers that must establish compliance programs by or before September 29th. They include:

- § providers subject to Public Health Law Article 28 (hospitals, residential health care facilities) and Article 36 (home care services agencies);
- § providers subject to Mental Hygiene Law Article 16 (providers of services to mentally retarded and developmentally disabled persons) and Article 31 (providers of services to mentally disabled persons); and
- § providers who order, receive, or submit claims (or could reasonably expect to order, receive, or submit claims) of at least \$500,000 from the Medicaid program, in any consecutive 12-month period.

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Providers who are subject to the mandatory compliance program provisions that have not yet established compliance programs have until September 29, 2009 to get their programs up and running or run the risk of the OMIG imposing sanctions.

What Are the Necessary Requirements for Compliance Programs

The new regulations mirror the Social Service Law's requirements that compliance programs contain eight specific elements. These include having written policies and procedures, a compliance officer, training, appropriate communication, disciplinary policies, auditing, investigation and response, and a policy of non-intimidation and non-retaliation. The requirements further delineate risk areas that compliance programs must address. In addition to such common compliance areas as billing, payments, and medical necessity, the OMIG's regulations mandate that compliance programs be made applicable to quality of care, governance, mandatory reporting, credentialing, and other risk areas that "are or should with due diligence be identified by the provider."

This is noteworthy because these additional requirements are not specifically identified in the Federal Department of Health and Human Services' Office of Inspector General's ("OIG") Compliance Program Guidance for Hospitals. Therefore, providers who have established voluntary compliance programs that may be consistent with the OIG's guidelines will need to update their programs to ensure that these additional risk areas are identified and addressed prior to the September 29th deadline.

To assist providers in navigating through these new mandatory requirements, the OMIG says it will be publishing compliance program guidance on its website at an unspecified time in the future.

Certification that Compliance Program Meets OMIG's Requirements

Upon enrollment, and every December thereafter, providers must certify to the OMIG that they have established an effective compliance program that meets the requirements summarized above. Mandatory certification forms for providers to use to attest to the existence of their compliance programs will be available on the OMIG's website at www.omig.state.ny.us.

Ability of DOH and OMIG to Determine Adequacy of Compliance Program

The new regulations permit DOH and the OMIG to "determine at any time" if a provider has a compliance program that is effective and meets the requirements of the regulations. If DOH or the OMIG finds that a provider does not have a satisfactory program, the provider may be subject to sanctions or penalties, including revocation of the provider's agreement with the Medicaid program. We understand that the OMIG intends to begin enforcement of the new regulations starting in October of 2009.

FEDERAL FRAUD ENFORCEMENT RECOVERY ACT OF 2009 REQUIRES CHANGES TO FALSE CLAIMS ACT POLICIES

In addition to the mandatory compliance program requirements, providers should also be aware that the Federal Fraud Enforcement Recovery Act of 2009 ("FERA"), signed into law by President Obama on May 20, 2009, significantly amended the Federal False Claims Act. Providers who are required by the Deficit Reduction Act of 2005 (the "DRA") to establish written policies educating their employees, contractors and agents regarding false claims laws and whistleblower protections will need to update those policies to reflect these changes. (The DRA affects providers who receive over \$5 million annually in Medicaid payments.) Therefore, if you have a policy entitled "Compliance with Applicable Federal and State False Claims Acts" or another similar policy adopted to comply with the DRA, it will need to be revised.

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FERA amended the Federal False Claims Act in several important ways, particularly by making it clear that fraudulent claims do not have to be directly submitted to the government to be subject to the statute's reach. In addition, the knowing retention of an overpayment from the government is actionable under the False Claims Act. Whistleblower provisions have also been expanded to protect from acts of retaliation, contractors and agents (as well as employees) who take steps in furtherance of efforts to stop one or more violations of the False Claims Act.

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For further information or assistance with updating your existing compliance program and policies, please contact the GWT attorney with whom you normally work.

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