DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF MEDICAID AND MEDICAL ASSISTANCE

Statutory Authority: 31 **Delaware Code**, Section 512 (31 **Del.C.** §512)

FINAL

ORDER

Employee Education About False Claims Act

Nature of the Proceedings:

Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance initiated proceedings to provide notice to the public of the filing of a Title XIX Medicaid State Plan Amendment (SPA) with the Centers for Medicare and Medicaid Services (CMS) to comply with the mandated provisions of the Deficit Reduction Act (DRA) of 2005 (Public Law 109-171) pertaining to Employee Education About False Claims Recovery. The Department's proceedings to amend its regulations were initiated pursuant to 29 **Delaware Code** Section 10114 and its authority as prescribed by 31 **Delaware Code** Section 512.

The Department published its notice of proposed regulation changes pursuant to 29 **Delaware Code** Section 10115 in the May 2007 *Delaware Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by May 31, 2007 at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

Summary of Proposed Amendment

Statutory Authority

Deficit Reduction Act of 2005 (Public Law 109-171), enacted on February 8, 2006, Section 6032, *Employee Education About False Claims Recovery*

Background

The federal Deficit Reduction Act of 2005 (DRA) calls for active enforcement of Medicaid fraud and abuse as part of a "Medicaid Integrity Program" (MIP). In particular, effective January 1, 2007, Section 6032 of the DRA requires any entities that receive or make annual payments under the Title XIX Medicaid State Plan of at least $5 million dollars, as a condition of receiving such payments, to have established written policies and procedures about the Federal and State False Claims Act for their employees, agents and contractors.

Specifically, Section 6032 amends the Social Security Act, Title 42, United States Code, Section 1396a(a), by inserting an additional relevant paragraph. To summarize, this new paragraph mandates that any entity that receives or makes annual payments under the State Plan of at least $5 million dollars annually, as a condition of receiving such payments, must comply with the following requirements:

1) Establish written policies for **all** employees of the entity, including management and any contractor(s) or agent(s) of the entity. These written policies shall provide detailed information about the following:

- Federal False Claims Act, including administrative remedies for false claims and statements established under Title 31, USC, Chapter 38.
- State laws pertaining to civil or criminal penalties for false claims and statements; whistleblower protections under such laws; and the role of these laws in preventing and detecting fraud, waste and abuse in Federal health care programs.

2) The written policies must include details about the entity's policies and procedures for detecting and preventing fraud, waste and abuse.

3) Any employee handbook for the entity must include specific discussion of the laws about false

claims and statements, the rights of employees to be protected as whistleblowers, and the entity's policies and procedures for detecting and preventing fraud, waste and abuse.

Based on guidance in the form of State Medicaid Director Letter (SMDL) #06-024, dated December 13, 2006,

CMS has interpreted the word "entity" to include:

> a governmental agency, organization, unit, corporation, partnership, or other business arrangement (including any Medicaid managed care organization, irrespective of the form of business structure or arrangement by which it exists), whether for-profit or not-for profit, which receives or makes payments, under a State plan approved under title XIX or under any waiver of such plan, totaling at least $5,000,000 annually.

CMS has clarified that payments to the entity are to be aggregated for purposes of the annual threshold:

> If an entity furnishes items or services at more than a single location or under more than one contractual or other payment arrangement, the provisions of [Section 6032] apply if the aggregate payments to that entity meet the $5,000,000 annual threshold. This applies whether the entity submits claims for payments using one or more provider identification or tax identification numbers.

CMS has clarified that the annual threshold is based on the Federal fiscal year:

> An entity will have met the $5,000,000 annual threshold as of January 1, 2007, if it received or made payments in that amount in Federal fiscal year 2006. Future determinations regarding an entity's responsibility stemming from the requirements of [Section 6032] will be made by January 1 of each subsequent year, based upon the amount of payments an entity either received or made under the State Plan during the preceding Federal fiscal year.

These changes are effective January 1, 2007.

Summary of Proposal

The state plan amendment establishes DHSS's oversight of policies and procedures to implement the education of employees regarding the false claims act.

Pursuant to this plan amendment, the Department provides oversight and monitoring of entities that receives or makes Title XIX Medicaid payments of at least $5,000,000 annually based on payments received or made in Federal fiscal year 2006.

DMMA received CMS-approval of the provisions of this amendment on July 6, 2007, effective January 1, 2007.

Summary of Comments Received with Agency Response

The Governor's Advisory Council for Exceptional Citizens (GACEC) and the State Council for Persons with Disabilities (SCPD) offered the following endorsement with recommendation summarized below. DMMA has considered each comment and responds as follows:

The Councils **endorse** the regulations subject to elaboration on the requirement of inclusion of State law fraud references which we will highlight below.

DMMA has essentially followed the Centers for Medicare and Medicaid Services (CMS) template for its proposed State Plan amendment. However, the "background" section of the regulations recites that covered entities must also include in policies State law provisions, both civil and criminal, dealing with whistleblowers, fraud, waste, and abuse. At 1661. This requirement is only obliquely addressed in the text of the regulation. At 1664. Relevant state law provisions could include the following: insurance and health care fraud (Title 11 **Del.C.** §§913 and 913A); official misconduct (Title 11 **Del.C.** §1211); insurance fraud (Title 18 **Del.C.** Ch. 24); and public

assistance fraud (Title 31 **Del.C.** Ch. 10). The Councils recommends that DMMA consider including some specific references to such State law provisions in its regulations.

Agency Response: Thank you for the endorsement. DMMA followed the approach approved by CMS to the state Medicaid plan as specified in Section 4.42 and Attachment 4.42. DMMA received approval for its state plan amendment regarding Employee Education About False Claims Recovery on July 6, 2007 with an effective date of January 1, 2007. The DRA nor CMS provide any guidance regarding the level of detail of an entity's employee handbook and policy requirement. It is up to the entity in consultation with their legal counsel as long as their policy complies with DRA provisions. No change to the state plan amendment was made because of these comments.

Based on CMS guidance, DMMA made the following changes to Attachment 4.42, [indicated by bold bracketed type]:

- In #1: revised to state that DHSS will identify those entities that must comply for Current Year (CY) 2007.
- In #2, 3, 4, 5: changed "providers" to "entities" as this section requires compliance not only from providers but other entities that provide Medicaid health care items or services, like MCOs and other contractors.
- In #3: revised to refer to the preprint for what the policies should include rather than restating the requirements.

Also, dates were inserted where appropriate, as follows:

- In #3: inserted "July 1, 2007" as the date entities will be required to submit their policies to the state so that the state can review them as set forth in #3.
- In #3 and #5: inserted "July 1, 2007" as the date entities will be required to submit employee handbooks, if the entities have them.
- In #4: inserted "by January 31st"as the date the state will contact entities each year.
- In #5: inserted "by April 1st" as the date entities will be required to submit their policies each year.

Findings of Fact:

The Department finds that the proposed changes as set forth in the May 2007 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation to amend the Title XIX Medicaid State Plan pertaining to the mandated provisions of the Deficit Reduction Act (DRA) of 2005 (Public Law 109-171) regarding Employee Education About False Claims Recovery is adopted and shall be final effective September 10, 2007.

Vincent P. Meconi, Secretary, DHSS, 8/14/07

DMMA FINAL ORDER REGULATION #07-37
NEW:

79 x 1

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
State/Territory: DELAWARE

Citation
1902(a)(68) of the Act, P.L. 109-171 (section 6032)

4.42 Employee Education About False Claims Recoveries.

(a) The Medicaid agency meets the requirements regarding establishment of policies and procedures for the education of employees of entities covered by section 1902(a)(68) of the Social Security Act (the Act) regarding false claims recoveries and methodologies for oversight of entities' compliance with these requirements.

(1) Definitions

(A) An "entity" includes a governmental agency, organization, unit, corporation, partnership, or other business arrangement (including any Medicaid managed care organization, irrespective of the form of business structure or arrangement by which it exists), whether for-profit or not-for-profit, which receives or makes payments, under a State Plan approved under title XIX or under any waiver of such plan, totaling at least $5,000,000 annually.

If an entity furnishes items or services at more than a single location or under more than one contractual or other payment arrangement, the provisions of section 1902(a)(68) apply if the aggregate payments to that entity meet the $5,000,000 annual threshold. This applies whether the entity submits claims for payments using one or more provider identification or tax identification numbers.

A governmental component providing Medicaid health care items or services for which Medicaid payments are made would qualify as an "entity" (e.g., a state mental health facility or school district providing school-based health services). A government agency which merely administers the Medicaid program, in whole or part (e.g., managing the claims processing system or determining beneficiary eligibility), is not, for these purposes, considered to be an entity:

An entity will have met the $5,000,000 annual threshold as of January 1, 2007, if it received or made payments in that amount in Federal fiscal year 2006. Future determinations regarding an entity's responsibility stemming from the requirements of section 1902(a)(68) will be made January 1 of each subsequent year, based upon the amount of payments an entity either received or made under the State Plan during the preceding Federal fiscal year.

(B) An "employee" includes any officer or employee of the entity.

(C) A "contractor" or "agent" includes any contractor, subcontractor, agent, or other person which or who, on behalf of the entity furnishes, or otherwise authorizes the furnishing of, Medicaid health care items or services, performs billing or coding functions, or is involved in the monitoring of health care provided by the entity.

(2) The entity must establish and disseminate written policies which must also be adopted by its contractors or agents. Written policies may be on paper or in electronic form, but must be readily available to all employees, contractors, or agents. The entity need not create an employee handbook, if none already exists.

(3) An entity shall establish written policies for all employees (including management0, and of any contractor or agent of the entity, that include detailed information about the False Claims Act and the other provisions named in section 1920(a)(68)(A). The entity shall include in those written policies detailed information about the entity's policies and procedures for detecting and preventing waste, fraud, and abuse. The entity shall also include in any employee handbook a specific discussion of the laws described in the written policies, the rights of employees to be protected as whistleblowers and a specific discussion of the entity's policies and procedures for detecting and preventing fraud, waste, and abuse.

(4) The requirements of this law should be incorporated into each State's provider enrollment agreements.

(5) The State will implement this State Plan amendment of **January 1, 2007**.

(b) ATTACHMENT 4.42-A describes, in accordance with section 1902(a)(68) of the Act, the methodology of compliance oversight and the frequency with which the State will re-assess compliance on an ongoing basis.

ATTACHMENT 4.42-A

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
State/Territory: DELAWARE

FALSE CLAIMS ACT ATTACHMENT

1. The Delaware Health and Social Services (DHSS), the single state agency, will **[~~send a letter to any entity that receives annual payments of at least $5 million during the October 1, 2005 to September 31, 2006 period regarding the requirements of Section 6032 of the Deficit Reduction Act of 2005, the "Employee Education About False Claims Recovery," These letters will be sent by March 30, 2007~~ indentify those entities, defined in §4.42(a)(1)(A), that must comply for CY 2007.]**

2. DHSS will request copies of an affected **[~~provider's~~ entity's]** written policies, and the plan to disseminate those policies to staff, within three (3) months of State Plan approval.

3. Affected **[~~providers~~ entities]** written policies and procedures**[, except employee handbooks,]** will be reviewed for compliance **[~~with the Act~~ in accordance with §4.42(a)(3)]**. **[~~Said policies and procedures will include an explanation of the false claims act; the providers' policies and procedures for detecting and preventing waste, fraud and abuse; the rights of the employee to be protected as whistle blowers; and, the telephone numbers and/or addresses for reporting fraud and abuse~~ These written policies and procedures must be submitted to DHSS by July 1, 2007]**.

4. Thereafter, DHSS will contact affected **[~~providers~~ entities ~~on a yearly basis~~ by January 31st]** for any update or change to its written policies. DHSS will accomplish this verification by **[~~provider~~ entity]** survey.

5. New affected **[~~providers~~ entities]** identified each year will be required to submit **[by April 1st]** their polices and dissemination plan **[except employee handbooks,]** and will be handled per #2, 3, 4.

6. DHSS has a range of sanctions contained in its administrative regulation for non-compliance with Medicaid policies. These sanctions range from requiring a plan of correction to termination from the Medicaid program. These sanctions will be applied to non-compliance with the "Employee Education About False Claims Recovery."