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

Pharmaceutical Services Program – Tamper-Resistant Prescription Pads

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance. The Department's proceedings to amend the Delaware Medical Assistance Program (DMAP) Provider Manuals to bring Medicaid policies into compliance with the Federal law regarding tamper-resistant prescription pads 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 July 2008 *Delaware Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by July 31, 2008 at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

SUMMARY OF PROPOSAL

As a reminder, the purpose of this proposal is to update implementation of the federal law that mandates the use of tamper-resistant prescriptions for all Medicaid, non-electronic prescriptions.

Statutory Authority

Public Law 110-28, U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007, signed into law on May 25, 2007

Background

This proposal provides information regarding policy changes to the Delaware Medical Assistance Program (DMAP) Provider Manuals that outlines requirements for pharmacies that bill DMAP for prescriptions.

As previously announced [See 11 DE Reg 793, December 1, 2007], Congress passed H.R. 2206, U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007, Public Law 110-28, regarding use of tamper-resistant prescription pads. Section 7002(b) of the Act amends the federal Medicaid statute to prevent payment of prescriptions "for which the prescription was executed in written (and non-electronic) form unless the prescription was executed on a tamper-resistant pad".

Failure of a State to enforce the tamper-resistant requirement of section 7002(b) may result in the loss of Federal Financial Participation (FFP).

The Division of Medicaid and Medical Assistance (DMMA) implemented this mandate in two phases. For the first, DMMA required that, on October 1, 2007, a prescription must contain at least one of the three tamper-resistant characteristics in order to be considered "tamper resistant". For the second, a prescription must contain all three characteristics beginning October 1, 2008.

Summary of Proposed Regulation

For a pharmacy claim to be eligible for reimbursement by DMAP, any prescription executed in written (and non-electronic format) must be executed on a tamper-resistant form. DMAP will enforce the federal implementation date, as follows:

A. To be considered tamper-resistant beginning **OCTOBER 1, 2008**, a prescription form must contain **ALL THREE** of the following characteristics:

1. One or more industry-recognized features designed **to prevent unauthorized copying** of a completed or blank prescription form;

2. One or more industry-recognized features designed **to prevent the erasure or modification** of information written on the prescription by the prescriber;

3. One or more industry-recognized features designed **to prevent the use of counterfeit** prescription forms.

B. Appropriate DMAP Provider Manuals have been updated to provide additional detail including examples of features, which comply with the above requirements.

Delaware Medical Assistance Program (DMAP) provider manuals and official notices are available for downloading from the DMAP website: **www.dmap.state.de.us** or EDS Pharmacy Services may be contacted at (800) 999-3371- Select #0, then #1.

The Delaware Medical Assistance Program (DMAP) is merely adopting the federal statute without changing content or incorporating additional state requirements concerning the use of federally mandated tamper-resistant prescriptions.

SUMMARY OF COMMENTS RECEIVED WITH AGENCY RESPONSE

No public comments were received.

FINDINGS OF FACT:

The Department finds that the proposed changes as set forth in the July 2008 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation regarding the three required characteristics of tamper-resistant prescription pads is adopted and shall be final effective September 10, 2008.

Vincent P. Meconi, Secretary, DHSS, August 14, 2008

DMMA FINAL REGULATION #08-37
REVISION:

(Regulation Number will be assigned pending further review and analysis by Department staff)

~~Effective October 1, 2007,~~ Section 1903(i) of the Social Security Act requires that written (non-electronic) prescriptions for covered outpatient drugs for Medicaid clients be executed on a tamper-resistant pad in order to be eligible for federal matching funds. To meet this requirement, DMAP will only reimburse for covered Medicaid outpatient drugs when the written (non-electronic) prescription is executed on a tamper-resistant pad, or the prescription is electronic, faxed, or verbal.

To be considered tamper-resistant beginning October 1, 2008, a prescription form must contain all three of the following characteristics:

1. One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;

2. One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber;

3. One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.