

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF MEDICAID AND MEDICAL ASSISTANCE

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

PROPOSED

PUBLIC NOTICE

Pharmaceutical Services Program – Tamper-Resistant Prescription Pads

In compliance with the State's Administrative Procedures Act (APA - Title 29, Chapter 101 of the **Delaware Code**) and under the authority of Title 31 of the **Delaware Code**, Chapter 5, Section 512, Delaware Health and Social Services (DHSS) / Division of Medicaid and Medical Assistance (DMMA) is amending the Delaware Medical Assistance Program (DMAP) Provider Manuals to bring the Medicaid regulations into compliance with Federal law.

Any person who wishes to make written suggestions, compilations of data, testimony, briefs or other written materials concerning the proposed new regulations must submit same to Sharon L. Summers, Planning & Policy Development Unit, Division of Medicaid and Medical Assistance, 1901 North DuPont Highway, P.O. Box 906, New Castle, Delaware 19720-0906 or by fax to (302) 255-4454 by July 31, 2008.

The action concerning the determination of whether to adopt the proposed regulation will be based upon the results of Department and Division staff analysis and the consideration of the comments and written materials filed by other interested persons.

SUMMARY OF PROPOSAL

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.

DMMA PROPOSED REGULATION #08-23

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.

12 DE Reg. 20 (07/01/08) (Prop.)