

**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 new 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 October 31, 2007.

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**

**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**

The federal U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007 provides that effective October 1, 2007, federal Medicaid funding shall not be available for any amounts expended for prescription drugs for which the prescription was executed in written and non-electronic form unless the prescription was executed on a tamper-resistant pad.

To be in compliance with the federal mandate, for prescription drug claims with dates of service on or after October 1, 2007, Delaware Medicaid must be in compliance with this section of the Social Security Act by requiring the use of tamper proof prescription pads: §1903(i) – Payment under the preceding provisions of this section shall not be made: "(23) with respect to amounts expended for medical assistance for covered outpatient drugs (as defined in section 1927(k)(2) for which the prescription was executed in written (and non-electronic) form unless the prescription was executed on a tamper-resistant pad."

On August 17, 2007, the Centers for Medicare & Medicaid Services (CMS), issued a letter to State Medicaid Directors with guidance on implementing the new requirement. CMS has outlined three baseline characteristics of tamper-resistant prescription pads, but each State will define which features it will require to meet those characteristics in order to be considered tamper-resistant. The baseline characteristics are one or more industry-recognized features that: (1) prevent unauthorized copying of a completed or blank prescription form; (2) prevent the erasure or modification of information written on the prescription by the prescriber; (3) and prevent the use of counterfeit prescription forms. On October 1, 2007, States must require at least one of these baseline requirements. Then, no later than October 1, 2008, States must require all three characteristics on prescription pads in order to be considered tamper-resistant.

The letter to State Medicaid Directors outlines situations where the new requirement does and does not apply. The requirement does not apply: when the prescription is electronic, faxed, or verbal; when a managed care entity pays for the prescription; or in most situations when drugs are provided in certain institutional and clinical facilities. The letter also allows emergency fills as long as a prescriber provides a verbal, faxed, electronic, or compliant prescription within 72 hours. This restriction applies to all outpatient drugs, including over-the-counter drugs in States that reimburse for prescriptions for such items.

### **Summary of Proposed Regulation**

The Delaware Medical Assistance Program (DMAP) provider policies are revised to comply with Public Law 110-28 known as the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007 requiring prescriptions in written form to be executed on tamper-resistant prescription pads in order to qualify for reimbursement by the DMAP. Currently, there is no rule in place to require that written prescriptions be printed on certain types of paper, which cannot be copied. The requirement does not apply to prescriptions transmitted by telephone, facsimile, or electronic prescribing.

A. Beginning October 1, 2007, DMAP will require that a tamper-resistant prescription pad must contain at least one of the following three CMS defined 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 will be 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](http://www.dmap.state.de.us) or EDS Pharmacy Services may be contacted at (800) 999-3371- Select #0, then #1.

This proposed regulation is also published concurrently herein under "Emergency Regulations".

### **DMMA PROPOSED REGULATION #07-49**

#### **REVISIONS:**

(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.

**11 DE Reg. 425 (10/01/07) (Prop.)**