

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF MEDICAID AND MEDICAL ASSISTANCE

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

FINAL

PUBLIC NOTICE

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 new 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 October 2007 *Delaware Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by October 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 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 and 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 or EDS Pharmacy Services may be contacted at (800) 999-3371- Select #0, then #1.

This proposed regulation was also published concurrently under "Emergency Regulations".

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 October 2007 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation regarding tamper-resistant prescription pads is adopted and shall be final effective December 10, 2007.

Vincent P. Meconi, Secretary, DHSS, November 14, 2007

DMMA FINAL ORDER REGULATION #07-55

REVISIONS:

(Variations of the following text can be found in the following sections of the DMAP Provider Specific Policy Manuals: General 1.6; 1.10.4; and Appendix N-19.0; Pharmacy: 2.1.2; and Practitioner: 1.11.1.5)

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. 793 (12/01/07) (Final)