

CMS CLARIFICATION ON TAMPER-RESISTANT PRESCRIPTION FEATURES

The Centers for Medicare and Medicaid Services (CMS) has reviewed their policy with respect to tamper-resistant prescriptions and are providing two updates to that policy:

1) Provider Additions to Otherwise Non-Tamper Resistant Paper: Several States have had specific questions about whether a provider can add a feature to a prescription to make it compliant with the requirements. States have proposed various features, including particular kinds of ink to write the prescription (gel or indelible); writing out the drug quantities rather than just the number (i.e. "thirty" vs. "30"); and embossed logos. The statute states that all written prescriptions must be "**executed on a tamper-resistant pad.**" As a result, features added to the prescription after they are printed do not meet the requirement of the statute. Features that would make the prescription tamper-resistant include certain types of paper as well as certain items that can be pre-printed on the paper.

The National Council for Prescription Drug Programs (NCPDP) has convened a focus group to identify consensus best practices and make a recommendation to State Medicaid programs on a standard approach to this requirement. Representatives from provider groups, pharmacy groups, prescription pad vendors, the National Governors Association, the National Association of State Medicaid Directors, the National Conference of State Legislators and several State Medicaid programs are participating. This group is developing a document for State Medicaid programs that identifies a minimum set of features that satisfy the requirements for April 1, 2008 and October 1, 2008. CMS will share the clarification provided above with the NCPDP group so that no recommendations are included in the document that conflict with the requirement.

2) Computer Generated Prescriptions: CMS is also clarifying that during the period between April 1, 2008 and October 1, 2008, computer generated prescriptions printed by a provider on plain paper, including Electronic Medical Record (EMR) computer generated prescriptions, may meet CMS guidance by containing one or more industry-recognized features designed either to prevent the erasure or modification of information contained on the prescription, or to prevent the use of counterfeit prescription forms.

However, based on its understanding of current prescription security technology, CMS does not believe that computer generated prescriptions printed by a prescriber on plain paper will be able to meet the first baseline requirement that prescriptions contain one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form. In other words, prescriptions printed on plain paper will not be able to meet all three baseline characteristics outlined by CMS. Therefore, beginning October 1, computer generated prescriptions must be printed on paper that meets that requirement. The NCPDP focus group has developed a list of examples of industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form which include, but are not limited to: watermarks, micro-printing, and paper on which the word "void" appears when copied.

Please Note: All other guidance included in the [State Medicaid Directors Letter](#) and the [Frequently Asked Questions](#) continues to be in effect. For further information, please see a [resource](#), "Medicaid Tamper-Resistant Prescription Information for State Health Policymakers".