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Medical Assistance Letter (MAL) No. 546

March 17, 2008

TO: All Providers of Pharmacy Services and Prescribers
Directors, County Departments of Job and Family Services
Medical Assistance Coordinators

FROM: Helen E. Jones-Kelley, Director

SUBJECT: Pharmacy Recordkeeping: Requirement for Tamper-Resistant Prescription Forms

This letter provides information regarding changes to Ohio Administrative Code (OAC) rule 5101:3-9-06, entitled "Prescription billing and recordkeeping requirements." This rule outlines requirements for pharmacies that bill ODJFS for prescriptions. This letter is being sent to both pharmacies and prescribers to specify the new requirement to use tamper-resistant prescription forms when executing a written prescription for a consumer enrolled in the Ohio Medicaid or Disability Medical Assistance programs and billed to the Ohio Department of Job and Family Services (ODJFS). The effective date for the tamper-resistant prescription requirement is April 1, 2008.

As previously announced, Congress passed H.R. 2206, U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007, Public Law 110-28, which 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." This federal law was scheduled to be effective October 1, 2007. On September 29, 2007, the President signed H.R. 3668, the "TMA, Abstinence Education, and QI Programs Extension Act of 2007." This bill delays the implementation of the tamper-resistant requirement until April 1, 2008. ODJFS will enforce this new federal implementation date.

All prescriptions that are written by the prescriber and given to the patient or patient's representative to present to the pharmacy must be executed on tamper-resistant paper. The use of ink, stamps, embossers, or other features added by the prescriber do not meet the tamper-resistant requirement. The tamper-resistant features must be integral to the prescription form.

Prescriptions transmitted to the pharmacy via telephone, fax, or e-prescribing, in accordance with Ohio Board of Pharmacy regulations, are exempt from this requirement.

To be considered tamper resistant on April 1, 2008, a prescription form must contain at least one of the following three characteristics:

Required characteristic:	Examples include but not limited to:
1. One or more features designed to prevent unauthorized copying of a completed or blank prescription form	<ul style="list-style-type: none"> • Text that appears when photocopied or scanned (e.g., "void" or "illegal") • Microprint borders that cannot be copied
2. One or more features designed to prevent the erasure or modification of information written on the prescription by the prescriber	<ul style="list-style-type: none"> • Erasure or use of solvents will discolor background • Check-off boxes to indicate the quantity prescribed (e.g., 1-24, 25-49, 50-74, etc.)
3. One or more features designed to prevent the use of counterfeit prescription forms	<ul style="list-style-type: none"> • Thermochromic ink • Sequentially numbered

To be considered tamper-resistant beginning October 1, 2008, a prescription form must contain all three characteristics.

The tamper-resistant requirement applies in both of the following situations:

- All written prescriptions presented at the pharmacy on or after April 1, 2008, regardless of the date the prescription was written, including prescriptions for over-the-counter, legend, and controlled drugs; and
- All written prescriptions when ODJFS pays any part of the claim, including when ODJFS is not the primary payer.

The tamper-resistant requirement does not apply in the following situations:

- Refills of written prescriptions presented at the pharmacy before April 1, 2008;
- Prescriptions transmitted to the pharmacy via e-prescribing, fax, or telephone, in accordance with Ohio Board of Pharmacy regulations;
- Prescriptions for which payment will be made by an ODJFS-contracting managed care plan (i.e., only prescriptions billed to the fee-for-service program must be tamper resistant);
- Orders for medications administered in a provider setting and billed by the administering provider (i.e., medications not billed through the pharmacy);
- Orders for medications administered in a long-term care facility (LTCF), provided the order is written in the patient's medical record and given by medical staff directly to the pharmacy. A prescription for a LTCF resident is considered tamper resistant if the patient does not have opportunity to handle the written order.

If a written prescription that is not tamper resistant is presented at the pharmacy on or after April 1, 2008, the pharmacy may fill the prescription on an emergency basis and obtain a compliant tamper-resistant replacement from the prescriber within 72 hours of dispensing. The pharmacist should use professional judgment to define an emergency situation. The replacement may be a compliant written prescription, a fax copy, or an electronically transmitted copy. The replacement should be filed with the original, non-tamper-resistant prescription. Alternatively, the pharmacy may verify the prescription by telephone. In this

case, the verification must be documented on the prescription including the name of the prescriber or prescriber's office staff member verifying the prescription, date of verification, and identification of the pharmacy staff member requesting verification.

If a consumer is determined to be retroactively eligible for Medicaid or Disability Medical Assistance coverage, and the pharmacy has filled a prescription for a date of service that falls into the retroactive eligibility period, the pharmacy must verify that the original prescription was tamper resistant, or must determine that the prescription is exempt from the requirements as stated above. If the original prescription was not tamper resistant or exempt from the requirements, the pharmacy may follow the procedures listed above to obtain a replacement tamper-resistant prescription or verify the prescription by phone, prior to billing the claim to ODJFS.

Web Page and Paper Distribution:

The Ohio Department of Job and Family Services maintains an "electronic manuals" web page for the department's rules, manuals, letters, forms and handbooks. The URL is <http://emanuals.odjfs.state.oh.us/emanuals/>

Providers may view documents online by:

- (1) Selecting "Ohio Health Plans – Provider"
- (2) Selecting "Pharmacy Services"; and
- (3) Selecting the desired item from the "Table of Contents" pull-down menu

The Legal/Policy Central Calendar (<http://www.odjfs.state.oh.us/lpc/calendar>) site is a quick reference of documents recently published. The Legal/Policy Center Calendar site also provides a link to a listing of ODJFS Letters (<http://www.odjfs.state.oh.us/lpc/mtl>). The listing is categorized by letter number and subject and a link is provided to the easy print (PDF) document.

Providers will receive one printed copy of this letter and an accompanying JFS 03400, "Ohio Department of Job and Family Services, Service Provider Update Request Form." Providers may request a second printed copy of this letter with a copy of the OAC rule by completing the JFS 03400 and returning it to the Ohio Department of Job and Family Services in accordance with the instructions at the top of the form.

Questions:

Questions pertaining to this letter should be addressed to:

Office of Ohio Health Plans
Provider Services Section
P.O. Box 1461
Columbus, OH 43216-1461
Toll Free Telephone Number 1-800-686-1516