

Federal Requirement for Tamper-Resistant Prescription Forms

Congress passed HR2206, U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007, Public Law 110-28, which amended the 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 effective April 1, 2008.

Medical Assistance Letters (MAL) 568 and 546 are attached.

MAL 568 clarifies that the tamper-resistant requirement applies to all prescriptions for Medicaid consumers, including those issued to members of Medicaid-contracting managed care plans.

MAL 546 outlines the policy regarding tamper-resistant prescription forms.

Providers should also refer to Ohio Administrative Code rule 5101:3-9-06. 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/>, select "Ohio Health Plans – Provider" then "Pharmacy Services," then select the rule from the "Table of Contents" pull-down menu.

To be considered tamper resistant a prescription pad must contain all of the following three 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; or
- 3) one or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

After you have read the attached document, if you have further questions about this requirement, please email Medicaid_pharmacy@odjfs.state.oh.us.



September 21, 2010

Medical Assistance Letter (MAL) No. 568

TO: All Eligible Pharmacy Providers
Directors, County Departments of Job and Family Services

FROM: Douglas E. Lumpkin, Director

SUBJECT: Pharmacy influenza vaccine administration and tamper-resistant prescription pad requirements

This letter provides information regarding changes to the following Ohio Administrative Code (OAC) rules:

- 5101:3-9-03, "Covered Drugs and Associated Limitations"
- 5101:3-9-05, "Reimbursement"
- 5101:3-9-06, "Prescription Billing and Recordkeeping Requirements"
- 5101:3-9-13, "Influenza Vaccine Administration" is being rescinded.

OAC 5101:3-9-13 regarding influenza vaccine administration is being rescinded because the rule specifies dates of service October 1, 2009 through May 31, 2010. The information in this rule is being incorporated into OAC rules 5101:3-9-03 and 5101:3-9-05 to continue payment of influenza vaccine administered at the pharmacy for future influenza seasons.

OAC 5101:3-9-06 is being amended to clarify that tamper-resistant prescription pads are required for all Ohio Medicaid prescriptions.

Web Page:

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

Providers may view documents online by:

- (1) Selecting the "Ohio Health Plans – Provider" folder;
- (2) Selecting "Pharmacy Services";

- (3) Selecting the "Table of Contents";
- (4) Selecting the desired document type;
- (5) Selecting the desired item from the "Table of Contents" pull-down menu.

The Legal/Policy Central – Calendar site (<http://www.odjfs.state.oh.us/lpc/calendar/>) is a quick reference for finding documents that have recently been published. This site also provides a link to a listing of ODJFS manual transmittal letters (<http://www.odjfs.state.oh.us/lpc/mtl/>). The listing is categorized by letter number and subject, and a link is provided to each easy-print (PDF) document.

To receive electronic notification when new Medicaid transmittal letters are published, subscribe at: <http://www.odjfs.state.oh.us/subscribe/>.

Questions:

Questions pertaining to this letter should be addressed to:

Ohio Department of Job and Family Services
Office of Ohio Health Plans, Bureau of Provider Services
P.O. Box 1461
Columbus, OH 43216-1461
Telephone 800-686-1516

5101:3-9-06

Prescription billing and recordkeeping requirements.

- (A) The pharmacy claim to the Ohio department of job and family services (ODJFS) or its designee, the pharmacy point-of-sale vendor, must reflect the actual national drug code (NDC) on the container from which the product was dispensed except for unit dose products that must be billed in accordance with paragraph (G) of rule 5101:3-9-03 of the Administrative Code.
- (B) All records of prescriptions must comply with federal and state regulations and shall be retained by the provider for a period of six years from the date of reimbursement of the claim and if an audit is initiated during this time, records must be retained until the audit is resolved.
- (C) For a pharmacy claim to be eligible for reimbursement by ODJFS, any prescription executed in written (and non-electronic) format must be executed on a tamper-resistant form.
- (1) To be considered tamper resistant ~~between April 1, 2008, and September 30, 2008,~~ a prescription form must contain ~~at least one~~ all of the following three characteristics:
- (a) One or more features designed to prevent unauthorized copying of a completed or blank prescription form;
 - (b) One or more features designed to prevent the erasure or modification of information written on the prescription by the prescriber; ~~or~~ and
 - (c) One or more features designed to prevent the use of counterfeit prescription forms.
- (2) The tamper-resistant requirement applies to all written prescriptions presented at the pharmacy when ODJFS pays any part of the claim, including when ODJFS is not the primary payer, in accordance with paragraphs (F) and (G) of this rule.
- ~~(2) To be considered tamper resistant beginning October 1, 2008, a prescription form must contain all three of the features in paragraph (C)(1) of this rule.~~
- ~~(3) The tamper-resistant requirement applies in both of the following situations:~~
- ~~(a) All written prescriptions presented at the pharmacy on or after April 1, 2008, regardless of the date the prescription was written; and~~
 - ~~(b) All written prescriptions when ODJFS pays any part of the claim, including when ODJFS is not the primary payer, in accordance with~~

~~paragraphs (F) and (G) of this rule.~~

~~(4)~~(3) The tamper-resistant requirement does not apply in the following situations:

~~(a)~~ Refills of written prescriptions presented at the pharmacy before April 1, 2008;

~~(b)~~(a) Prescriptions transmitted to the pharmacy via an electronic prescription transmission system, facsimile device, or telephone, in accordance with rules promulgated by the state board of pharmacy in agency 4729 of the Administrative Code;

~~(c)~~ Prescriptions for which payment will be made by an ODJFS contracting managed care plan;

~~(d)~~(b) Orders for medications administered in a provider setting and billed by the administering provider in accordance with paragraph (I) of rule 5101:3-9-03 of the Administrative Code; or

~~(e)~~(c) Orders for medications administered in a ~~long-term care facility (LTCF)~~, ~~including~~ nursing facility (NF) or intermediate care facility for the mentally retarded (ICF-MR), if the order is written in the patient's medical record and given by medical staff directly to the pharmacy. The prescription is considered tamper resistant if the patient does not have opportunity to handle the written order.

~~(5)~~(4) 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 seventy-two hours of dispensing.

(a) A tamper-resistant replacement may be obtained via any of the following methods:

(i) Telephone verification from the prescriber or prescriber's staff, documented on the prescription with the name of the person at the prescriber's office verifying the prescription, date of verification, and identification of the pharmacist or pharmacy staff member requesting verification;

(ii) Obtaining a copy of the prescription from the prescriber via facsimile device;

- (iii) Obtaining an electronic prescription from the prescriber; or
 - (iv) Obtaining a replacement written prescription from the prescriber on a tamper-resistant form.
- (b) The replacement tamper-resistant prescription shall be filed with the original, non-tamper-resistant prescription.
- (c) The dispensing pharmacist shall use professional judgment to define an emergency situation.
- ~~(6)~~(5) When it is determined that a consumer is retroactively eligible, and the consumer's original or refill prescription was filled during a period when the consumer is retroactively eligible, the pharmacy must ensure that the original prescription was tamper resistant before billing the pharmacy claim to ODJFS.
- (a) If the prescription meets the provisions of paragraph ~~(C)(4)~~ (C)(3) of this rule, the tamper-resistant requirement does not apply.
 - (b) If the original prescription was not tamper resistant, the pharmacy may obtain a tamper-resistant replacement as described in paragraphs ~~(C)(5)(a) and (C)(5)(b)~~ (C)(4)(a) and (C)(4)(b) of this rule.
- (D) The quantity of the product dispensed must be submitted in a metric decimal format for payment.
- (E) Voids and reversals
- (1) Return to stock
 - (a) When patients fail to pick up their prescriptions, pharmacies must reverse the claim submitted to ODJFS as soon as possible. Reversing a claim within fourteen days will simplify claim reconciliation for providers.
 - (b) When prescriptions have been dispensed to ~~residents~~a resident of a ~~LTCFNF~~ or ICF-MR and there is an unutilized portion of a legally redispensible drug remaining, the drug must either be:
 - (i) ~~Be destroyed~~Destroyed; or

- (ii) Returned to the pharmacy to be redispensed and the product cost, not including the dispensing fee, must be credited to ODJFS. This shall be done by voiding or reversing the original claim and submitting a new claim for the utilized amount plus dispensing fee.

(2) Voids, reversals, and replacement claims for other reasons

- (a) Original claims shall be submitted within three hundred sixty-five days of the date of service. Claims may be reversed, voided, or replaced (i.e., re-billed) at any time within the first three hundred sixty-five days after the date of service.
- (b) Claims may be reversed, voided, or replaced beyond three hundred sixty-five days after the date of service in the following circumstances:
 - (i) Adjudicated paid claims may be reversed and replaced (i.e., re-billed) beyond three hundred sixty-five days after the date of service if the adjudication date of the replacement claim is within ninety days after the date of original claim payment.
 - (ii) Adjudicated denied claims may be replaced (i.e., re-billed) beyond three hundred sixty-five days after the date of service if the adjudication date of the replacement claim is within ninety days after the date of adjudication of an original denied claim.
 - (iii) Adjudicated paid claims may be reversed or voided beyond three hundred sixty-five days after the date of service if the adjudication date of the reversal or void is within five hundred forty-five days after the date of original claim payment.

(F) Third party liability

- (1) In accordance with rules 5101:3-1-17.2 and 5101:3-1-08 of the Administrative Code, ODJFS is the payer of last resort.
- (2) ODJFS shall reimburse the difference between the third party payment and the medicaid calculated allowable minus any co-payments imposed by medicaid in accordance with rule 5101:3-1-09 of the Administrative Code. This shall be considered payment in full.

(G) Medicare part B-covered services

Drugs covered by medicare part B for dually eligible consumers must be billed to medicare. ODJFS shall reimburse the medicare part B cost sharing in accordance with rule 5101:3-1-05 of the Administrative Code.

(H) Medicare part D-covered services

Drugs that are covered or may be covered by medicare part D for dually eligible consumers must be billed to the appropriate medicare part D prescription drug plan (PDP) and are not covered by medicaid. Medicare cost sharing for medicare part D services is not reimbursable by ODJFS.

(I) Point-of-sale claims processing

(1) Pharmacy claims must be billed through the electronic point-of-sale system provided by the ODJFS pharmacy point-of-sale vendor or using a paper claim format as approved by the pharmacy point-of-sale vendor.

(2) ~~Effective July 1, 2006, batch~~ Batch process claims are not accepted.

Effective: 10/01/2010

R.C. 119.032 review dates: 06/30/2010 and 10/01/2015

CERTIFIED ELECTRONICALLY

Certification

09/15/2010

Date

Promulgated Under: 119.03
Statutory Authority: 5111.02, 5111.98
Rule Amplifies: 5111.01, 5111.02, 5111.021, 5111.98
Prior Effective Dates: 4/7/77, 12/21/77, 12/30/77, 7/8/78, 10/1/78, 5/9/86,
11/1/86, 10/1/87, 2/1/88, 1/13/89 (Emer), 4/13/89,
6/1/89, 7/1/94, 10/1/97, 2/3/00 (Emer), 5/1/00,
8/30/01, 10/16/03 (Emer), 1/1/04, 1/1/06, 7/1/06,
4/1/08



30 East Broad Street Columbus, Ohio 43215-3414
jfs.ohio.gov

March 20, 2008

Medical Assistance Letter (MAL) No. 546

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:

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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