

**FREQUENTLY ASKED QUESTIONS CONCERNING
THE TAMPER-RESISTANT PRESCRIPTION LAW
(SECTION 7002(b) OF THE U.S. TROOP READINESS,
VETERANS' CARE, KATRINA RECOVERY, AND IRAQ
ACCOUNTABILITY APPROPRIATIONS ACT OF 2007)**

Effective Date of the New Law (Section 7002(b))

Q: When does the tamper-resistant prescription law go into effect?

A: The first of two phases of implementation went into effect on April 1, 2008. At that time, all impacted Medicaid prescriptions were required to contain at least one tamper-resistant feature. States are responsible for the full implementation and enforcement of the new law as of October 1, 2008.

Retroactive Eligibility

Sometimes, a person becomes eligible for Medicaid benefits after he has submitted a written prescription to a pharmacy and has had the pharmacy fill the prescription. In these retroactive eligibility situations, the recipient often will return to the pharmacy and present evidence of his eligibility in order to get reimbursed by the pharmacy for whatever money the recipient previously paid the pharmacy to fill the prescription. Many have asked whether, in order to submit a claim to Medicaid, the pharmacy must obtain a compliant prescription.

Q: When it is determined that a Medicaid recipient is retroactively eligible for Medicaid and the recipient's original, written prescription was filled during a period when the recipient is now deemed to have been Medicaid eligible, must the pharmacy, prior to submitting a claim to Medicaid, obtain a tamper-resistant written prescription, a verbal order, a faxed prescription, or an e-prescription prior to submitting a claim to Medicaid?

A: When a Medicaid recipient is retroactively eligible for Medicaid after a pharmacy has already filled the recipient's prescription, CMS will presume that the prescription was compliant with section 7002(b), unless there is evidence that the prescription was non-compliant. This presumption applies to the filling of the prescription that occurred *before* the recipient became retroactively eligible for Medicaid. This presumption does *not* extend to any refills that occurred *after* the date on which the recipient is determined to be eligible for Medicaid. Such refills require that the pharmacy obtain a new, tamper-resistant prescription in compliance with section 7002(b). Alternatively, the pharmacy may obtain verbal confirmation of the prescription from the prescriber or may obtain the prescription from the prescriber by facsimile or e-prescription.

Emergency Prescription Fills

Q: Page two of CMS' August 17, 2007 State Medicaid Director letter (the "SMD Letter") allows a pharmacy to fill prescriptions on an emergency basis and, within 72 hours after the fill date, obtain a written prescription that complies with section 7002(b) or obtain the prescription by verbal communication from the prescribing doctor, by facsimile, or by e-prescription. Will CMS define "emergency fill," as discussed in the SMD Letter? Is the emergency fill provision limited to certain drugs or to instances when the individual has no supply left?

A: CMS will not further define the "emergency fill" provision of the SMD Letter. Each State should refer to its own statutes, rules, and regulations to define the term.

Q: May the pharmacy provide the full prescription to the patient in the emergency fill situation, or must the pharmacy only provide a 72-hour supply?

A: The pharmacy may provide the full prescription to the patient in the emergency fill situation, so long as the pharmacy obtains a compliant prescription in writing, or by telephone, fax, or e-prescription, within 72 hours.

Q: Do States have the authority to implement a "hold harmless" provision for pharmacies that document their pharmacists' calls, faxes, or other efforts to obtain a compliant prescription but that do not receive a response from the prescriber within the 72-hour period?

A: No. Section 7002(b) does not contain a "hold harmless" provision.

Drug Orders in Certain Institutional Settings

As noted on page one of the SMD Letter, section 1927(k)(3) of the Social Security Act describes certain institutional settings, including nursing facilities, where outpatient drugs are not subject to section 7002(b). CMS has received many questions about drugs prescribed in institutional settings referred to in section 1927(k)(3) that are ordered by way of drug orders written in patient charts or in other written formats, where these orders are not written on prescription pads.

Q: Must a written order provided in an institutional setting described in section 1927(k)(3), and separately reimbursed by Medicaid, that is written into the medical record and conveyed by medical staff to a pharmacy be executed on a tamper-resistant prescription pad?

A: CMS has concluded that a written order prepared in an institutional setting where the doctor or medical assistant writes the order into the medical record and then the order is given by medical staff directly to the pharmacy is considered “tamper resistant,” so long as the patient never has the opportunity to handle that written order.

Prescriptions for Controlled Substances

Q: Federal law and many State laws require that all prescriptions for Schedule II controlled substances be written. If a non-tamper-resistant controlled substance prescription that complies with Federal and State law is presented to a pharmacy, may the pharmacy obtain verbal confirmation from the prescriber in order to satisfy the tamper-resistant requirement of section 7002(b)?

A: Yes. As long as the Schedule II requirements are satisfied, section 7002(b) can be satisfied through any of the methods set forth in the SMD letter, that is, through a prescription that is transmitted verbally, sent by facsimile, or sent through an e-prescription, or is written on compliant, tamper-resistant prescription pad.

Q: Does CMS’ reference to “controlled dangerous substances” include State schedules of controlled substances?

A: Yes.

Physician-Provided Drugs

In many cases physicians provide prescription drugs directly to patients (e.g., via samples).

Q: If the prescriber provides a drug directly to a Medicaid recipient, is a tamper-resistant prescription required?

A: No.

Communication between Physician/Prescriber and Pharmacy

As noted on page one of the SMD letter, section 7002(b) does not apply to non-written prescriptions, that is, it does not apply to: e-prescriptions; prescriptions transmitted to the pharmacy by facsimile; and prescriptions communicated to the pharmacy by telephone.

Q: Does the physician/prescriber have to be the individual who transmits a non-written prescription to a pharmacy?

- A: No. A nurse or administrative staff person who is authorized to act on the prescriber's behalf may phone the pharmacy the order, send the order by facsimile, or electronically transmit the order to the pharmacy.
- Q: Will the action of a pharmacist calling back a physician/prescriber and making appropriate documentation on the original, non-compliant written prescription make the prescription compliant for purposes of a subsequent Medicaid audit?
- A: Yes. Documentation by the pharmacy of verbal confirmation of a non-compliant written prescription satisfies the requirements of section 7002(b).

Prescription Transfers between Pharmacies

- Q: When Pharmacy # 1 transfers a tamper-resistant prescription to Pharmacy # 2 to be filled, will a facsimile or telephone call from Pharmacy # 1 to Pharmacy # 2 satisfy section 7002(b), or must Pharmacy # 2 obtain direct confirmation from the physician/prescriber?
- A: Pharmacy # 2 need only obtain a phone call or a facsimile from Pharmacy # 1 in order to confirm the authenticity of the tamper-resistant prescription that was previously delivered to Pharmacy # 1. There is no need for Pharmacy # 2 to obtain direct confirmation of the original prescription from the physician/prescriber.

Record Retention

Page two of the SMD letter states that section 7002(b) "does not impose additional requirements on States regarding retention of hard copy prescriptions. States may follow current State and Federal laws and regulations for record retention." Several States only require a pharmacy to retain a scanned copy of the original prescription.

- Q: If a pharmacy notes in writing on the original prescription that it is tamper resistant and then scans the prescription, will this comply with section 7002(b) for purposes of a later audit?
- A: It depends upon the law of the individual State. Each State will determine what, if any, changes the State will require to its record retention policies in light of section 7002(b).

Characteristics of tamper-resistant prescriptions

- Q: Will CMS provide examples of existing State practices that meet CMS requirements?
- A: The tamper-resistant prescription characteristics set forth by the several States that currently have tamper-resistant prescription laws and/or regulations in effect are all acceptable examples of all three of the characteristics set forth on page two of the SMD Letter. These States are California, Florida, Indiana, Kentucky, Maine, New Jersey, New York, Texas, and Wyoming. (Idaho's regulations currently require one tamper-resistant feature; therefore, Idaho's law is compliant with the guidance given in the SMD Letter through September 30, 2008, but not thereafter.)
- Q: What are the "industry-recognized features" that CMS recognizes for the prevention of copying, erasure, or counterfeiting?
- A: The tamper-resistant prescription characteristics set forth by each of the States that currently have tamper-resistant prescription laws and/or regulations in effect are all acceptable examples of existing State practices that meet the requirements set forth by the SMD Letter. Additionally, CMS has reviewed and approved the list of tamper-resistant characteristics included by the National Council on Prescription Drug Programs in its letters to State Medicaid Directors dated February 1, 2008.
- Q: Does the requirement of the use of an ink pen satisfy the second characteristic set forth on page two of the SMD Letter (i.e., a feature that "prevent[s] the erasure or modification" of information on a prescription)?
- A: No, it does not. Ink can be erased and modified, and in part for those reasons, the use of an ink pen is not an industry recognized standard.
- Q: How do the characteristics set forth on page two of the SMD Letter apply to computer-generated prescriptions that are printed on plain paper and are then signed by the prescriber? Is there an industry-recognized feature to address computer printer paper?
- A: While special paper may be used to achieve copy resistance, it is not necessary. Electronic medical record (EMR) or ePrescribing generated prescriptions may be printed on plain paper and be fully compliant with all three categories of the tamper-resistant regulations presuming they contain at least one feature from each of the three categories. When feasible, any other industry recognized feature that is designed to prevent unauthorized copying of a completed or blank prescription form may also be utilized on a plain paper computer generated prescription. Since issuing its last guidance on this issue, CMS has determined that at least two such features utilized to prevent passing a copied prescription as an original can also be incorporated into plain paper computer generated prescriptions. The first of these is

microprinting, which is the use of very small font that is readable when viewed at 5x magnification or greater, and illegible when copied. The second feature is a “void” pantograph accompanied by a reverse “Rx”, which causes a word such as “Void,” “Illegal,” or “Copy” to appear when the prescription is photocopied. Except where state law mandates the word “Void” or “Illegal”, it is recommended that the pantograph show the word “Copy” if the prescription is copied.

- Q: Will CMS publish a list of approved vendors that print prescription pads on compliant, tamper-resistant paper?
- A: No. As long as the prescription pads meet the requirements of the guidance in the SMD Letter and the laws and regulations of the relevant State, providers are free to choose whatever vendor they wish.
- Q: Is there any restriction on who may supply prescribers with compliant tamper-resistant prescription pads?
- A: Each State may determine the vendors from which a prescriber may obtain tamper-resistant prescription pads.

Compliance

- Q: Who will be responsible for ensuring that there is compliance with the requirements of section 7002(b)?
- A: Primary responsibility for auditing Medicaid providers rests with the States. However, there are some circumstances in which CMS, the Office of the Inspector General of the U.S. Department of Health & Human Services, or some other Federal agency may have occasion to audit a pharmacy provider. When that occurs, the Federal agency will have authority to determine compliance with section 7002(b).

Medicaid as Secondary Payor

- Q: Will there be resources to help pharmacists identify Medicaid as the secondary payor to help limit the number or prescriptions that may need to be reprocessed if the prescription was non-compliant?
- A: Pharmacist-providers should consult with their State Medicaid agency for assistance in this area.