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Opinion No. 09-185

Tamper-Resistant Prescription Paper

QUESTIONS

In 2008 the General Assembly enacted Public Chapter 1035, relating to certain prescriptions. The legislation was codified at Tenn. Code Ann. § 53-10-401 and other sections. The statute appears to require prescribers to use tamper-resistant paper that meets certain requirements from certain federal agencies for prescriptions and for pharmacists to process such prescriptions. Questions have arisen during the implementation of this legislation.

1. Does Public Chapter 1035, as codified, require prescribers to use and pharmacists to process prescriptions on tamper-resistant prescription paper from manufacturers that have an annual industry-approved SAS 70 audit?

2. What duties does Public Chapter 1035 give the Board of Pharmacy concerning implementation of such law concerning prescription pads?

OPINIONS

1. No. Prescribers may use and pharmacists may fill prescriptions on tamper-resistant prescription paper regardless of whether the manufacturer thereof has the required audit, so long as the paper otherwise meets the requirements of the law.

2. The Board of Pharmacy ("Board") has duties to maintain a list of manufacturers who fail, upon the Board's request, to show proof of an annual industry-approved SAS 70 audit; to make the list available to Tennessee prescribers and pharmacists in a manner deemed appropriate by the Board; and to enforce the law against pharmacists who fill prescriptions that are not issued on tamper-resistant paper.

ANALYSIS

1. 2008 Acts, Public Chapter 1035, as codified in Tenn. Code Ann. § 53-10-401, provides in pertinent part:

> (a) All prescriptions written or printed by practitioners authorized to write prescriptions in this state shall be written on tamper-resistant prescription paper that meets the current centers for medicare and medicaid services guidance to state medicaid

> directors regarding § 7002(b) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007, P.L. 110-28, and meets or exceeds specific TennCare requirements for temper-resistant prescription paper.
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> (b) A pharmacist shall not fill a written prescription from a Tennessee practitioner unless issued on tamper-resistant prescription paper, except that a pharmacist may provide emergency supplies in accordance with TennCare or other insurance contract requirements. Nothing in this section shall be construed to impact regulations regarding verbal, facsimile, electronic, or out-of-state prescription practices.
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> . . .
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> (f) Manufacturers of tamper-resistant prescription paper shall have an annual industry-approved SAS 70 audit that shall be made available by the manufacturer upon request by the board of pharmacy. The board of pharmacy shall maintain a list of any manufacturers who fail to show proof of such audit. The list shall be made available to prescribers and pharmacists in this state in a manner deemed appropriate by the board of pharmacy.

Thus, for purposes of Tenn. Code Ann. § 53-10-401,"tamper-resistant prescription paper" is paper that meets requirements contained in the referenced guidance to State Medicaid Directors issued by the Centers for Medicare and Medicaid Services ("CMS") and that meets or exceeds any specific requirements of the TennCare program.[1] CMS's guidance letter sets out three (3) characteristics that, no later than October 1, 2008, must be contained in a prescription pad in order for it to be considered "tamper resistant." (Centers for Medicare and Medicaid Services State Medicaid Directors Letter #07-012 (August 17, 2007) (http://www.securerxpads.net/CMSLETTERANDFAQS.pdf) (visited 11/19/09)). The required characteristics are:

> 1) One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;
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> 2) One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber; and

[1] This Office is not aware of any additional standards imposed by the TennCare program.

3) One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.[2]

Each of these CMS requirements pertains to the physical characteristics of the prescription paper. Auditing of paper manufacturers is not mentioned in the guidance letter; however CMS does note that it "strongly supports State program integrity measures. . ."

The CMS guidance letter states that the three characteristics constitute a baseline standard that states may choose to exceed. Aspects of Tenn. Code Ann. § 53-10-401 do appear to exceed the standard, including the requirement that manufacturers of tamper-resistant prescription paper have an annual industry-approved SAS 70 audit. However, the state statute contains no language that expressly prohibits prescribers from using - and pharmacists from filling - otherwise compliant tamper-resistant prescription paper solely because the paper's manufacturer has not undergone such audit. While Tenn. Code Ann. § 53-10-401(f) requires the Board of Pharmacy to provide prescribers and pharmacists with a list of manufacturers who cannot provide proof of an annual audit, this appears to us to be a measure enacted for the purpose of deterring manufacturers from avoiding audits and to provide notice to prescribers and pharmacists that some manufacturers' paper has not been verified for compliance.

It thus is our opinion that prescribers may use and pharmacists may fill prescriptions on tamper-resistant prescription paper regardless of whether the manufacturer thereof has the required audit, so long as the paper otherwise meets the requirements of the law.

2. 2008 Acts, Public Chapter 1035 explicitly imposes duties on the Board of Pharmacy, namely, that it shall maintain a list of any manufacturers who fail to show proof of an industry-approved SAS 70 audit and shall make such list available to prescribers and pharmacists in Tennessee in a manner that the Board deems appropriate. Tenn. Code Ann. § 53-10-401(f). Thus, the Board has a duty to maintain a list of noncompliant manufacturers and to make the list available to prescribers and pharmacists.

Moreover, the Board of Pharmacy also has a general duty "to enforce all the laws of the state. . . that pertain to the practice of pharmacy." Tenn. Code Ann. § 63-10-304(a). As set out in the Tennessee Pharmacy Practice Act, such enforcement would include revocation or

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[2] The health related boards that regulate Tennessee prescribers recently have adopted rules that provide additional detail with respect to the required characteristics. *See, e.g.,* Tenn. Comp. R. & Regs. 0880-02-.23 (Tennessee Board of Medical Examiners). The rules provide that tamper-resistant prescriptions shall contain the following features:

1) Either a void or illegal pantograph or a watermark designed to prevent copying;

2) Either quantity check-off boxes with refill indicators or a uniform, non-white background color designed to prevent erasure or modification; and

3) Security features and descriptions listed on the prescriptions designed to prevent use of counterfeit forms.

(Tenn. Comp. R. & Regs. 0880-02-.23(3)(a)).

suspension of a pharmacist's license and assessment of civil penalties against him upon a finding that the pharmacist had engaged in conduct prohibited by state law relating to the practice of pharmacy. Tenn. Code Ann. § 63-10-305(4). Because Public Chapter 1035 specifies that pharmacists may not fill certain prescriptions that are not issued on tamper-resistant paper (Tenn. Code Ann. § 53-10-401(b)), the Board has an enforcement duty to ensure that pharmacists do not illegally fill prescriptions on non-tamper-resistant paper.

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