

# Public Health Law

Office for State, Tribal, Local and Territorial Support Centers for Disease Control and Prevention

# Tamper-Resistant Prescription Form Requirements

The United States is in the midst of an unprecedented epidemic of prescription drug overdose deaths.<sup>1</sup> More than 38,000 people died of drug overdoses in 2010, and most of these deaths (22,134) were caused by overdoses involving prescription drugs.<sup>2</sup> Three-quarters of prescription drug overdose deaths in 2010 (16,651) involved a prescription opioid pain reliever (OPR), which is a drug derived from the opium poppy or synthetic versions of it such as oxycodone, hydrocodone, or methadone.<sup>3</sup> The prescription drug overdose epidemic has not affected all states equally, and overdose death rates vary widely between states.

States have the primary responsibility to regulate and enforce prescription drug practice. Although state laws are commonly used to prevent injuries, and their benefits have been demonstrated for a variety of injury types,<sup>4</sup> there is little information on the effectiveness of state statutes and regulations designed to prevent prescription drug abuse and diversion. This menu is a first step in assessing laws on tamper-resistant prescription form requirements by creating an inventory of state legal strategies in this domain.

### Introduction

One type of law aimed at inhibiting diversion of prescription drugs establishes requirements for tamperresistant prescription forms in an attempt to prevent fraudulent prescriptions for controlled substances. A law was included in this resource if it requires special tamper-resistant prescription forms<sup>5</sup> for controlled substances

<sup>&</sup>lt;sup>5</sup> While many states use the phrases "tamper-resistant prescription pads" or "tamper-resistant prescription forms" in their laws, some states differ in their language and use terms such as "counterfeit-resistant prescriptions," "counterfeit-proof prescription pads," or "security prescription blanks."



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<sup>&</sup>lt;sup>1</sup> For the purpose of this document, "overdose death" refers to death resulting from either intentional overdose or accidental overdose, which could be caused by a patient being given the wrong drug, taking the wrong drug in error, or taking too much of a drug inadvertently. CDC's National Center for Injury Prevention and Control also refers to overdose as a drug poisoning, which may or may not result in death.

 <sup>&</sup>lt;sup>2</sup> Centers for Disease Control and Prevention, Wide-ranging Online Data for Epidemiologic Research (WONDER) Database (2012) <u>http://wonder.cdc.gov</u> [hereinafter WONDER Database 2012].
 <sup>3</sup> Id

<sup>&</sup>lt;sup>4</sup> Julie Gilchrist, Richard A. Schieber & David A. Sleet, *Legislative and Regulatory Strategies to Reduce Childhood Injuries*, 10 UNINTENTIONAL INJURIES IN CHILDHOOD 111, 111–30 (2000).

either in reference to the entire state population or in reference to the Medicaid-eligible population.<sup>6</sup> Laws requiring the use of tamper-resistant prescription forms pertaining to alternate modes of transmission such as electronically prepared or electronically signed prescriptions, faxed prescriptions, oral prescriptions, prescriptions communicated via telephone by a prescriber or pharmacy-generated prescription transfers were excluded from this resource. Laws concerning unlawful activities, criminal offenses or administrative penalties related to tamper-resistant form requirements were also excluded from this resource. Laws relating to the medical use of marijuana, treatment of narcotic addiction or chemical dependence and the filling of out-of-state prescriptions were also excluded. Laws requiring the use of tamper-resistant prescription forms were included for physicians (doctors of medicine and doctors of osteopathic medicine) but not for other professions. Twenty-seven states<sup>7</sup> and the District of Columbia have one or more laws requiring the use tamper-resistant prescription forms.

# **Tamper-Resistant Prescription Forms and the Federal Social Security Act**

Several states<sup>8</sup> have laws that require prescription forms adhere to Section 1903(i)(23) of the Social Security Act for tamper-resistance.<sup>9</sup> For example, **Maine** law states that

MaineCare does not reimburse for the following drugs or products as drugs: Effective October 1, 2007, prescriptions in written and non-electronic form that are not executed on a tamper-resistant pad, as required by section 1903(i)(23) of the Social Security Act . . . . Providers must comply with all of the provisions of this Act in order to be appropriately reimbursed.<sup>10</sup>

Similarly, **Texas** law provides that "[e]ffective April 1, 2008, prescriptions for covered pharmaceuticals submitted to a pharmacy in written form will be eligible for payment only if the prescription is executed on tamper-resistant prescription paper, as required by § 1903(i)(23) of the Social Security Act .....<sup>11</sup>

# **Circumstances Requiring Tamper-Resistant Prescription Forms and Exemptions**

Some states<sup>12</sup> have laws that require the use of tamper-resistant prescription forms for all prescriptions or all controlled substance prescriptions. For example, **Delaware**'s statute reads, "Effective October 1, 2010, every prescription written in this [s]tate by a practitioner shall be written on a statewide authorized tamper-resistant

<sup>&</sup>lt;sup>6</sup> In this menu, the first effective dates of the specific provisions referenced are cited as "[legal citation] (eff. [year])." Where dates were either not provided within the laws or were unclear due to multiple revisions, this fact is cited as "[legal citation] (eff. date unclear, [estimated year])."

<sup>&</sup>lt;sup>7</sup> Alabama, Alaska, California, Colorado, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kentucky, Maine, Maryland, Mississippi, Nebraska, New York, Ohio, Oklahoma, Oregon, South Dakota, Tennessee, Texas, Vermont, Washington, West Virginia and Wyoming.

<sup>&</sup>lt;sup>8</sup>Five states. *See, e.g.,* IOWA ADMIN. CODE r. 441-78.2(249A) (eff. 2008); 10-144-101 ME. CODE R. § 80.06 (eff. 2007); OKLA. ADMIN. CODE § 317:30-5-70.2 (eff. 2007); OR. ADMIN. R. 410-121-0147 (eff. 2007); 1 TEX. ADMIN. CODE § 354.1863 (eff. 2008).

<sup>&</sup>lt;sup>9</sup> 42 U.S.C. § 1396b(i)(23) (West, Westlaw through P.L. 112-95 (excluding P.L. 112-40 and 112-41)). This Act created the Social Security system in the United States. Section 1903(i)(23) provides for the requirement of the use of tamper-resistant prescription pads under the Medicaid program stating that payment shall not be made for "... amounts expended for medical assistance for covered outpatient drugs...for which the prescription was executed in written (and non-electronic) form unless the prescription was executed on a tamper-resistant pad."

<sup>&</sup>lt;sup>10</sup> 10-144-101 ME. CODE R. § 80.06 (eff. 2007).

<sup>&</sup>lt;sup>11</sup> 1 Tex. Admin. Code § 354.1863 (eff. 2008).

<sup>&</sup>lt;sup>12</sup> Twelve states. *See, e.g.*, CAL. HEALTH & SAFETY CODE § 11162.1 (eff. 2004); DEL. CODE ANN. tit. 16, § 4797 (eff. 2008); FLA. STAT. ANN. § 456.42 (eff. date unclear); IDAHO CODE ANN. § 37-2725 (eff. 2002); 902 KY. ADMIN. REGS. 55:105 (eff. 1998); N.Y. PUB. HEALTH LAW § 3332 (eff. date unclear); N.Y. COMP. CODES R. & REGS. tit. 10, § 910.2 (eff. 2008); TENN. CODE ANN. § 53-10-401 (eff. 2008); 20-4 VT. CODE R. § 1400:9.5 (eff. 2010); WASH. REV. CODE ANN. § 18.64.500 (eff. 2009); W. VA. CODE ANN. § 16-5W-4 (eff. 2010); 060-006 WYO. CODE R. § 5 (eff. 2011).

prescription form."<sup>13</sup> Similarly, **Idaho'**s statute provides that "[a] prescription shall be required for all scheduled drugs. Paper prescriptions shall comply with federal law and shall utilize noncopyable paper that contains security provisions against copying that results in some indication on the copy that it is a copy and therefore rendering it null and void."<sup>14</sup> **West Virginia** not only requires prescribers to utilize tamper-resistant prescriptions, but also places responsibility on the pharmacist to verify these forms. Its statute provides that

The board shall establish and maintain an official prescription program in the state. The board may contract with a program vendor or vendors to establish and maintain the official state prescription program . . . . A pharmacist may not fill a written prescription from a West Virginia practitioner unless issued upon an official state issued prescription form.<sup>15</sup>

A few states<sup>16</sup> have laws that require the use of tamper-resistant prescription forms specifically for Schedule II controlled substance prescriptions. For example, **Georgia**'s statute provides that "Effective October 1, 2011, every hard copy prescription drug order for any Schedule II controlled substance written in this state by a practitioner must be written on security paper."<sup>17</sup>

Twenty-three states<sup>18</sup> and the District of Columbia<sup>19</sup> have laws that require tamper-resistant prescription forms if patients are to be reimbursed for such prescriptions under Medicaid. Medicaid-related laws are written to comply with the provisions included in Section 7002(b) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007,<sup>20</sup> which requires the use of special tamper-resistant prescription forms for prescriptions covered by the Medicaid program. The Centers for Medicare and Medicaid Services issued guidance specifying that as of October 1, 2008, "to be considered tamper resistant, a prescription pad must contain . . . industry-recognized features designed to prevent" all of the following forms of prescription tampering: (1) "copying of a completed or blank prescription form" (e.g., a void pantograph, white area on the prescription, or special paper containing watermarking); (2) "the erasure or modification of information written on the prescription by the prescriber" (e.g., quantity check boxes, refill indicators, or chemically reactive paper); and (3) "the use of counterfeit prescription forms" (e.g., serial numbers or logos printed on the prescription form). Despite these federal requirements, a law did not have to require all these features to be included in the scope of this assessment.

<sup>&</sup>lt;sup>13</sup> Del. Code Ann. tit. 16, § 4797 (eff. 2008).

<sup>&</sup>lt;sup>14</sup> IDAHO CODE ANN. § 37-2725 (eff. 2002).

<sup>&</sup>lt;sup>15</sup> W. VA. CODE ANN. § 16-5W-4 (eff. 2010).

<sup>&</sup>lt;sup>16</sup> Three states. *See, e.g.,* GA. CODE ANN. § 26-4-80.1 (eff. 2011); 16-230-001 ME. CODE R. § 2 (eff. date unclear); 22 TEX. ADMIN. CODE § 291.34 (eff. date unclear).

<sup>&</sup>lt;sup>17</sup> GA. CODE ANN. § 26-4-80.1 (eff. 2011).

<sup>&</sup>lt;sup>18</sup> ALA. ADMIN. CODE r. 560-x-6-.01 (eff. 2008); ALASKA. ADMIN. CODE tit. 7, § 120.110 (eff. date unclear, 2010-2011); CAL. WELF. & INST. CODE § 14132 (eff. 2008); 10 COLO. CODE REGS. § 2505-10:8.800.11.D (eff. 2009); 16 DEL. ADMIN. CODE § 1.6 (eff. date unclear); FLA. STAT. ANN. § 409.912 (eff. date unclear); IDAHO ADMIN. CODE r. 16.03.09.661 (eff. 2008); ILL. ADMIN. CODE tit. 89, § 140.443 (eff. 2009); IOWA ADMIN. CODE r. 441-78.2(249A) (eff. 2008); 907 KY. ADMIN. REGS. 1:019 (eff. date unclear); 10-144-101 ME. CODE R. § 80.06 (eff. 2007); MD. CODE REGS. 10.09.03.05 (eff. 2008); 010-214 MISS. CODE R. § 1.6 (eff. 2012); 471 NEB. ADMIN. CODE § 1-002.02N (eff. 2008); N.Y. COMP. CODES R. & REGS. tit. 18, § 505.3 (eff. date unclear); OHIO ADMIN. CODE 5101:3-9-06 (eff. 2008); OKLA. ADMIN. CODE § 317:30-5-70.2 (eff. 2007); OR. ADMIN. R. 410-121-0147 (eff. 2007); S.D. ADMIN. R. 67:16:14:06.11 (eff. 2008); TENN. CODE ANN. §53-10-401 (eff. 2008); 1 TEX. ADMIN. CODE § 354.1863 (eff. 2008); WASH. ADMIN. CODE § 182-530-1075 (eff. 2008); W. VA. CODE ANN. § 16-5W-2 (eff. 2010).

<sup>&</sup>lt;sup>19</sup> D.C. MUN. REGS. tit. 22-B, § 1333 (eff. 2008).

<sup>&</sup>lt;sup>20</sup> 42 U.S.C. § 1396b(i)(23) (West, Westlaw through P.L. 112-95 (excluding P.L. 112-40 and 112-41)).

For example, **Alabama** law requires that "[e]ffective April 1, 2008, all prescriptions for outpatient drugs for Medicaid recipients which are executed in written (and non-electronic) form must be executed on tamperresistant prescription pads."<sup>21</sup> Similarly, the **District of Columbia**'s regulation reads, "Effective April 1, 2008, a written prescription for any drug, including over-the-counter drugs, for a Medicaid fee for service beneficiary shall only be written on tamper resistant prescription pads."<sup>22</sup> **Maryland**'s regulation also provides that

Prescriptions written on or after April 1, 2008, that do not contain at least one of the tamper-resistant features as defined in . . . this chapter are not covered. Prescriptions written on or after October 1, 2008, that do not contain all three tamper-resistant features as defined in . . . this chapter are not covered.<sup>23</sup>

**South Dakota**'s regulation expressly states that "[f]or written prescriptions, the cost of the prescribed drug or over-the-counter item is not covered unless the prescription was written on a tamper-resistant prescription drug pad." <sup>24</sup>

Eighteen states<sup>25</sup> and the District of Columbia<sup>26</sup> have laws requiring the use of tamper-resistant prescription forms, unless specific exceptions apply.<sup>27</sup> States provide exceptions for particular kinds of facilities or institutional settings, certain situations and emergencies.<sup>28</sup> For example, the **District of Columbia**'s regulation on tamper-resistant prescription forms states, "The exceptions set forth under . . . the Social Security Act . . . concerning nursing facilities, hospitals, and other institutional and clinical settings, shall also be an exception to the requirements of this section."<sup>29</sup>

In **Alaska**'s regulation, the tamper-resistant requirement does not apply in certain situations:

(1) prescription for which retroactive Medicaid eligibility has been determined under 7 AAC 100.072, except for refills that are filled after the retroactive eligibility determination date; or (2) prescription prepared in an institutional pharmacy, if the prescriber writes the prescription into the medical record,

<sup>26</sup> D.C. MUN. REGS. tit. 22-B, § 1333 (eff. 2008).

<sup>&</sup>lt;sup>21</sup> ALA. ADMIN. CODE r. 560-x-6-.01 (eff. 2008)

<sup>&</sup>lt;sup>22</sup> D.C. MUN. REGS. tit. 22-B, § 1333 (eff. 2008)

<sup>&</sup>lt;sup>23</sup> MD. CODE REGS. 10.09.03.05 (eff. 2008).

<sup>&</sup>lt;sup>24</sup> S.D. Admin. R. 67:16:14:06.11 (eff. 2008).

<sup>&</sup>lt;sup>25</sup> ALA. ADMIN. CODE r. 560-x-6-.01 (eff. 2008); ALASKA. ADMIN. CODE tit. 7, § 120.110 (eff. date unclear, 2010-2011); CAL. HEALTH & SAFETY CODE § 11159.2 (eff. 2004); 10 COLO. CODE REGS. § 2505-10:8.800.11.D (eff. 2009); DEL. CODE ANN. tit. 16, § 4797 (eff. 2008); GA. CODE ANN. § 26-4-80.1 (eff. 2011); IDAHO ADMIN. CODE r. 16.03.09.661 (eff. 2008); ILL. ADMIN. CODE tit. 89, § 140.443 (eff. 2009); 16-230-1 ME. CODE R. § 4 (eff. date unclear); 010-214 MISS. CODE R. § 1.6 (eff. 2012); 471 NEB. ADMIN. CODE § 1-002.02N (eff. 2008); N.Y. COMP. CODES R. & REGS. tit. 10, § 910.2 (eff. 2008); OHIO ADMIN. CODE 5101:3-9-06 (eff. 2008); S.D. ADMIN. R. 67:16:14:06.11 (eff. 2008); TENN. CODE ANN. § 53-10-401 (eff. 2008); WASH. REV. CODE ANN. § 18.64.500 (eff. 2009); W. VA. CODE ANN. § 16-5W-6 (eff. 2010); 060-006 WYO. CODE R. § 5 (eff. 2011).

<sup>&</sup>lt;sup>27</sup> Certain types of transmittal of prescriptions are not considered as exceptions to tamper-resistance requirements as they are different modes of transmission and thus excluded from the scope of this research. Also, waivers for an alternative to tamper-resistance forms are not considered as an exception to tamper-resistance requirements as these alternate forms must still contain approved security features.

<sup>&</sup>lt;sup>28</sup> Emergencies here do not refer to state of emergencies declared by government, but refers to circumstances wherein the prescriber is unable to provide a written prescription form immediately to the pharmacist and an emergency oral prescription is accepted by the pharmacist in order to avoid delay in providing necessary medications (written prescription forms for such emergency oral prescription must still be obtained from prescriber within a certain timeframe).
<sup>29</sup> Id.

the medical staff gives the order directly to the institutional pharmacy, and the patient does not handle or have the opportunity to handle the prescription...<sup>30</sup>

Nebraska's regulation provides exceptions for particular facilities and situations:

The following prescriptions and other items are not required to be written on tamper-resistant prescription pads:

1. Orders for drugs provided in Nursing Facilities, ICF/MR facilities, and other specified institutional and clinical settings (inpatient and outpatient hospital, hospice, dental, laboratory, x-ray and renal dialysis) for which the drug is not separately reimbursed, but is reimbursed as part of a total service;

2. Refills of written prescriptions that are presented at a pharmacy before April 1, 2008; ...

6. Prescriptions for Medicaid recipients that are paid entirely by a managed care entity; and

7. Co-pays covered by DHHS funds for prescriptions for drugs covered by Medicare Part D, for certain dual eligible persons.<sup>31</sup>

Washington is another example of a state that provides exceptions for particular facilities. **Washington** law reads,

The tamper-resistant prescription pad or paper requirements in this section shall not apply to:... Prescriptions written for inpatients of a hospital, outpatients of a hospital, residents of a nursing home, inpatients or residents of a mental health facility, or individuals incarcerated in a local, state, or federal correction facility, when the health care practitioner authorized to write prescriptions writes the order into the patient's medical or clinical record, the order is given directly to the pharmacy, and the patient never has the opportunity to handle the written order.<sup>32</sup>

Tamper-resistant prescription requirements may also be waived in emergency situation in some states. For example, **South Dakota** law provides that "[i]f the prescription fails to meet the requirements of this section and an emergency exists, the pharmacy may fill the prescription and receive reimbursement if the pharmacist obtains a . . . prescription that complies with this section . . . within [seventy-two] hours after the fill date."<sup>33</sup>

### **Deadlines for Practitioners to Use Tamper-Resistant Prescription Forms**

Many states<sup>34</sup> and the District of Columbia<sup>35</sup> have laws that provide deadlines for practitioners to begin using tamper-resistant prescription forms. **California** law, for example, provides that "[t]o the extent required by federal law, the purchase of outpatient prescribed drugs, for which the prescription is executed by a prescriber in written, nonelectronic form on or after April 1, 2008, is covered only when executed on a tamper resistant prescription form."<sup>36</sup> **Delaware**'s statute also provides that "[e]ffective October 1, 2010, every prescription

<sup>&</sup>lt;sup>30</sup> ALASKA. ADMIN. CODE tit. 7, § 120.110 (eff. date unclear, 2010-2011).

<sup>&</sup>lt;sup>31</sup> 471 NEB. ADMIN. CODE § 1-002.02N1 (eff. 2008).

<sup>&</sup>lt;sup>32</sup> WASH. REV. CODE ANN. § 18.64.500 (eff. 2009).

<sup>&</sup>lt;sup>33</sup> S.D. ADMIN. R. 67:16:14:06.11 (eff. 2008).

 <sup>&</sup>lt;sup>34</sup> Sixteen states. *See, e.g.*, ALA. ADMIN. CODE r. 560-x-6-.01 (eff. 2008); CAL. WELF. & INST. CODE § 14132 (eff. 2008); DEL. CODE ANN. tit. 16, § 4797 (eff. 2008); GA. CODE ANN.§ 26-4-80.1 (eff. 2011); ILL. ADMIN. CODE tit. 89, § 140.443 (eff. 2009); 902 KY. ADMIN. REGS. 55:105 (eff. 1998); 10-144-101 ME. CODE R. § 80.06 (eff. 2007); MD. CODE REGS. 10.09.03.05 (eff. 2008); 471 NEB. ADMIN. CODE § 1-002.02N (eff. 2008); N.Y. COMP. CODES R. & REGS. tit. 10, § 910.2 (eff. 2008); OR. ADMIN. R. 410-121-0147 (eff. 2007); 1 TEX. ADMIN. CODE § 354.1863 (eff. 2008); 20-4 VT. CODE R. § 1400:9.5 (eff. 2010); WASH. REV. CODE ANN. § 18.64.500 (eff. 2009); W. VA. CODE ANN. § 16-5W-5 (eff. 2010); 060-006 WYO. CODE R. § 5 (eff. 2011).

<sup>&</sup>lt;sup>35</sup> D.C. MUN. REGS. tit. 22-B, § 1333 (eff. 2008).

<sup>&</sup>lt;sup>36</sup> CAL. WELF. & INST. CODE § 14132 (eff. 2008).

written in this State by a practitioner shall be written on a statewide authorized tamper-resistant prescription form."<sup>37</sup> **Wyoming**'s regulation reads, "[e]ffective January 1, 2007, all controlled substance prescriptions written by a Wyoming practitioner shall be issued on security paper..."<sup>38</sup>Similarly, **West Virginia**'s statute provides, "That on and after January 1, 2012, every prescription written in West Virginia by a practitioner shall be written on official West Virginia tamper-resistant prescription paper.."<sup>39</sup>

## **Security Features in Tamper-Resistant Prescription Forms**

States' laws on tamper-resistant prescription forms include provisions pertaining to security features of tamperresistant prescription forms. At least two states<sup>40</sup> include serialized numbering of forms as a security feature for tamper-resistant prescription forms. For example, **New York** law states, "[o]fficial New York state prescription forms shall be prepared and issued by the department in the manner and detail as the commissioner in consultation with the commissioner of education may, by regulation, require, and, each form shall be serialized."<sup>41</sup>

Six states<sup>42</sup> contain legal provisions listing security features with options to choose which of these features may be used in tamper-resistant prescription forms.

**Oregon** law provides a list of security features that may be selected for use in tamper-resistant forms. It provides that "[f]ormatted features *may include but are not limited to* characteristics such as: [t]he word "void" appear[ing] when photocopies are attempted [and] [b]ackground ink which reveals attempted alterations . . . .<sup>"43</sup> **Tennessee** also provides options within a list of selections in its law which states, "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 . . . .<sup>"44</sup> **Vermont** law gives examples of what features could be chosen; its provision reads, "Prescription form features which will satisfy this rule *could, for example,* include the following properties: (1) a colored background with a watermark; (2) when photocopied read "void" in the background . . . .<sup>"45</sup>

Other legal provisions on security features in tamper-resistant forms are narrow and specify required security features. Several states<sup>46</sup> and the District of Columbia<sup>47</sup> have legal provisions that enumerate categories,

<sup>&</sup>lt;sup>37</sup> Del. Code Ann. tit. 16, § 4797 (eff. 2008).

<sup>&</sup>lt;sup>38</sup> 060-006 Wyo. Code R. § 5 (eff. 2011).

<sup>&</sup>lt;sup>39</sup> W. VA. CODE ANN. § 16-5W-5 (eff. 2010).

<sup>&</sup>lt;sup>40</sup> Delaware and New York. While the laws requiring serialization were not part of the research protocol, they are included in this menu as an area of interest and a potential area for future research and coding.

<sup>&</sup>lt;sup>41</sup> N.Y. PUB. HEALTH LAW § 3338 (eff. date unclear).

<sup>&</sup>lt;sup>42</sup> 16 DEL. ADMIN. CODE MED APP. N (eff. date unclear); FLA. STAT. ANN. § 893.065 (eff. 2007); OR. ADMIN. R. 855-006-0015 (eff. 2007); TENN. COMP. R. & REGS. 0880-02-.23 (eff. 2008); 20-4 VT. CODE R. § 1400:9.5 (eff. 2010); W. VA. CODE ANN. § 16-5W-4 (eff. 2010).

<sup>&</sup>lt;sup>43</sup> OR. ADMIN. R. 855-006-0015 (eff. 2007) (emphasis added).

<sup>&</sup>lt;sup>44</sup> TENN. COMP. R. & REGS. 0880-02-.23 (eff. 2008) (emphasis added).

<sup>&</sup>lt;sup>45</sup> 20-4 VT. CODE R. § 1400:9.5 (eff. 2010) (emphasis added).

<sup>&</sup>lt;sup>46</sup> Fourteen states. *See, e.g.,* ALA. ADMIN. CODE r. 560-x-6-.01 (eff. 2008); ALASKA. ADMIN. CODE tit. 7, § 120.110 (eff. date unclear, 2010-2011); DEL. CODE ANN. tit. 16, § 4797 (eff. 2008); GA. CODE ANN. § 26-4-80.1 (eff. 2011); IDAHO ADMIN. CODE r. 16.03.09.661 (eff. 2008); ILL. ADMIN. CODE tit. 89, § 140.443 (eff. 2009); 907 KY. ADMIN. REGS. 1:1019 (eff. date unclear); MD. CODE REGS. 10.09.03.05 (eff. 2008); 471 NEB. ADMIN. CODE § 1-002.02N (eff. 2008); OHIO ADMIN. CODE 5101:3-9-06 (eff. 2008); S.D. ADMIN. R. 67:16:14:06.11 (eff. 2008); 20-4 VT. CODE R. § 1400:9.5 (eff. 2009); WASH. REV. CODE ANN. § 18.64.500 (eff. 2009); W. VA. CODE ANN. § 16-5W-3 (eff. 2010).

sometimes spelled out in required characteristics of security features which prescription forms must contain. For example, **Idaho** law on tamper-resistant prescription requires that "[t]he paper on which the prescription is written *must have* [one] or more industry-recognized features . . . . "<sup>48</sup> **South Dakota** law provides that

To be considered tamper resistant, a prescription pad *must contain* the following three characteristics: (1) One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form, such as a high security watermark;

(2) One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber, such as a tamper-resistant background ink that shows erasures or attempts to change written information  $\dots$ .<sup>49</sup>

One state not only enumerates these categories, but also specifies particular security features within categories that prescription forms must contain. **Colorado** law provides that "[t]o be considered tamper-resistant, the pad/paper used for a written or electronically printed prescription shall integrate three distinct characteristics."<sup>50</sup> The law describes the first characteristic as "[o]ne or more industry-recognized features," which includes options such as a "Void/Illegal/Copy Pantograph" and "[m]icro-fine printed security message generated by a computer, electronic medical records system or other electronic means."<sup>51</sup> The second characteristic is "[o]ne or more industry recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber."<sup>52</sup> This could include a feature like "[a]n erasure-revealing background."<sup>53</sup> The third characteristic required by Colorado law is "[o]ne or more industry recognized features in a box, band or border on the prescription" or "[s]ecurity threads."<sup>54</sup>

Other states<sup>55</sup> have laws that specify security feature details wherein state law mandates one or more security features which prescription forms must contain. For example, **California** law states,

The prescription forms for controlled substances shall be printed with the following features:

- (1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank . . .
- (2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist
- of the words "California Security Prescription."
- (3) A chemical void protection that prevents alteration by chemical washing.
- (4) A feature printed in thermochromic ink.
- (5) An area of opaque writing so that the writing disappears if the prescription is lightened.
- (6) A description of the security features included on each prescription form.

<sup>54</sup> Id.

<sup>&</sup>lt;sup>47</sup> D.C. MUN. REGS. tit. 22-B, § 1333 (eff. 2008).

<sup>&</sup>lt;sup>48</sup> IDAHO ADMIN. CODE r. 16.03.09.661 (eff. 2008) (emphasis added).

<sup>&</sup>lt;sup>49</sup> S.D. ADMIN. R. 67:16:14:06 (eff. 2008) (emphasis added).

<sup>&</sup>lt;sup>50</sup> 10 COLO. CODE REGS. § 2505-10:8.800.11.D (eff. 2009) (emphasis added).

<sup>&</sup>lt;sup>51</sup> Id.

<sup>&</sup>lt;sup>52</sup> Id.

<sup>&</sup>lt;sup>53</sup> Id.

<sup>&</sup>lt;sup>55</sup> Twelve states. *See, e.g.*, CAL. HEALTH & SAFETY CODE § 11162.1 (eff. 2004); 24 DEL. ADMIN. CODE § 2501-5.0 (eff. 2012); FLA. ADMIN. CODE ANN. r. 64B-3.005 (eff. 2008); GA. CODE ANN. § 26-4-5 (eff. date unclear); IND. CODE ANN. § 25-26-13-4 (eff. 2009); 902 KY. ADMIN. REGS. 55:105 (eff. 1998); 16-230-001 ME. CODE R. § 3 (eff. date unclear); N.Y. PUB. HEALTH LAW § 3332 (eff. date unclear); TENN. COMP. R. & REGS. 0880-02-.23 (eff. 2008); TEX. HEALTH & SAFETY CODE ANN. § 481.075 (eff. date unclear); W. VA. CODE ANN. § 16-5W-4 (eff. 2010); 060-006 WYO. CODE R. § 5 (eff. 2011).

(7)(A) Six quantity check off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box  $\dots$ .<sup>56</sup>

Similarly, Indiana's statute provides that

The standard format for a prescription drug form . . . must include the following:
(1) A counterfeit protection bar code with human readable representation of the data in the bar code.
(2) A thermochromic mark on the front and the back of the prescription that: (A) is at least one-fourth
(¼) of one (1) inch in height and width; and (B) changes from blue to clear when exposed to heat.<sup>57</sup>

### Conclusion

This inventory provides a collection of laws on tamper-resistant prescription form requirements. Additional legal strategies related to prescription drug overdose fall outside the scope of this section. This inventory does not contain a full assessment of all relevant prescription drug laws, which often include provisions setting forth professional licensing penalties or criminal sanctions. Practitioners should consult with legal counsel to become fully informed of the legal landscape concerning prescription drugs and how the laws are implemented and enforced in their state.

This document was written by researchers in the Public Health Law Program in the Office for State, Tribal, Local and Territorial Support,<sup>58</sup> with assistance from the Division of Unintentional Injury Prevention in the National Center for Injury Prevention and Control.<sup>59</sup> For further technical assistance with this inventory or prescription drug laws, please contact the Public Health Law Program.<sup>60</sup> For technical assistance on all other opioid pain reliever-related topics, please contact the Division of Unintentional Injury Prevention.<sup>61</sup>

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This menu includes laws enacted through September 28, 2012.

<sup>&</sup>lt;sup>56</sup> Cal. Health & Safety Code § 11162.1 (eff. 2004).

<sup>&</sup>lt;sup>57</sup> IND. CODE ANN. § 25-26-13-4 (eff. 2009).

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