

REFERENCE TITLE: **opioids; containers; labeling; requirements; repeal**

State of Arizona
Senate
Fifty-sixth Legislature
First Regular Session
2023

SB 1254

Introduced by
Senators Shamp: Borrelli, Gowan, Kaiser; Representative Smith

AN ACT

AMENDING SECTION 36-2525, ARIZONA REVISED STATUTES; RELATING TO CONTROLLED SUBSTANCES.

(TEXT OF BILL BEGINS ON NEXT PAGE)

1 Be it enacted by the Legislature of the State of Arizona:

2 Section 1. Section 36-2525, Arizona Revised Statutes, is amended to
3 read:

4 36-2525. Prescription orders; labels; recordkeeping;
5 definition

6 A. In addition to the requirements of section 32-1968 pertaining to
7 prescription orders for prescription-only drugs, the prescription order
8 for a controlled substance shall bear the name, address and federal
9 registration number of the prescriber. A prescription order for a
10 schedule II controlled substance drug other than a hospital drug order for
11 a hospital inpatient shall contain only one drug order per prescription
12 blank. If authorized verbally by the prescriber, the pharmacist may make
13 changes to a written or electronic schedule II controlled substance
14 prescription order, except for any of the following:

- 15 1. The patient's name.
- 16 2. The prescriber's name.
- 17 3. The drug name.

18 B. The pharmacist must document on the original prescription order
19 the changes that were made pursuant to the verbal authorization and record
20 the time and date the authorization was granted.

21 C. A person who is registered to dispense controlled substances
22 under this chapter must keep and maintain prescription orders for
23 controlled substances as follows:

24 1. Prescription orders for controlled substances listed in
25 schedules I and II must be maintained in a separate prescription file for
26 controlled substances listed in schedules I and II only.

27 2. Prescription orders for controlled substances listed in
28 schedules III, IV and V must be maintained either in a separate
29 prescription file for controlled substances listed in schedules III, IV
30 and V only or in a form that allows them to be readily retrievable from
31 the other prescription records of the registrant. For the purposes of
32 this paragraph, "readily retrievable" means that, when the prescription is
33 initially filed, the face of the prescription is stamped in red ink in the
34 lower right corner with the letter "C" in a font that is ~~not less than~~ AT
35 LEAST one inch high and that the prescription is filed in the usual
36 consecutively numbered prescription file for noncontrolled substance
37 prescriptions. The requirement to stamp the hard copy prescription with a
38 red "C" is waived if a registrant employs an electronic data processing
39 system or other electronic recordkeeping system for prescriptions that
40 ~~permits~~ **ALLOWS** identification by prescription number and retrieval of
41 original documents by the prescriber's name, patient's name, drug
42 dispensed and date filled.

43 D. Except in emergency situations in conformity with subsection E
44 of this section, under the conditions specified in subsections F and G of
45 this section or when dispensed directly by a medical practitioner to an

1 ultimate user, a controlled substance in schedule II shall not be
2 dispensed without either the written prescription order in ink or
3 indelible pencil or typewritten and manually signed by the medical
4 practitioner or an electronic prescription order as prescribed by federal
5 law or regulation. ~~Beginning January 1, 2020,~~ A schedule II controlled
6 substance that is an opioid may be dispensed only with an electronic
7 prescription order as prescribed by federal law or regulation. A
8 prescription order for a schedule II controlled substance shall not be
9 dispensed more than ninety days after the date on which the prescription
10 order was issued. Notwithstanding any other provision of this section, a
11 pharmacy may sell and dispense a schedule II controlled substance
12 prescribed by a medical practitioner who is located in another state if
13 the prescription was issued to the patient according to and in compliance
14 with the applicable laws of the state of the prescribing medical
15 practitioner and federal law. A prescription order for a schedule II
16 controlled substance shall not be refilled. A pharmacist is not in
17 violation of this subsection and may dispense a prescription order in the
18 following circumstances:

19 1. During any time period in which an established electronic
20 prescribing system or a pharmacy management system is not operational or
21 available in a timely manner. If the electronic prescribing system or a
22 pharmacy management system is not operational or available, the pharmacist
23 may dispense a prescription order that is written for a schedule II
24 controlled substance that is an opioid. The pharmacist must maintain a
25 record, for a period of time prescribed by the board, of when the
26 electronic prescribing system or pharmacy management system is not
27 operational or available in a timely manner.

28 2. The prescription order for a schedule II controlled substance
29 that is an opioid is in writing and indicates that the medical
30 practitioner who issued the prescription order provided care for the
31 patient in a veterans administration facility, a health facility on a
32 military base, an Indian health services hospital or other Indian health
33 service facility, or a tribal-owned clinic.

34 E. In emergency situations, emergency quantities of schedule II
35 controlled substances may be dispensed on an oral prescription order of a
36 medical practitioner. Such an emergency prescription order shall be
37 immediately reduced to writing by the pharmacist and shall contain all the
38 information required for schedule II controlled substances except for the
39 manual signing of the order by the medical practitioner. Within seven
40 days after authorizing an emergency oral prescription order, the
41 prescribing medical practitioner shall cause a written prescription order
42 manually signed for the emergency quantity prescribed to be delivered to
43 the dispensing pharmacist or an electronic prescription order to be
44 transmitted to the dispensing pharmacist. In addition to conforming to
45 other requirements for prescription orders for schedule II controlled

1 substances, the prescription order shall indicate electronically or have
2 written on its face "authorization for emergency dispensing" and the date
3 of the oral order. If the prescribing medical practitioner fails to
4 deliver such an emergency prescription order within seven days in
5 conformance with board rules, the pharmacist shall notify the board.
6 Failure of the pharmacist to notify the board voids the authority
7 conferred by this subsection to dispense without a prescription order of a
8 medical practitioner that is electronic or that is written and manually
9 signed.

10 F. Notwithstanding subsections D and N of this section, a patient's
11 medical practitioner or the medical practitioner's agent may transmit to a
12 pharmacy by fax a prescription order written for a schedule II controlled
13 substance, including opioids, if the prescription order is any of the
14 following:

15 1. To be compounded for the direct administration to a patient by
16 parenteral, intravenous, intramuscular, subcutaneous or intraspinal
17 infusion.

18 2. For a resident of a long-term care facility.

19 3. For a patient who is enrolled in a hospice care program that is
20 certified or paid for by medicare under title XVIII or a hospice program
21 that is licensed by this state. The medical practitioner or the medical
22 practitioner's agent must note on the prescription that the patient is a
23 hospice patient.

24 G. A fax transmitted pursuant to subsection F of this section is
25 the original written prescription order for purposes of this section and
26 must be maintained as required by subsection C of this section.

27 H. Except when dispensed directly by a medical practitioner to an
28 ultimate user, a controlled substance included in schedule III or IV that
29 requires a prescription order as determined under state or federal laws
30 shall not be dispensed without a written or oral prescription order of a
31 medical practitioner or an electronic prescription order as prescribed by
32 federal law or regulation. The prescription order shall not be filled or
33 refilled more than six months after the date on which the prescription
34 order was issued. A prescription order authorized to be refilled shall
35 not be refilled more than five times. Additional quantities may only be
36 authorized by the prescribing medical practitioner through issuance of a
37 new prescription order that shall be treated by the pharmacist as a new
38 and separate prescription order.

39 I. Except when dispensed directly by a medical practitioner to an
40 ultimate user, a controlled substance that is included in schedule V and
41 that requires a prescription order as determined under state or federal
42 laws shall not be dispensed without a written or oral prescription order
43 of a medical practitioner. The prescription order may be refilled as
44 authorized by the prescribing medical practitioner but shall not be filled
45 or refilled more than one year after the date of issuance.

1 J. A controlled substance that is listed in schedule III, IV or V
2 and that does not require a prescription order as determined under state
3 or federal laws may be dispensed at retail by a pharmacist or a pharmacy
4 intern under the pharmacist's supervision without a prescription order to
5 a purchaser who is at least eighteen years of age if all of the following
6 are true:

7 1. It is for a legitimate medical purpose.

8 2. Not more than two hundred forty cubic centimeters (eight ounces)
9 of any such controlled substance containing opium, nor more than one
10 hundred twenty cubic centimeters (four ounces) of any other such
11 controlled substance, nor more than forty-eight dosage units of any such
12 controlled substance containing opium, nor more than twenty-four dosage
13 units of any other controlled substance may be dispensed at retail to the
14 same purchaser in any given forty-eight-hour period.

15 3. ~~No~~ NOT more than one hundred dosage units of any single active
16 ingredient ephedrine preparation may be sold, offered for sale, bartered
17 or given away to any one person in any one thirty-day period.

18 4. The pharmacist or pharmacy intern requires every purchaser of a
19 controlled substance under this subsection who is not known to that person
20 to furnish suitable identification, including proof of age if appropriate.

21 5. A bound record book for dispensing controlled substances under
22 this subsection is maintained by the pharmacist and contains the name and
23 address of the purchaser, the name and quantity of the controlled
24 substance purchased, the date of each purchase and the name or initials of
25 the pharmacist or pharmacy intern who dispensed the substance to the
26 purchaser. The book shall be maintained in conformity with the
27 recordkeeping requirements of section 36-2523.

28 K. In the absence of a law requiring a prescription for a schedule
29 V controlled substance, the board, by rules, may require, or remove the
30 requirement of, a prescription order for a schedule V controlled
31 substance.

32 L. The label on a container of a controlled substance that is
33 directly dispensed by a medical practitioner or pharmacist and that is not
34 for the immediate administration to the ultimate user, such as a bed
35 patient in a hospital, shall bear the name and address of the dispensing
36 medical practitioner or pharmacist, the serial number, the date of
37 dispensing, the name of the prescriber, the name of the patient or, if an
38 animal, the name of the owner of the animal and the species of the animal,
39 the directions for use and cautionary statements, if any, contained in the
40 prescription order or required by law. If the controlled substance is
41 included in schedule II, III or IV, the label shall bear a transfer
42 warning to the effect: "Caution: federal law prohibits the transfer of
43 this drug to any person other than the patient for whom it was
44 prescribed". The container of a schedule II controlled substance that is
45 an opioid that is directly dispensed by a pharmacist and that is not for

1 the immediate administration to the ultimate user shall have ~~a red cap and~~
2 a warning label prescribed by the board about potential addiction. ~~The~~
3 ~~board or the executive director, if delegated by the board, may waive the~~
4 ~~red cap requirement if implementing the requirement is not feasible~~
5 ~~because of the specific dosage form or packaging type.~~

6 M. Controlled substances in schedules II, III, IV and V may be
7 dispensed as electronically transmitted prescriptions if the prescribing
8 medical practitioner is all of the following:

9 1. Properly registered by the United States drug enforcement
10 administration.

11 2. Licensed in good standing in the United States jurisdiction in
12 which the medical practitioner practices.

13 3. Authorized to issue such prescriptions in the jurisdiction in
14 which the medical practitioner is licensed.

15 N. Notwithstanding any other provision of this section, ~~beginning~~
16 ~~January 1, 2020,~~ each prescription order, except a prescription order
17 under subsection F of this section, that is issued by a medical
18 practitioner for a schedule II controlled substance that is an opioid
19 shall be transmitted electronically to the dispensing pharmacy. A medical
20 practitioner is not in violation of this subsection:

21 1. During any time in which an established electronic prescribing
22 system or a pharmacy management system is not operational or available in
23 a timely manner. If the electronic prescribing system or a pharmacy
24 management system is not operational or available, the medical
25 practitioner may write a prescription order for a schedule II controlled
26 substance that is an opioid. The medical practitioner shall indicate on
27 the written prescription order that the electronic prescribing system or
28 pharmacy management system is not operational or available. The medical
29 practitioner must maintain a record, for a period of time prescribed by
30 the board, of when the electronic prescribing system or pharmacy
31 management system is not operational or available in a timely manner.

32 2. If the medical practitioner writes a prescription order for a
33 schedule II controlled substance that is an opioid that will be dispensed
34 for the patient from a veterans administration facility, a health facility
35 on a military base, an Indian health services hospital or other Indian
36 health service facility, or a tribal-owned clinic.

37 O. The requirement in subsections D and N of this section for an
38 electronic prescription order does not apply to a prescription order for a
39 schedule II controlled substance that is an opioid that is issued for
40 medication-assisted treatment for a substance use disorder.

41 P. The board, by rule, may provide additional requirements for
42 prescribing and dispensing controlled substances.

43 Q. In consultation with the task force established pursuant to
44 section 36-2603, the board may prescribe by rule additional exceptions to

1 the electronic prescribing requirements specified in this section for both
2 pharmacists and medical practitioners.

3 R. Notwithstanding subsections D and N of this section, a medical
4 practitioner who is licensed pursuant to title 32, chapter 21 is not
5 required to comply with the electronic prescribing requirements of
6 subsections D and N of this section until the Arizona state veterinary
7 medical examining board determines that electronic prescribing software is
8 widely available for veterinarians and notifies the Arizona state board of
9 pharmacy of that determination.

10 S. For the purposes of this section, "medication-assisted
11 treatment" has the same meaning prescribed in section 32-3201.01.