

Proposed Rule
LSA Document #20-455

DIGEST

Amends [856 IAC 2-3-4](#) and [856 IAC 2-3-5](#) to remove the waiver of the controlled substance registration (CSR) requirement for EMS providers. Adds [856 IAC 2-3-4.5](#) concerning EMS CSR. Effective 30 days after filing with the Publisher.

[IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses](#)

[856 IAC 2-3-4](#); [856 IAC 2-3-4.5](#); [856 IAC 2-3-5](#)

SECTION 1. [856 IAC 2-3-4](#) IS AMENDED TO READ AS FOLLOWS:

[856 IAC 2-3-4](#) Separate registrations for separate locations; exceptions

Authority: [IC 35-48-3-1](#)

Affected: [IC 35-48-3-3](#)

Sec. 4. ~~Separate registrations for separate locations.~~ (a) A separate registration is required for each principal place of business or professional practice at one **(1)** general physical location where controlled substances are manufactured, distributed, dispensed, or possessed by a person.

(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

- (1) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered or to persons not required to register by virtue of [IC 1971, 35-24.1-3-2\(e\)\(2\)](#) as amended: **under [IC 35-48-3-3](#)**.
- (2) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains such substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders. ~~and~~
- (3) An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

~~(c) The requirement of registration is waived for ambulances as defined by [IC 16-1-39-2](#) and [836 IAC 1-1-1](#) operated by an ambulance service provider also defined at [836 IAC 1-1-1](#) which holds certification as a provider organization as this term is defined in [IC 16-1-40](#) from the Indiana Emergency Medical Services Commission, providing that the pharmacies of the supervising or sponsoring hospitals hold a valid Indiana Board of Pharmacy permit and valid Indiana and Federal Controlled Substances Registration.~~

(Indiana Board of Pharmacy; Reg 28, Ch III, Sec 3.13; filed Jul 9, 1974, 9:29 a.m.: unpublished; filed Feb 11, 1981, 9:05 a.m.: 4 IR 377; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341; readopted filed Oct 4, 2007, 3:33 p.m.: [20071031-IR-856070060RFA](#); readopted filed Nov 25, 2013, 9:24 a.m.: [20131225-IR-856130308RFA](#); readopted filed Nov 18, 2019, 11:41 a.m.: [20191218-IR-856190076RFA](#))

SECTION 2. [856 IAC 2-3-4.5](#) IS ADDED TO READ AS FOLLOWS:

[856 IAC 2-3-4.5](#) Registration of ambulance service providers

Authority: [IC 35-48-3-1](#)

Affected: [IC 16-18-2](#); [IC 35-48](#)

Sec. 4.5. (a) The following definitions apply throughout this section:

- (1) "Advanced emergency medical technician" has the meaning set forth in [IC 16-18-2-6.5](#).
- (2) "Ambulance" has the meaning set forth in [IC 16-18-2-13](#).

- (3) "Ambulance service provider" has the meaning set forth in [836 IAC 1-1-1](#).
- (4) "Contracting hospital" means a licensed hospital pharmacy that has a written agreement with one (1) or more ambulance service providers to provide stocks of controlled substances to such providers.
- (5) "Health care practitioner" means a licensed physician, physician assistant, or advanced nurse practitioner.
- (6) "Medical director" has the meaning set forth in [836 IAC 1-1-1](#).
- (7) "Paramedic" has the meaning set forth in [IC 16-18-2-266](#).
- (8) "Stock" means the controlled substances that are held by an ambulance service provider.
- (9) "Sub-stock" means the controlled substances that are stored on a specific ambulance, or those controlled substances that are stored by an ambulance service provider that is owned or operated by, or utilizing a contract with, a hospital pharmacy.

(b) Each ambulance service provider that purchases, stores, or dispenses any controlled substance shall obtain a registration. A separate registration is required for each principal place of business where controlled substances are stored. A separate registration is not required for each ambulance owned or operated by the provider. Agents or employees of the provider are not required to register if such agent or employee is acting in the usual course of business or employment.

(c) A hospital pharmacy may, but is not required to:

- (1) enter into a written agreement with an ambulance service provider to provide, sell, or deliver stocks of controlled substances to such provider for use in an ambulance; or
- (2) enter into a written agreement with an ambulance service provider to act as an agent for such provider and supply a sub-stock of controlled substances for use in the provider's ambulances.

(d) A hospital pharmacy may, but is not required to, provide only those controlled substances approved by the medical director.

(e) All registrants under this section shall do the following:

- (1) Purchase, possess, deliver, or cause to be administered only those controlled substances approved by the medical director.
- (2) Permit only a person who is approved by the medical director and is a licensed health care practitioner, advanced emergency medical technician, or paramedic to administer a controlled substance within the individual's approved scope of practice.

(f) A registrant owned or operated by a hospital, or utilizing a contracting hospital, shall also:

- (1) utilize the hospital pharmacy's registration for the delivery of controlled substances for use in any authorized ambulance;
- (2) maintain the provider's controlled substances as part of the hospital's controlled substances sub-stock; and
- (3) have the hospital act as the agent for the provider.

(g) Registrants shall ensure the following:

- (1) Controlled substances shall be safeguarded properly and kept securely at the registered address on file with the board.
- (2) All stocks or sub-stocks will be made available for inspection by authorized representatives of the board or emergency medical services commission staff.
- (3) Access to controlled substances stocks shall be limited to the minimum number of individuals actually required to manage the administration, delivering, and handling of such controlled substances efficiently.
- (4) A plan is submitted to the board for review and approval that details the location or locations of all stocks or sub-stocks, the safeguarding or access to, and security standards for all controlled substances.
- (5) A quality assurance plan for the administration of controlled substances is submitted to the department.
- (6) Only a reasonable quantity of controlled substances as approved by the medical director in the written medication list as required by [836 IAC 2-2-3](#) or listed in medical protocols is stored as sub-stocks.

(7) Monitor controlled substances for diversion and loss and report any initial loss or theft to the board within twenty-four (24) hours and any final determination of loss or theft within thirty (30) days.

(h) All controlled substances stock shall be secured and stored in accordance with sections 30, 31, and 33 of this rule.

(i) Registrants shall comply with the following storage and security requirements for sub-stocks in ambulances:

(1) Access to any sub-stock of controlled substances shall be limited to advanced emergency medical technicians or paramedics within their approved scope of practice and require at least two (2) locks with different keys or other secured access.

(2) Controlled substances must be secured in a locked box within a locked stationary cabinet under two (2) separate, secured, and independent locking systems.

(3) The key or keys to access the cabinet where controlled substances are stored must be maintained under the direct control of an advanced emergency medical technician or paramedic within their approved scope of practice.

(4) Controlled substances may be maintained in the direct possession and control of an advanced emergency medical technician or paramedic within their approved scope of practice while such individual is on duty; however, at no time shall controlled substances be carried in any personal automobile.

(5) A written change of shift inventory for any sub-stock shall be conducted when custody of controlled substances passes during a shift change.

(6) Alternative forms of securing or maintaining controlled substances in ambulances are subject to the approval of the board. The registrant must describe the alternative methods, state reasons why the alternative method is necessary, and fully describe procedures for safeguarding and controlling controlled substances and limiting access to only authorized individuals.

(j) Controlled substances may only be administered pursuant to a licensed health care practitioner's order or a protocol authorized by the medical director. Controlled substances stock shall only be ordered or purchased upon authorization of the medical director.

(k) An individual making any administration of a controlled substance pursuant to an order or protocol shall make a record of the administration on all required forms of the registrant. Such documentation shall be made during or immediately following the run.

(l) The health care practitioner ordering or confirming the administration of a controlled substance shall make and maintain a record of such administration to include:

(1) health care practitioner's name and signature, or if administered under authorization of written medical protocol, noted as per protocol;

(2) date, time, and run identification;

(3) patient name;

(4) paramedic service provider name;

(5) advanced emergency medical technician or paramedic name;

(6) patient's chief complaint and presenting problem;

(7) name of controlled substance;

(8) dosage and route of administration;

(9) quantity administered; and

(10) receiving hospital name and record number.

(m) Each individual receiving an order or using a protocol to administer a controlled substance shall make a record of the administration to include:

(1) ordering physician identification;

(2) date, time, and run identification;

(3) patient name;

(4) paramedic service provider name;

(5) advanced emergency medical technician or paramedic name;

(6) patient's chief complaint and presenting problem;

(7) name of controlled substance;

- (8) dosage and route of administration;
- (9) quantity administered; and
- (10) receiving hospital name and record number.

This record shall be the prehospital care report and any necessary supplement. A copy of the prehospital record shall be submitted to the receiving facility as well as a verbal report of the controlled substance administration.

(n) An individual administering a controlled substance shall maintain an administration inventory record for all controlled substances. This record shall be returned to the registrant before any controlled substances can be replenished.

(o) Registrants shall comply with all record keeping requirements as found in [IC 35-48](#) and this article. Registrants shall also maintain the following records related to sub-stocks:

- (1) Date and the amount of the controlled substance delivered to a sub-stock.
- (2) Signature of the individual who delivered the controlled substance sub-stock.
- (3) Signature of the individual receiving the controlled substance sub-stock. Only advanced emergency medical technicians and paramedics may receive sub-stock.
- (4) Vehicle identification number or location of sub-stock.
- (5) Remaining amount of controlled substance on hand.

(p) A separate record shall be maintained of all nonadministered losses from any stock or sub-stock.

(q) The registrant shall maintain a perpetual inventory for all controlled substances stock and sub-stock.

(r) Controlled substances may be destroyed or properly disposed of provided that:

- (1) a notation is made on the administration record;
- (2) the destruction is witnessed by a second licensed health care practitioner, advanced emergency medical technician, or paramedic, but if no such person is available, then witnessed by an emergency medical technician; and
- (3) all destroyed or disposed product must be irretrievable and in accordance with current proper disposal practice.

(s) The medical director shall be accountable for education, protocol development, and oversight on the proper use and administration of the controlled substances and for maintaining a quality assurance plan and protocols.

(t) The registrant is responsible for the proper safeguarding, handling, and accountability of controlled substances and for ensuring that all reports and reporting procedures are carried out. The registrant shall designate which executive or operating individual is responsible for controlled substance oversight.

(Indiana Board of Pharmacy; [856 IAC 2-3-4.5](#))

SECTION 3. [856 IAC 2-3-5](#) IS AMENDED TO READ AS FOLLOWS:

[856 IAC 2-3-5](#) Exemption of agents or employees; affiliated practitioners; paramedics

Authority: [IC 35-48-3-1](#)

Affected: [IC 35-48-3-3](#)

~~Sec. 5. Exemption of agents and employees; affiliated practitioners.~~ (a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his **or her** business or employment.

(b) An individual practitioner (other than an intern, **a** resident, or **a** foreign-trained physician) who is an agent or employee of another practitioner registered to dispense controlled substances may, when acting in the usual course of his **or her** employment, administer and dispense (other than by issuance of prescription) controlled

substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he **or she** practices, under the registration of the employer or principal practitioner in lieu of being registered himself **or herself**. For example, a pharmacist employed by a pharmacy need not be registered individually to fill a prescription for controlled substances in a pharmacy if so registered.

(c) An individual practitioner who is an intern, **a resident**, or **a foreign-trained physician** may dispense, administer, and prescribe controlled substances **as follows** under the registration of the hospital or other institution ~~which that~~ is registered and by whom he **or she** is employed in lieu of being registered himself **or herself**, provided that:

- (1) Such dispensing or prescribing is done in the usual course of his **or her** professional practice.
- (2) Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he **or she** is practicing.
- (3) The hospital or other institution by whom he **or she** is employed has determined that the individual practitioner is so permitted to dispense, administer, or prescribe drugs by the jurisdiction.
- (4) Such individual practitioner is acting only within the scope of his **or her** employment with the hospital or institution.
- (5) The hospital or other institution authorizes the intern, resident, or foreign-trained physician to dispense or prescribe under the hospital registration and designates a specific internal code number for each intern, resident, or foreign-trained physician so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's **Drug Enforcement Agency** (DEA) registration number, preceded by a hyphen (e.g., AP 0123456-10 or AP 0123456-A12). ~~and~~
- (6) A current list of internal codes and the corresponding individual practitioner is kept by the hospital or other institution and is made available to the public upon request for the purpose of verifying the authority of the prescribing individual practitioner.

~~(d) The requirement of registration is waived for advanced emergency medical technicians and emergency paramedics as described in [IC 16-1-40](#) and [836 IAC 2-1-1](#) insofar as they administer controlled substances within the applicable requirements and standards of [IC 16-1-40](#) as well as the rules and regulations promulgated thereunder by the Indiana Emergency Medical Services Commission.~~

(Indiana Board of Pharmacy; Reg 28, Ch III, Sec 3.14; filed Jul 9, 1974, 9:29 a.m.: unpublished; filed Feb 11, 1981, 9:05 a.m.: 4 IR 378; errata, 4 IR 536; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341; readopted filed Oct 4, 2007, 3:33 p.m.: [20071031-IR-856070060RFA](#); readopted filed Nov 25, 2013, 9:24 a.m.: [20131225-IR-856130308RFA](#); readopted filed Nov 18, 2019, 11:41 a.m.: [20191218-IR-856190076RFA](#))

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