



AMBULANCE CSR FREQUENTLY ASKED QUESTIONS

Updated: Thursday, November 18, 2021

The EMS Section has been working with the pharmacy section of the Professional Licensing Agency (PLA) with regards to the controlled substances registration (CSR) for ambulances. We currently have resources available on our main EMS webpage including the Final Rule as well as this helpful overview of the steps in the CSR application process:

- [Overview of the CSR/DEA requirements and process](#)

Both IDHS and PLA/Board of Pharmacy are asking everyone's patience with these new changes that impact how EMS handles controlled substances after nearly 50 years of using the borrowed controlled substances system.

The EMS Section has received a lot of questions about the ambulance CSR and has developed the following Frequently Asked Questions (FAQ) that will hopefully answer the most common inquiries:

What is the Timeline for Enforcement of the CSR Requirement?

The Final Rule took effect on August 25, 2021. However, the Board of Pharmacy anticipated a transition period with hundreds of ambulance provider organizations needed to qualify and obtain their own CSR independent from their supervising hospital or medical director's own CSR. Currently, we are in a grace period for PLA to monitor how to process the new applicants and give organizations time to prepare their applications. Information will be sent out once PLA determines that enough information is available and applicants have been processed to being full enforcement of the new rule.

The form instructions indicates that a signature is required from the medical director but there is no dedicated signature line for the medical director so where do they sign?

The form is used for many types of providers so adding a separate medical director signature line would not be applicable to other non-EMS providers. So, both the organization representative and the medical director can sign on the provided line and indicate their titles.

Is there a specific requirement for the training and documentation for the training records of those giving controlled substances?

Currently, the PLA will defer to the paramedic license as evidence of completion on education on controlled substances in the paramedic curriculum. Thus, training records are not required, but compliance staff highly recommends an annual review of policy & procedures with EMS staff (in-service) for any procedural changes. Best practices, but not required, include orientation records if the paramedic is shown how your organization tracks and handles controlled substances. Also, any policy on controlled substances and then any written acknowledgements of receipt of that policy could be beneficial. There is some preliminary discussion of whether PLA and IDHS may partner for some basic training to include in ACADIS that organizations could have their paramedics complete.

Currently, most EMS organizations are disposing of their remainder waste narcotics via disposal at a receiving facility (sharps, sink, trash) with a witness. Is this permissible or does there need to be a professional waste disposal?

Unfortunately, disposal of controlled substance waste must be to protect the medication from being obtained for illegal usage but also cannot be a risk to the environment. The compliance officers at PLA cannot accept prior practices of disposal that create risks or violate other agency protocols. 856 IAC 2-3-4.5(r) addresses disposal:

- (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.

Cactus sink, CsRx container or a registered reverse distributor would be acceptable but not disposal of controlled substances in a sink, biohazard, or trash bins.

Some providers are reading the 856 pharmacy rules and noting that the requirements for storage reference tamper resistance by hours, etc. Any further guidance for on-station security for on-site storage other than the double secured means?

Refer to 856 IAC 2-3-4.5(h)(i)(1-2) for ambulance storage requirements which is the standard two-lock systems that are parallel to EMS rules. Organizations may be reading more stringent requirements for pharmacy and hospital locations.

For station storage, PLA staff will look at storage based upon 856 IAC 2-3-30 with the highlighted sections being most applicable to EMS organizations:

Sec. 30. Security requirements generally. (a) ***All applicants and registrants shall provide and maintain effective controls and procedures to guard against theft and diversion of controlled substances.***

In evaluating the overall security system of a registrant or applicant, the Indiana Board of Pharmacy may consider any of the following factors as it may deem relevant to the need for strict compliance with security requirements but the bold items are the ones most applicable.

- (1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);
- (2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units usable powders or nonusable powders);
- (3) The quantity of controlled substance handled;**
- (4) The location of the premises and the relationship such location bears on security needs; (e.g., high vs. low crime areas, waterfront boundaries, adjacent/attached buildings, urban vs. suburban vs. rural areas, etc.)
- (5) The type of building construction comprising the facility and the general characteristics of the building or buildings; (e.g., metal curtain, wood frame, masonry, number and type of doors, windows and other openings, etc.).
- (6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used; (e.g., automatic storage and retrieval, construction of vaults and cages, modular vaults, container weight and type, UL listing/GSA rating, etc.)
- (7) The type of closures on vaults, safes, and secure enclosures; (e.g., built-in combination locks, key locks, padlocks, self closing and locking day gates, vault doors and frames, etc.).**
- (8) The adequacy of key control systems and/or combination lock control systems; (e.g., adequacy, accountability, routine changing, issuance and control procedures, logging, central repository, combination security, etc.).**
- (9) The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources; s (e.g., adequacy of

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supervision, method of signal transmission, proprietary vs. central station vs. police connection, adequacy of standby power sources, maintenance and testing, signal and response time, etc.).

(10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any; (e.g., adequacy of gates and fencing, if any, control at entry/exit points, parking location and proximity to facility, extent of unsupervised public access to the facility, etc.)

(11) The adequacy of supervision over employees having access to manufacturing and storage areas; (e.g., access control to manufacturing and storage areas, identification media and systems, control of and accountability for identification, responsibilities of employees, etc.

(12) The procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel; (e.g., access control, logging procedures, identification media, internal movement control, etc.)

(13) The availability of local police protection or of the registrant's or applicant's security personnel, and; (e.g., availability, legal obligation to respond, frequency of patrol, adequacy of training, alarm response time, size of force, etc.).

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations. (e.g., storage security, common or contract carrier security, etc.).

Initial attempts at contacting the pharmacy office via phone were not successful, what is the best means of addressing questions about the ambulance CSR?

First, you can continue to utilize the EMS staff at IDHS who is working closely with PLA and pharmacy board staff. The main PLA line which handles a large number of different occupations that was given out initially was just taken off their website for the IDHS materials. The main receptionist was not briefed on this change and commonly informs EMS professional calls to IDHS EMS since PLA does not include EMS licensing so that created confusion. Organizations can call Pharmacy and Medical at PLA via 317-234-2067 or 317-234-2060 but they are on ring down to anywhere in PLA if no one is available to answer. The best practice is to always clarify that you have a pharmacy question if you need to call.

Will there be additional information available about ambulance CSR?

Yes, it is anticipated that there will be continued communications as the new ambulance CSR system develops. The pharmacy section of PLA is developing a plan for some webinars that can provide further information and answer questions. The EMS Section of IDHS will help spread the announcements for this opportunity and determine if we can place it in ACADIS for future reference.

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UPDATES: NOVEMBER 18, 2021

Is there a cutoff date for full enforcement of the new CSR rules?

No, it is not possible to enforce full rule compliance until the DEA begins issuing registrations. At this time, we do not know when that will be. PLA can still require the CSR, but provider organizations will have to order drugs under the MD's CSR until the DEA registration is issued. However, even after full implementation, the MD will have to sign off on the orders.

Can an ambulance provider still obtain controlled substances from their affiliated hospitals?

There are some statutory restrictions to a hospital purchase, but this situation does not appear to fall under the restrictions. See IC 25-26-14-11. However, this can be the traditional process of "borrowing" controlled substances but must be an official transfer and completing appropriate DEA forms to create a full transfer where the controlled substances are owned and controlled by the ambulance provider.

Is it possible to have an agreement with a hospital to have the hospital dispose of unused remainders of controlled substances via the hospital disposal system?

Yes, agreements with hospitals for disposal of controlled substances through the hospital system appear to be acceptable. However, the loss or destruction must be recorded by the provider organization on its DEA registration records. It would not be agreeable to have the hospital report the waste as part of their records — ownership/possession does not change for the controlled substances, just the location of the destruction by agreement of the provider organization and the receiving hospital.