Draft Policy Public Comments Received: 04/14 - 05/13/2023

S-400 Management of Controlled Substances for ALS Agencies		
DATE	**NAME**	**PUBLIC COMMENT**
4/14/2023	Christopher Kahn	There are several points of inconsistency between Policy S-400 ("Management of Controlled Substances for ALS Agencies") and the Federal and State laws upon which it is based. Prior to noting the specific inconsistencies, however, it is worth bringing up the larger issue of whether this policy needs to exist. I am not able to answer that, as it is a matter of determining the intent of County of San Diego EMS leadership. If that intent is to be more restrictive than Federal and State law, then there is a need for this policy. If that intent is simply to ensure that ALS agencies are compliant with Federal and State law, then it seems unnecessary to have a policy which essentially states, "Don't break the laws, and here's what they are." This would be particularly onerous for County of San Diego EMS staff and the agencies/personnel you regulate if this were applied equitably to the several tens of thousands of statutes that exist across Federal and California code.

		There is also the inevitability that as Federal and State law/regulation changes, our County of San Diego EMS policy will again become inconsistent, forcing agencies to navigate conflicting guidance and requirements from multiple agencies that each have independent investigation and regulatory authority over their operations. While the intent of opening Policy S-400 for review appears to have been a simple update to remove references to the County of San Diego EMS Medical Director as an option for being an ALS agency's registrant for controlled substances, this moment of requiring all ALS agencies to take on these responsibilities within their own organizations appears to be the proper moment to ensure that they are not being asked to meet standards that are not consistent with Federal and State law. Accordingly, if this policy is to continue to exist, I would suggest modifications to the following specific line items to bring this policy into concordance with the controlling statutes. I've listed them in the order they appear in the policy, and hopefully in a format that will make them easier to categorize and otherwise address. They are numbered for ease of reference.# Section Main Issue and Detailed Comments 1 IV Form 222 reference is incomplete In 2005, the DEA published the Final Rule implementing the Controlled Substances Ordering System (CSOS). While CSOS is often referred to as an "electronic Form 222", this is not accurate. Requiring ALS agencies to use Form 222 exclusively will prohibit them from using CSOS. CSOS is generally preferred, as it: - does not require manual submission of paper forms for orders - allows multiple orders to be placed without waiting for new paper Form 222s to be ordered and delivered - enables just-in-time ordering and rapid ordering - during times of drug shortages in particular, is the recommended method of order submission by pharmaceutical distributors due to the increased likelihood of being able to fill some number of several small orders but not being able to fill a single large order While this line was struck from V.A.2, that change is not reflected here. 2 IV 21 CFR compliance reference is inconsistent As noted below, this policy is inconsistent with 21 CFR, therefore it is not reasonable to require agencies to be compliant with both 21 CFR and this policy. 3 IV DEA registration number reference is inconsistent This refers to "their" (the agency's) DEA registration number, but the policy also refers to requiring a physician registrant, which would then be the physician's DEA registration number, not the agency's DEA registration number. 4 V.A.3 Ordering reference is incomplete Note – this was V.A.4 prior to the numbering change in the track-change version. The DEA allows registrants to designate an attorney-in-fact (please refer to 21 CFR 1305.05) to place controlled substance orders on their behalf. Many (and perhaps almost all) larger

		agencies employ a dedicated logistics manager to support all supply chain processes, including controlled substance processes. As written, this policy does not allow that logistics manager to manage this portion of the supply chain, and creates a single point of failure for these critical medications. 5 V.B.3 Inconsistent with DEA regulations The separate registration requirement was amended in the Protecting Patient Access to Emergency Medications Act of 2017 (PPAEMA). Notably, this legislation, which was designed to facilitate appropriate EMS use of controlled substances, was so non-controversial that despite our polarized national political climate it passed through the House on a 404-0 vote on 1/9/2017, was amended in Senate on unanimous consent on 10/24/17, then was agreed to in House on unanimous consent on 11/2/17 (please refer to HR 304 of the 115th Congress and 21 USC 823(j)(6)). This policy ignores the thrice unanimous and explicit instructions of the Congress of the United States and instead requires outdated measures which hinder the delivery of care to EMS patients by prohibiting satellite storage locations. In terms of registrations, the DEA only requires that the central shipment location matches the address on the DEA registration application. 6 V.B.4 Inconsistent with V.B.3 V.B.3, while inaccurate in how it restates DEA requirements, does at least allow for the possibility of restocking from more than one location. This line immediately follows that requirement and states something different, which is that all units most resupply from a central location. This is not only inconsistent with the preceding line but is also inconsistent with how larger agencies are required to function to maintain efficiency of operations. Larger agencies will often use satellite stocking locations. Many also have policy allowing the transport of controlled substances from a designated secure stocking location to a unit in the field for the purpose of restocking to maintain unit availability and consequently the ability to respond to emergency calls from the community. Again, please refer to 21 USC 823(j)(6) for supporting documentation. 7 V.C.1.a Duplicative and inconsistent This is word-for-word duplicative from V.A.3 (previously V.A.4), and remains inappropriate for the reasons described in Comment 4 above. 8 V.C.2.a.2 Vague As written, this policy requires witnessed counting at most once a month, and allows for less-frequent witnessed counting if the master vault is accessed less often. I do not believe that is the intent of this policy, particularly given the “daily” logs referenced (but undefined) in V.C.4.b. 9 V.C.3.a Incomplete This does not allow for the possibility of CSOS documentation, for which the DEA does not require hard copies to be maintained in any location. This also does not mention the “copy of current DEA registration” specifically required in V.C.2.c, the line immediately preceding this one,

		despite this being a documentation requirement rather than a security measure. 10 V.C.4.b Incomplete This again does not take CSOS into consideration. Further, this refers to daily logs and maintenance that are not described elsewhere in this policy, making compliance with this policy a matter of guesswork rather than diligence and collaboration. The remainder of this policy refers only to inventory logs performed on initial registration, monthly, and biennially. For reference, 21 CFR 1304.11 does not require monthly logs to be kept. 11 V.C.4.c Incomplete While the California State Board of Pharmacy does require three years of records to be maintained per BPC 4105, the DEA only requires two years of records to be maintained per 21 CFR 1304.04(a). It may be helpful to amend this to clarify that the additional year of required records maintenance is a State requirement, such as by stating: "The following logs must be maintained at the agency for a period of no less than three years per California law:". This would then introduce an inconsistency, however, as it is not California law which requires that Schedule I/II and Schedule III/IV/V records be separately maintained. 12 V.C.4.c.3 Incomplete Ketamine (as noted in Part III of this policy) is a Schedule III medication. This line does not inform ALS agencies of how they need to maintain records related to Schedule III substances. They would need to directly consult 21 CFR 1304.04(f)(2) and 21 CFR 1304.04(g) to determine that they may be kept with the Schedule IV records (that in turn must be separate from the Schedule II records). 13 V.D.1 Inconsistent with good practice This should be updated to clarify that the individual units of administration should remain intact until administration (even though this is also not a DEA requirement). The "original manufacturer containers" contain larger amounts than should be reasonably stocked on a single EMS unit (e.g., an original manufacturer container of fentanyl vials may contain as many as 25 vials). 14 V.F.3 Inconsistent with DEA requirements This one sentence contains four distinct inconsistencies from DEA requirements: - the DEA only requires reporting for "theft or SIGNIFICANT loss" (emphasis added), not "any discrepancy" (see "1" below) - the DEA requires written reporting within one business day, not immediately - the DEA allows for paper Form 106 reporting in addition to the online Form 106 submission process - Form 106 is not the report for which written submission is required within one business day (see "2" below) 1) 21 CFR 1301.76(b) provides guidance on determining whether a loss is considered significant, which is also available at https://www.deadiversion.usdoj.gov/faq/theft_loss_faq.htm . 2) Form 106 asks questions that cannot be reasonably answered within one business day, much less "immediately",

		such as whether there have been previous losses from the common carrier used to transport controlled substances and what corrective measures HAVE been taken – not WILL be taken (emphasis added for both) – to prevent a future theft or loss. This distinction is made clear in 21 CFR 1301.76(b). 15 V.F.5 Inconsistent with DEA requirements The DEA neither requires nor desires several reports for a single incident, which is what this policy is requiring. At a minimum, I would expect at least one paramedic and the DEA registrant to "[have] knowledge of controlled substance diversion", and the pool of people having that knowledge could easily expand to other paramedics who witnessed an inventory count along with the agency's logistics manager, QA staff, field supervisor(s), and division/agency manager. If working with a fire department, that department's QA staff, EMS captain/chief, and fire chief/assistant chief would also likely be aware of the issue. Not only would the DEA frown upon receiving duplicative reports that each require independent investigation, but since V.F.3 (inaccurately – see Comment 14) requires this reporting to be done on Form 106, each person who files this report other than the registrant would be doing so inappropriately; the DEA registrant is the person who bears the statutory responsibility of submitting Form 106 (again, please refer to 21 CFR 1301.76(b)). 16 VI.B Inconsistent with V.F. V.F. requires reporting to both County of San Diego EMS and the DEA regardless of substantiation – no allowance is made in this section for investigation and verification of an inventory discrepancy – but this line requires reporting to County of San Diego EMS only if the suspicion is substantiated. 17 VI.C.1 Inconsistent with DEA requirements This line requires that reverse distribution be the method used for disposal of controlled substances. This is inconsistent with 21 CFR 1317.05(a), which allows for on-site destruction of controlled substances if the method of destruction meets the non-retrievable standard (see 21 CFR 1317.90).

County of San Diego EMS
A Division of San Diego County Fire

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S-400 Management of Controlled Substances for ALS Agencies		
DATE	**NAME**	**PUBLIC COMMENT**
2/23/2023	Sal Ruiz	It may be more effective language to include the form of record maintained must be a "durable and permanent record available for inspection at all times" (or some similar language over stating it must be "printed" or "written". This is because the language systems must print hard copies of their daily records and maintain them at the presently used in vault. If this is not what it is saying, it can certainly be interpreted that way. This conflicts with the waste reduction strategies of most public organizations and is a redundant process. Additionally, it could discourage agencies from using electronic inventory control systems, which have been favored thus far, a much more effective means of inventory control for CS.