August 11, 2017

By electronic mail

Mr. Timothy Lockwood
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Re: Comments Regarding Proposed Lethal Injection Regulations
CDCR's Second Notice of Change to Text as Originally Proposed

Dear Mr. Lockwood,

The American Civil Liberties Union of California continues to have grave concerns about the California Department of Corrections and Rehabilitation's ("CDCR" or "the Department") proposed lethal injection regulations.[1] The revisions do not address the defects raised by the Office of Administrative Law's December 28, 2016 Decision of Disapproval and only introduce additional areas of noncompliance with the Administrative Procedure Act. In addition, the flaws in the proposed regulations remain fundamental and cannot be remedied by amendments that tinker around the edges. CDCR should therefore decline to proceed with the proposed action. *See* Gov't Code § 11347. Instead, it should recommence its process for developing proposed lethal injection regulations and address in a meaningful fashion the fundamental flaws in its proposed protocol identified in these comments and the ACLU's previously submitted comments.

CDCR's changes in the text as originally proposed raise the following concerns:

1. Section 3349.1(h). Lack of clarity as to meaning of term "barbiturate."

This section defines the term "Lethal Injection Chemical" to mean a "barbiturate used to perform an execution." The term is a pharmacological term of art that does not have a meaning generally familiar to those directly affected by the regulation. Moreover, a barbiturate could take the form of a manufactured drug, a compounded drug, or the active pharmaceutical ingredient. The definition does not specify which form is intended, an ambiguity that is exacerbated by the

[1] The American Civil Liberties Union of California consists of the American Civil Liberties Union of Northern California, the American Civil Liberties Union of San Diego and Imperial Counties, and the American Civil Liberties Union of Southern California.

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revised definition of "Lethal Injection Supplier," which could include everything from a wholesaler (which might sell the active pharmaceutical ingredient), to a manufacturer (which would sell a manufactured drug), or a compounding pharmacy (which would sell a compounded drug). The regulation should be amended to address this ambiguity.

2. Section 3349.1(i). Lack of clarity as to the nouns that are modified by "licensed."

This section defines the term "Lethal Injection Chemical Supplier" to "mean[] a licensed pharmacy, pharmacist, or compounding pharmacy, or a manufacturer, supplier, wholesaler, or distributor."

The definition uses the conjunction "or" twice, which creates an ambiguity as to whether the modifier "licensed" modifies only those nouns that precede the first conjunction (pharmacy, pharmacist, or compounding pharmacy) or is also intended to modify the nouns that appear after the second "or" (manufacturer, supplier, wholesaler, or distributor). In other words, it is unclear whether the Lethal Injection Chemical Supplier must be licensed, regardless of whether it is a pharmacy, pharmacist, compounding pharmacy, manufacturer, supplier, wholesaler, or distributor, or instead whether it can be an *unlicensed* manufacturer, supplier, wholesaler, or distributor. Concerns about CDCR purchasing the lethal injection chemical from an unlicensed manufacturer are not abstract. Nebraska and South Dakota obtained sodium thiopental from India-based Kayem Pharmaceutical, whose owner publicly stated his company was not licensed to import the drug into the United States. *See* ACLU Substantive Comments, dated July 8, 2016, page 10 & Exh. 4. The definition should be amended to address this lack of clarity.

3. Section 3349.1(i). Lack of clarity as to meaning of term "licensed."

This section defines the term "Lethal Injection Chemical Supplier" to "mean[] a licensed pharmacy, pharmacist, or compounding pharmacy, or a manufacturer, supplier, wholesaler, or distributor." The term "licensed" is not defined. There are many types of licenses and licensing entities. State law, for example, requires a pharmacy to be "license[d]" by the California State Board of Pharmacy. Bus. & Prof. Code § 4200 (authorizing California State Board of Pharmacy to license pharmacists). But many local jurisdictions require businesses such as a pharmacy to obtain a local business license.[2] Does the regulation purport to authorize purchases from a pharmacy that had a local business license but not a license from the State Board of Pharmacy? Moreover, a pharmacy based out of state may have a license in that state, but not a license from the California State Pharmacy Board, which is necessary to sell compounded drugs in California. *See* Bus. & Prof. Code § 4112(a) ("Any pharmacy located outside this state that ships, mails, or delivery, in any manner, controlled substances… into this state shall be considered a nonresident pharmacy."); *id.* § 4112(b) ("A person may not act as a nonresident pharmacy unless he or she has obtained a license from the board."). Such a pharmacy would be "licensed" but any sale of drugs to CDCR would violate the state Pharmacy Act. *Id.* Does the regulation purport to

[2] *See, e.g.*, Oakland Business Assistance Center, "Get an Oakland Business License" ("To conduct any business in Oakland you must first obtain a Business License…."), available at https://oaklandbusinesscenter.com/index.php?option=com_content&task=view&id=63&Itemid=59.

authorize such a transaction? Further, federal law requires a pharmacy to be "registered" with the United States Attorney General in order to manufacture or distribute a controlled substance. 21 U.S.C. § 822. Does the regulation purport to authorize purchases from a pharmacy that has a state pharmacy license but is not registered with the federal government to sell controlled substances?

Moreover, even possession of a license does not ensure that the drugs are procured from a reputable source. For example, a compounding pharmacy known as the Apothecary Shoppe sold lethal injection drugs to Missouri corrections officials; it was licensed at the time but subsequent investigations by state and federal regulators revealed significant violations of pharmacy regulations.[3]

It is unclear what type of license the Lethal Injection Chemical Supplier must possess. The definition should be amended to address this lack of clarity.

4. Section 3349.1(i). Lack of clarity as to meaning of term "Lethal Injection Chemical Supplier."

This section defines the term "Lethal Injection Chemical Supplier" to "mean[] a licensed pharmacy, pharmacist, or compounding pharmacy, or a manufacturer, supplier, wholesaler, or distributor." In light of drug distribution chains, this term is confusing because it is unclear whether "Supplier" is intended to mean any of the entities in the distribution chain that fall into the enumerated categories, or only the last entity in the distribution chain that supplied the lethal injection chemical to CDCR. By way of illustration, the distribution chain for a manufactured version of the drug might look like this:

Manufacturer → Distributor → Pharmacy → CDCR

The distribution chain for a compounded version of the drug might look like this:

Wholesaler → Compounding Pharmacy → CDCR

Each of the entities in the chain would fall under the literal definition of the term "Lethal Injection Chemical Supplier." But in Sections 3349.2(d)(2)(A) and 3349.6(i)(3), the regulations refer to "*the* Lethal Injection Chemical Supplier." The use of the definitive "the" suggests that there is only one Lethal Injection Chemical Supplier," and creates an internal inconsistency with the definition of the term, which uses the article "a" in front of a long list of potential entities. This internal inconsistency creates an ambiguity as to whether "Lethal Injection Chemical Supplier" is intended to mean *all* of the entities in the distribution chain, or only *the last* entity in the chain. The definition should be amended to eliminate this ambiguity.

[3] Chris McDaniel, "Pharmacy That Mixed Executions Drugs Is Being Sold After Admitting Numerous Violations," Buzzfeed (April 21, 2016), available at https://www.buzzfeed.com/chrismcdaniel/pharmacy-that-mixed-execution-drugs-is-being-sold-after-disc?utm_term=.nymAQKDQ9#.dfyJ5bX5G, and attached as Exhibit 1.

5. Sections 3349.2(d)(2)(A) and 3349.6(i)(3). Lack of clarity as to term "the directions provided by the Lethal Injection Chemical Supplier."

Section 3349.2(d)(2)(A) provides that the Infusion Sub-Team members must "[b]e able to follow the directions provided by the Lethal Injection Chemical Supplier in preparing the Lethal Injection Chemical."

Section 3349.6(i)(3) provides: "The Lethal Injection Chemical shall be prepared according to the instructions provided by the Lethal Injection Chemical Supplier."

These changes were ostensibly made in order to address OAL's concern that the prior version of the proposed regulations did "not include procedures for when the Lethal Injection Chemical is obtained from compounding pharmacies." (OAL Decision of Disapproval at 10.) The new language simply introduces new problems.

The use of the definitive "the" to modify "directions" and "Lethal Injection Chemical Supplier" suggests that there is only *one* set of directions and *one* Lethal Injection Chemical Supplier.

But as discussed above, the definition of the term "Lethal Injection Chemical Supplier" could be construed to mean *all* of the entities in the distribution supply chain. But if that is so, what happens if multiple entities in the supply chain provide instructions: The regulations require the chemical to be prepared "according to *the* instructions," but which set of instructions? This situation is exacerbated if instructions from each entity are not consistent.

Alternatively, if "Lethal Injection Chemical Supplier" is construed to mean only the *last* entity in the supply chain (*e.g.*, the pharmacy), what happens if that entity provides no instructions and the only preparation instructions are provided by the manufacturer?

In addition, what if none of the entities in the supply chain provide instructions? How is the drug to be prepared? This is not an abstract concern. For example, what if CDCR obtains the Lethal Injection Chemical in the form of an Active Pharmaceutical Ingredient from a wholesaler? Wholesalers do not provide instructions on how to prepare drugs. In that instance, there would be no directions for the Infusion Sub-Team to follow.

The regulation's definition of the term "Lethal Injection Supplier" to encompass any entity in the distribution supply chain, coupled with the use of the definitive "the" to modify "directions" and "Lethal Injection Supplier," creates an ambiguity about which instructions are to be followed in preparing the Lethal Injection Chemical. The regulation should be amended to address this ambiguity.

6. Sections 3349.2(d)(2)(A) and 3349.6(i)(3). Failure to follow APA procedures regarding incorporation of documents by reference with respect to "the directions provided by the Lethal Injection Chemical Supplier."

These sections provide that the Lethal Injection Chemical is to be prepared "according to the directions provided by the Lethal Injection Chemical Supplier." The regulations do not themselves specify how the Lethal Injection Chemical is to be prepared and instead requires that it be prepared based on a document ("the directions provided by the Lethal Injection Chemical Supplier") that CDCR has not made available to the public. This deprives the public of the opportunity to provide meaningful comment on the preparation instructions, and violates the APA's requirements regarding incorporation of documents by reference. CCR, title 1, section 20, subdivision (c) sets forth the necessary demonstrations an agency must make when incorporating documents by reference. CDCR has not made any demonstrations justifying the incorporation by reference here.

7. Section 3349.6(i)(3). Lack of clarity as to term "prepared."

Section 3349.6(i)(3) provides: "The Lethal Injection Chemical shall be prepared according to the instructions provided by the Lethal Injection Chemical Supplier."

CDCR defines the term "Lethal Injection Chemical" to mean "barbiturate" but does not specify the form in which it will obtain the chemical (active pharmaceutical ingredient, manufactured, compounded). Section 3369.1(h). CDCR also defines the term "Lethal Injection Chemical Supplier" to include wholesalers (which sell active pharmaceutical ingredients), manufacturers (which sell manufactured drugs), and compounding pharmacies (which sell compounded drugs). Section 3369.1(i). It is unclear whether CDCR will purchase the Lethal Injection Chemical in the form of an active pharmaceutical ingredient, manufactured drug, or compounded drug. This is significant because the processes for preparing each of these different forms varies tremendously. *See* Comment of Professor Craig Stevens, dated March 24, 2017, at pages 2-7. As a result, it is unclear whether the term "prepared" refers to the complex chemical processes required to transform an active pharmaceutical ingredient into a drug that can be delivered to a person, or something else.

First, CDCR's explanatory text accompanying this change purports to address the ambiguity created by the regulatory language and states that it was made "for clarity to distinguish between the process of chemical preparation from the subsequent process of preparation for administration (i.e., filling and labeling syringes)…." (Second Notice at 3.) But this expansion of the regulation requirements creates a conflict between the language of the regulation (under which "prepare" could mean the complex chemical processes required to transform an active pharmaceutical ingredient into a drug that can be delivered to a person, or the less complex process of filling and labeling syringes), and the Department's description of the effect of the regulation (which appears to limit the definition of preparation to the latter).[4]

[4] To be sure, Section 3349.6(i)(4) now states "Preparation *for administration* of the lethal Injection Chemical shall be as follows:" and Section 3349.6(i)(4)(C) now states "The Infusion Sub-Team shall prepare the Lethal Injection Chemical *for administration* as follows:" (Emphasis added.) But "preparation for administration" could just as easily refer to the complex chemical processes needed to transform an active pharmaceutical ingredient into a form that can be administered to a person as the more straightforward processes of filling syringes for administration to a person. Thus, the modifier "for administration" does not resolve the ambiguity. Moreover, the modifier "for administration" appears in 3349.6(i)(4) and 3349.6(i)(4)(C), but not 3349.6(i)(3).

Second, to the extent the term "prepared" as used in 3349.6(i)(3) refers to the process of filling and labeling syringes, and does not refer to the chemical processes needed to transform an active pharmaceutical ingredient into a form that can be delivered to a person, the regulations contain no description of how CDCR is to undertake this latter process. In other words, to the extent "prepared" in this section means filling and labeling syringes, then the regulation means that CDCR staff are to fill and label syringes according to the instructions provided by the Lethal Injection Chemical Supplier, but provides no description of how CDCR is to perform the far more complex chemical process of preparing an active pharmaceutical ingredient into a form that can be administered to a person. As noted above, wholesalers that sell pharmaceutical ingredients do not typically provide instructions on how active pharmaceutical ingredients are to be prepared.

This ambiguity about the meaning of the word "prepared" and the lack of any instruction for how the Infusion Sub-Team is to prepare an active pharmaceutical ingredient, should CDCR acquire the Lethal Injection Chemical in that form, creates yet another clarity issue. The regulation should be amended to address these clarity concerns.

8. Section 3349.3(h)(2). Failure to follow APA procedures regarding incorporation of forms by reference.

The changes to the proposed text of 3349.3(h)(2) involve incorporation by reference of Forms 2177, 2177-B, 2179, 2181. But the Final Statement of Reasons does not contain the necessary demonstrations to incorporate documents by reference. *See* CCR, title 1, § 20(c). The Department's statement of reasons should be amended to address this defect.

9. Section 3349.5(f)(1)(C). Lack of necessity as to choice of drug.

First, CDCR initially included four drugs—Amobarbital, Pentobarbital, Secobarbital, and Thiopental—in the list of drugs from which the Warden was authorized to select the chemical to be used in a particular execution. The recent change removes Amobarbital and Secobarbital from the list. The Department states that these drugs were removed "in response to public comment that raised questions about the availability of these chemicals in the form needed by the Department, and whether these chemicals could be used as established in the proposed regulations." (Second Notice at 2.)

But prior public comment raised questions about the availability of *all* of the four drugs on the list. *See, e.g.,* ACLU Substantive Comments, dated July 8, 2016, at 11-12, Comment of Professor Craig Stevens, dated July 5, 2016, at 4-7. CDCR has not explained why, in light of the record evidence that all four drugs suffer from availability concerns, it chose to remove Amobarbital and Secobarbital. Are availability concerns with these drugs *more acute* than with the other two? CDCR has offered no explanation.

Second, CDCR has provided no explanation supported by the record for its choice of Pentobarbital. CDCR states:

> The original Initial Statement of Reasons for this subsection…noticed to the public in November 2015, contained the following statement: "All named barbiturates contained in the proposed regulations are equal to, or greater than, Thiopental in strength." After consideration of a public comment from a professor of pharmacology regarding the four chemicals originally established in the regulations, the Department believes that this statement is not sufficiently clear, as the meaning was not interpreted by the public as intended. The Department *believes* the remaining Lethal Injection Chemicals, Pentobarbital and Thiopental, are both effective in carrying out the purpose of the proposed regulations.

(Second Renotice at 2, emphasis added.) Professor Craig Stevens did indeed take issue with CDCR's assertion that the other barbiturates named in the regulations were equal to or greater than Thiopental in strength. He explained that the four drugs are not in fact pharmacologically equivalent. *See* Comment of Professor Craig Stevens, dated July 5, 2016, at 7-13. Although CDCR has at least attempted to articulate a rationale for its choice of Thiopental (*see* Second Renotice at 4), it points to no evidence regarding Pentobarbital, other than a conclusory "belief" that the drug will, for reasons unexplained, be "effective in carrying out the purpose of the proposed regulations."

The regulation fails to satisfy the necessity standard.

10. Section 3349.6(i)(1)(E). Lack of clarity as to Form to be used.

Section 3349.6(i)(1)(E) requires the Team Supervisor to ensure that a Record Keeping Sub-Team member initiate documentation procedures "on the CDCR Form 2177-A (06/17), San Quentin State Prison Lethal Injection Infusion Sub-Team Execution Log – Pentobarbital *or* CDCR Form 2177-B (06/17), San Quentin State Prison Lethal Injection Infusion Sub-Team Execution Log-Thiopental, upon receipt of the Lethal Injection Chemical by the Infusion Sub-Team members…." (Emphasis added.) But the regulation does not clarify which of these two forms are to be used. Can the form for Thiopental be used when the execution will be performed with Pentobarbital? The plain language of the regulation leaves open this possibility. The regulation should be amended to address this ambiguity.

11. Section 3349.6(i)(4). Lack of necessity regarding number of syringes.

The initial version of the regulation provided that the Lethal Injection Chemical was to be delivered in a 7.5 gram dose by means of five 60 cc syringes. The dosage and number of syringes was uniform, regardless of which barbiturate was designated for a particular execution. OAL's Decision of Disapproval stated: "The record does not explain why or how the Department determined that five syringes are necessary for administration of 7.5 grams…. Do the manufacturer's instructions …for each of the four listed barbiturates require or recommend use of a specified size and number of syringes, such as five 60 cc syringes?" (OAL Decision at 20.)

The current version maintains the 7.5 gram dose for all barbiturates, but now provides in Section 3349.6(i)(4) that Pentobarbital is to be delivered by three syringes, while Thiopental is to be delivered by five syringes. Regarding the decision to use three syringes for Pentobarbital, CDCR states "[t]he Department determined that using fewer syringes for Pentobarbital is preferable for simplicity of preparation of the syringes." (Second Notice at 4.) But if "simplicity" supported the decision to reduce the number of syringes being used, why did CDCR elect to use three, rather than two or one?

CDCR goes on to state: "The requirement to use five syringes [for Thiopental] … is unchanged." (*Id.*) The record still fails to explain why or how the Department determined that Thiopental should be delivered by means of five syringes. This is all the more troubling in that CDCR determined that three syringes, at least for Pentobarbital, was "preferable for simplicity of preparation of syringes." But if fewer than five syringes was preferable for Pentobarbital, why did CDCR choose to maintain the requirement of five for Thiopental?

CDCR references execution protocols in other states as support for its decision to use fewer than five syringes for Pentobarbital. (Second Notice at 4.) But none of these protocols support the regulation's requirement to use 5 syringes containing 1.5 grams each for Thiopental. Oklahoma and Idaho call for administration of a 5 gram dose to be delivered in *4* syringes containing *1.25* grams each.[5] Ohio calls for use of 5 syringes, but each syringe contains only 1 gram (because the total dose is 5 grams, unlike CDCR's 7.5 gram dose).[6]

Moreover, CDCR chose to omit reference in the regulations to the size of the syringe " because the Department will follow the instructions provided by the Lethal Injection Chemical Supplier, which may include instructions regarding the size of the syringe to be used." (Second Renotice at 5.) But what if the Lethal Injection Chemical Supplier's instructions include instructions regarding the number of syringes, and those instructions conflict with the requirement in the regulation to use 3 syringes for Pentobarbital or 5 syringes for Thiopental? In that situation, how many syringes should be used?

The Department's explanation does not demonstrate by substantial evidence the need for the regulation's requirement to use three syringes for Pentobarbital or five syringes for Thiopental, and therefore does not satisfy the necessity standard.

12. Section 3349.6(i)(4)(A). Lack of necessity as to dosage.

Issue 1: 7.5 gram dose. The regulation calls for the Lethal Injection Chemical to be administered in a 7.5 gram dose. OAL previously found CDCR's explanation of the need for a

[5] Oklahoma Dept. of Corrections, OP-040301, eff. June 30, 2015, Attachment D, page 2 of 10. (The Record contains a 2014 protocol from Oklahoma. See Record, Attachment G, Vol. VII, Doc. 9. These comments cite the more current 2015 protocol, which is attached as Exhibit 2 to these comments.)

[6] The only other protocol in the Record from a state that uses a one-drug protocol containing Thiopental is Kentucky, which calls for a 3 gram dose but does not specify the number of syringes. *See* 501 KAR 16:330, §3(2). The Record cites the 2012 version of the regulations. These comments cite the current version, which is attached as Exhibit 3 to these comments.

7.5 gram dose insufficient because CDCR failed to explain the basis for its decision to increase by 2.5 grams the purportedly lethal dose of 5 grams. (OAL Decision of Disapproval at 19.) The only explanation CDCR now provides that is not pure repetition of its earlier insufficient statements is the assertion that "the additional 2.5 grams was selected for simplicity and consistency, allowing an equal dose per syringe of Lethal Injection Chemical." (Second Notice at 4.) But CDCR offers no explanation why 2.5 grams is "simple" or "consistent." Choosing not to increase the dose beyond 5 grams is simple, as is doubling it or tripling it. All of these options are arbitrary. And as a mathematical matter, any dose could be divided equally among whatever number of syringes CDCR chooses.

Notably, the Record does not support the regulation's requirement regarding a 7.5 gram dose. None of the one-drug protocols cited in the Record call for a 7.5 gram dose.[7]

Although CDCR does not administer any excess drug after the inmate dies (Section 3349.7(c)(9)), any excess drug will be disposed and cannot be used for another purpose. (Section 3349.8(f).) CDCR will have had to purchase any excess drug at taxpayer expense.

The regulation's requirement to use a 7.5 gram dose does not satisfy the necessity standard.

Issue 2: Same dose for Pentobarbital and Thiopental. The regulation calls for the Lethal Injection Chemical to be administered in a 7.5 gram dose. Although the new changes now call for different means of administration for each drug, the regulation calls for the same total dosage for both drugs. CDCR at least attempts to cite evidence related to the dosage for Thiopental but cites no evidence related to the dosage for Pentobarbital. It then merely asserts the conclusion that "Both Pentobarbital and Thiopental are effective in carrying out the purpose of the proposed regulations." (Second Renotice at 4.) But it cites no Record evidence to support this conclusion, and this statement makes no reference to the *dosage* chosen.

Moreover, the Record evidence undercuts CDCR's decision to use the same dosage for both drugs. Kentucky uses a 3 gram dose for Thiopental and a 5 gram dose of Pentobarbital.[8] Even if some other states use the same dosage for Thiopental and Pentobarbital, what was the basis for CDCR's decision to follow that approach, rather than the approach in Kentucky?

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[7] *See, e.g.,* Georgia Dept. of Corrections, Lethal Injection Procedure (July 17, 2012) (Attachment I, Vol IX) at II-E-2, page 5 (5 grams); Idaho Dept. of Corrections, Execution Procedures (Adopted May 18, 1998, reviewed January 6, 2012) (Attachment I, Vol. IX) at Appendix A, pages 4-5 (5 grams); Texas Dept. of Criminal Justice, Execution Procedure (Juy 2012) (Attachment I, Vol. IX) at VI-B, page 8 (5 grams); Ohio Dept. of Rehabilitation and Correction, Number 01-COM-11, Execution Policy (October 7, 2016) (Attachment I, Vol. IX) at page 12 (5 grams); Kentucky Administrative Regulations, 501 KAR 16:330, §3(2) (3 grams Thiopental or 5 grams Pentobarbital) (attached as Exhibit 3). North Carolina Dept. of Corrections, Execution Procedure Manual for Single Drug Protocol (Pentobarbital) (October 24, 2013) (Attachment G, Vol. VII) at IX-4, page 14 (5 grams); Oklahoma Dept. of Corrections, OP-040301, eff. June 30, 2015, Attachment D, page 2 of 10 (2014 version cited in Record at Attachment G, Vol VII, Doc. 9; 2015 version attached as Exhibit 2 to these comments).

[8] Kentucky Administrative Regulations, 501 KAR 16:330, §3(2) (3 grams Thiopental or 5 grams Pentobarbital) (attached as Exhibit 3)

The regulation's requirement to use the same dosage for Thiopental and Pentobarbital fails to satisfy the necessity standard.

13. Section 3349.7(a)(3). Lack of clarity as to insertion of catheters.

Section 3349.7(a)(3) states that the Intravenous Sub-Team is to "[a]ttach the intravenous lines to the catheters and insert three catheters into pre-designated veins." This states that three catheters are to be inserted but does not make clear how they are to be distributed across the pre-designated veins, of which there are three. (See Section 3349.5(f)(6).) Is each of the three pre-designated veins to have one catheter inserted, or can more than one catheter be inserted into a single vein, in which case at least one of the veins will have no catheter?

CDCR's accompanying explanation states: "all three injections sites described in subsection 3349.5(f)(6) shall have catheters inserted…." (Second Renotice at 5.) This indicates that each of the three injection sites is to have at least one catheter inserted. To the extent this resolves the ambiguity created by the regulatory text, this expands the regulation's requirements and creates a conflict between the regulation and the Department's description of its effect. If CDCR intended that one catheter be inserted into each of the three pre-designated veins, it should have said so. But it did not, and the language it uses is unclear. The regulation should be amended to address this clarity issue.

14. Sections 3349.7(c)(4) and 3349.7(c)(5). Lack of clarity as to term "administer."

> Section 3349.7(c)(4) provides: "If Pentobarbital has been designated, the Lethal Injection Chemical shall be administered, beginning with Tray A and using the primary intravenous catheter, as follows…"
>
> Section 3349.7(c)(5) provides: "If Thiopental has been designated, the Lethal Injection Chemical shall be administered, beginning with Tray A and using the primary intravenous catheter, as follows…"

The regulation does not contain a description of *how* the Lethal Injection Chemical is to be "administered." There are multiple forms of IV administration. These include what is known as an "IV push," also known as a "bolus," which is "a rapid injection of medication" in which a syringe is inserted into a "catheter to quickly send a one-time dose" into the bloodstream.[9] Another standard method is "IV infusion," which "is a controlled administration of medication into [the] bloodstream over time. The two main methods of IV infusion use either gravity or a pump to send medication into your catheter."[10] "In the United States, a pump infusion is the most common method used"; pumps are "used when the medication dosage must be precise and controlled."

[9] "Intravenous Medication Administration: What to Know," healthline.com, available at http://www.healthline.com/health/intravenous-medication-administration#standard-iv-lines3, and attached as Exhibit 4.
[10] *Id.*

The regulation does not contain a description of whether the Lethal Injection Chemical is to be administered by IV push/bolus or IV infusion, and if the latter whether by gravity or pump. Critically, there is no description whatsoever of the rate of infusion.

While the regulation provides no clarity as to the method of administration or rate of infusion, CDCR's accompanying text states:

> A 1.5 gram bolus dose of Thiopental will result in unconsciousness….Bolus means a quantity of medicine given at a controlled rapid rate….*Thus administration of continuous bolus doses is required*…When the Lethal Injection Chemical is administered in continuous bolus doses via an intravenous line, rapid anesthesia followed by death without pain and suffering will result.

(Second Notice at 4; emphasis added.) This apparently indicates CDCR's intent to administer using the bolus, rather than infusion, method. But this expansion of the regulation requirements creates a conflict between the language of the regulation and the Department's description of it.

In addition, CDCR's statements underscore the importance of delivering the drug "at a *controlled* rapid rate" (*id.*; emphasis added), yet the rate is nowhere specified. This ambiguity creates an additional clarity issue.

The regulation should be amended to address these clarity issues.

15. Sections 3349.7(c)(3), 3349.7(c)(10), and 3349.7(c)(11). Lack of clarity as to "ten minute countdown."

The regulation provides for the administration of up to three doses of the Lethal Injection Chemical. Each dose is distributed among a specified number of syringes (three in the case of Pentobarbital and five in the case of Thiopental), on Trays labeled A, B and C, respectively. The regulation requires the syringes, in the case of Pentobarbital, to be labeled: "#A-1, #A-2, and #A-3 for Tray A, #B-1, #B-2, and #B-3 for Tray B, and #C-1, #C-2, and #C-3 for Tray C." Section 3349.6(i)(4)(D). The regulation requires the syringes, in the case of Thiopental, to be labeled: "#A-1, #A-2, #A-3, #A-4, and #A-5 for Tray A, #B-1, #B-2, #B-3, #B-4, and #B-5 for Tray B, and #C-1, #C-2, #C-3, #C-4, and #C-5 for Tray C." Section 3349.6(i)(4)(E).

> Section 3349.7(c)(3) provides: "A Record Keeping Sub-Team member in the Infusion Control Room shall initiate *a ten minute countdown* at the start of the infusion of syringe #1. (Emphasis added.)
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> Section 3349.7(c)(10) provides: "In the event all syringes from Tray A have been administered, *the ten minute countdown* has elapsed and death has not been declared, or an intravenous site cannot be maintained at the primary site, the Record Keeping Sub-Team member shall advise the Team Supervisor, who shall then advise the Team Administrator and the San Quentin Warden. The San Quentin Warden shall direct the

> Lethal Injection Chemical process set forth in subsections (2)-(9) be repeated, but using the backup intravenous catheter and the syringes from Tray B." (Emphasis added.)
>
> Section 3349.7(c)(11) provides: "In the event all syringes from Tray B have been administered, *the ten minute countdown* has elapsed and death has not been declared, or an intravenous site cannot be maintained at the backup site, the Record Keeping Sub-Team member shall advise the Team Supervisor, who shall then advise the Team Administrator and the San Quentin Warden. The San Quentin Warden shall direct the Lethal Injection Chemical process set forth in subsections (2)-(9) be repeated, but using the alternate backup site and Tray C." (Emphasis added.)

It is unclear if there is a single ten minute countdown initiated upon the start of the infusion of syringe #1 in Tray A, or if a new ten minute countdown is initiated upon the infusion of syringes #A-1, #B-1, and #C-1. The ambiguity arises for two reasons.

First, Section 3349.7(c)(3) calls for initiation of "a ten minute countdown at the start of the infusion of syringe #1." But Sections 3349.6(i)(4)(D) and 3349.6(i)(4)(E) specifically call for the syringes to be labeled with a number *and the letter* corresponding to the tray. There are no syringes that have solely a number without a letter corresponding to a tray. Thus, under the regulation, there is no syringe that has the label "#1," thus creating a clarity issue.

Second, use of the language "*a* ten minute countdown" in Section 3349.7(c)(3) is inconsistent with use of the definitive language "*the* ten minute countdown" in Sections 3349.7(c)(10) and 3349.7(c)(11), which means that there is only a single ten minute countdown. This internal inconsistency creates a clarity issue.

The regulation should be amended to address these clarity issues.

16. Section 3349.7(c)(12). Lack of clarity as to when "ten minutes" commence.

> Section 3349.7(c)(12) provides: "In the event all syringes of Lethal Injection Chemical from Tray C have been administered, *ten minutes has elapsed*, and death has not been declared, or an intravenous site cannot be maintained at the alternate backup site, the San Quentin Warden shall stop the execution and summon medical assistance for the inmate as set forth in subsection (d)."

(Emphasis added.)

It is unclear when the "ten minutes" referenced in this section was supposed to commence. This ambiguity is exacerbated by the contrasting use of the distinct (albeit ambiguous) term "ten minute countdown" in Sections 3349.7(c)(10) and 3349.7(c)(11). Ten minutes from when? Whenever this ten minute period commences, it is different from "the ten minute countdown" referenced in Sections 3349.7(c)(10) and 3349.7(c)(11) because CDCR explicitly chose to use a different term. The regulation should be amended to address this clarity issue.

17. Section 3349.7(c)(6.). Lack of clarity and necessity.

> Section 3349.7(c)(6) provides: "If, following the administration of syringe #1 the assessment indicates the inmate is not unconscious, the Intravenous Sub-Team member shall check the catheter for patency. After checking for patency, syringe #2 shall be administered followed by a second consciousness assessment of the inmate in the same manner as described in subsection (c)(4)(A). If the assessment indicates the inmate is not unconscious, the San Quentin Warden shall direct that the injection through the primary intravenous catheter be discontinued and the entire sequence re-initiated with the Lethal Injection Chemical on Tray B using the designated backup intravenous catheter."

Issue 17.1. Lack of clarity as to "patency."

The term "patency" does not have a meaning generally familiar to those directly affected by the regulation and is not defined in the regulation or governing statute. The regulation should be amended to address this clarity issue.

Issue 17.2. Lack of necessity as to patency check.

The regulation calls for the Intravenous Sub-Team member to check the catheter for patency after administration of syringe #1 if the consciousness assessment indicates the inmate is not unconscious. But it then directs the administration of syringe #2 "[a]fter checking for patency." The regulation thus requires syringe #2 to be administered "[a]fter" the patency check, and regardless of what it reveals. CDCR does not explain why it is necessary to engage in a patency check, and the regulation as drafted suggests that the patency check serves no purpose because the same outcome follows (administration of syringe #2) irrespective of the result of the patency check. The regulation's requirement to perform a patency check thus fails the necessity standard.

Issue 17.3 Lack of clarity as to consciousness assessment. This section calls for two consciousness assessments to be performed, one after syringe #1 and another after syringe #2. But it then provides that "If *the assessment* indicates the inmate is not unconscious, the San Quentin Warden shall direct" that certain steps occur. The use of the definitive "the" creates a clarity issue because the regulation calls for two assessments. To which assessment does this refer? The regulation should be amended to address this clarity issue.

Issue 17.4. Lack of necessity as to point at which primary intravenous catheter discontinued.

The regulation calls for discontinuation of the primary intravenous catheter and re-initiation of the sequence with Tray B if the consciousness assessment indicated the inmate is not unconscious. This step applies regardless of which barbiturate is designated as the Lethal Injection Chemical. But each syringe of Pentobarbital contains 2.5 grams and each syringe of Thiopental contains only 1.5 grams. (See Section 3349.6(i)(4)(A)&(B).) The consciousness

assessment that triggers discontinuation and re-initiation occurs either after administration of syringe #1 or syringe #2. (See Issue 17.3.) If it occurs after administration of syringe #1, then it occurs after administration of 2.5 grams of Pentobarbital but only 1.5 grams of Thiopental. If it occurs after administration of syringe #2, then it occurs after administration of 5 grams of Pentobarbital and 3 grams of Thiopental.

CDCR does not explain how it selected this particular point in the sequence for performance of the consciousness assessment that triggers discontinuation of the tray. Why is it appropriate after infusion of 2.5/5 grams of Pentobarbital, but only 1.5/3 grams of Thiopental? If the total dose of Pentobarbital and Thiopental is the same, why does this step occur when different proportions of the overall dose for each drug has been administered (1/3 or 2/3 for Pentobarbital but only 1/5 or 2/5 for Thiopental)?

The regulation's requirement to perform the consciousness assessment that triggers discontinuation of the tray at this particular juncture in the procedure does not satisfy the necessity standard.

18. Section 3349.7(c)(6), 3349.7(c)(10), and 3349.7(c)(11). Lack of clarity as to repetition of process set forth in subsection 3349.7(c)(6).

Sections 3349.7(c)(1)-(9) set forth the process for administering the first dose of the Lethal Injection Chemical in Tray A. One of the steps in that process provides as follows:

> If, following the administration of syringe #1 the assessment indicates the inmate is not unconscious, the Intravenous Sub-Team member shall check the catheter for patency. After checking for patency, syringe #2 shall be administered followed by a second consciousness assessment of the inmate in the same manner as described in subsection (c)(4)(A). If the assessment indicates the inmate is not unconscious, the San Quentin Warden shall direct that the injection through the primary intravenous catheter be discontinued and *the entire sequence re-initiated with the Lethal Injection Chemical on Tray B using the designated backup intravenous catheter*. (Section 3349.7(c)(6); emphasis added.)
>
> Section 3349.7(c)(10) provides that if certain triggering events occur during or upon completion of administration of Tray A, "[t]he San Quentin Warden shall direct the Lethal Injection Chemical process set forth in subsections (2)-(9) be repeated, *but using the backup intravenous catheter and the syringes from Tray B.*" (Emphasis added.)
>
> Section 3349.7(c)(11) provides that if certain triggering events occur during or upon completion of Tray B, "[t]he San Quentin Warden shall direct the Lethal Injection Chemical process set forth in subsections (2)-(9) be repeated, *but using the alternate backup site and Tray C*." (Emphasis added.)

Administration of Tray B. Per Section 3349.7(c)(10), if certain events occur, then the sequence set forth in subsections (2)-(9), including subsection (6), are to be repeated "but using

the backup intravenous catheter and the syringes from Tray B." CDCR staff must thus proceed through the sequence using the backup intravenous catheter and Tray B. But pursuant to subsection (6) of that sequence, if certain events occur, "the San Quentin Warden shall direct that the injection *through the primary intravenous catheter be discontinued* and *the entire sequence re-initiated with the Lethal Injection Chemical on Tray B using the designated backup intravenous catheter*." But at this juncture, staff are *already using* Tray B and the backup intravenous catheter. It is unclear how they could at this juncture "re-initiate" the sequence with Tray B and the designated backup intravenous catheter.

Administration of Tray C. Similarly, per Section 3349.7(c)(11), if certain events occur, then the sequence set forth in subsections (2)-(9), including subsection (6), are to be repeated, "but using the alternate backup site and the syringes from Tray C." CDCR staff must thus proceed through the sequence using the alternate backup site and Tray C, but pursuant to subsection (6) of that sequence, if certain events occur, "the San Quentin Warden shall direct that the injection *through the primary intravenous catheter be discontinued* and *the entire sequence re-initiated with the Lethal Injection Chemical on Tray B using the designated backup intravenous catheter*." But at this juncture, staff are using the alternate backup site and the syringes from Tray C. It is unclear how they could at this juncture "re-initiate" the sequence with Tray B, which has at this juncture either already been fully administered or was discontinued.

The regulation should be amended to address these ambiguities.

19. Sections 3349.7(c)(10) and 3349.7(c)(10). Lack of clarity as to non-parallel language regarding initiation of subsequent tray.

Section 3349.7(c)(10) provides that if certain triggering events occur during or upon completion of administration of Tray A, then the process will repeat "but using the backup intravenous *catheter* and *the syringes* from Tray B." (Emphasis added.)

Section 3349.7(c)(11) provides if certain triggering events occur during or upon completion of administration of Tray B, then the process will repeat "but using the alternate backup *site* and *Tray C*." (Emphasis added.)

It is unclear why (c)(10) refers to a "backup intravenous *catheter*" but (c)(11) refers to an "alternate backup *site.*" These provisions appear intended to be parallel but one uses the noun "catheter" and the other the different noun "site." There must be a reason for the different terminology but that reason is not clear.

Similarly, (c)(10) refers to "the syringes from Tray B" but (c)(11) refers to "Tray C," without any reference to the syringes in Tray C. What is the reason for the different terminology in these otherwise parallel provisions?

The regulation should be amended to address this ambiguity.

20. Sections 3349.7(c)(10) and 3349.7(c)(11). Lack of clarity as to triggering conditions for initiation of subsequent tray.

Section 3349.7(c)(10) provides: "In the event all syringes from Tray A have been administered, the ten minute countdown has elapsed *and death has not been declared*, or an intravenous site cannot be maintained at the primary site," then the process will repeat using the subsequent tray.

Section 3349.7(c)(11) provides "In the event all syringes from Tray B have been administered, the ten minute countdown has elapsed *and death has not been declared*, or an intravenous site cannot be maintained at the backup site," then the process will repeat using the subsequent tray.

There are three different triggering conditions in (c)(10) and (c)(11): (1) all syringes from the Tray were used, (2) the ten minute countdown elapsed, and (3) the intravenous site cannot be maintained. But only one of the three triggering conditions is coupled with the phrase "and death has not been declared." As a linguistic matter, this means that the other two conditions trigger the subsequent events *even if death has been declared*. In other words, use of all syringes or the fact that an intravenous site cannot be maintained requires administration of the next tray, even if the inmate has died.

But this creates a conflict with a separate provision that requires cessation of any infusion of the Lethal Injection Chemical once death has been declared. *See* Section 3349.7(c)(9). This conflict between (c)(9)'s requirement to cease the execution process once death is declared, but the requirement in (c)(10) and (c)(11) to proceed to the next tray when either all syringes have been administered or the intravenous site cannot be maintained – and even if death has been declared – creates a clarity issue.

The regulation should be amended to address this clarity issue.

21. Section 3349.7(c)(12). Lack of necessity as to Tray C.

In the event the inmate has not died after administration of the first dose (Tray A), the regulation calls for initiation of a second dose (Tray B), and if that does not cause the inmate's death, the regulation calls for initiation of a third dose (Tray C). CDCR has not explained why it is necessary to have *two* back-up doses. CDCR contends that 5 grams is lethal, and has already elected to administer an additional 2.5 grams. Even if the inmate dies, and the additional doses are not administered, the drug cannot be re-used. *See* Proposed Section 3349.8(f) (any unused chemical will be placed in a safe to await disposal). CDCR will still have had to purchase the drug at taxpayer expense. While Georgia's protocol calls for two back-up doses,[11] Texas and

[11] Georgia Dept. of Corrections, Lethal Injection Procedure (July 17, 2012) (Attachment I, Vol IX) at II-E, page 5.

Ohio only call for one back-up dose.[12] How did CDCR decide to opt for two back-up doses, rather than one?

The agency has not explained why the regulation's requirement for two back-up doses is necessary.

* * *

For the foregoing reasons, the proposed regulations are deeply flawed and CDCR has failed to remedy their defects. CDCR should decline to proceed with the proposed action. If it does not, OAL should disapprove these regulations.

Sincerely,

Linda Lye
Senior Staff Attorney

Enclosures

[12] Texas Dept. of Criminal Justice, Execution Procedure (Juy 2012) (Attachment I, Vol. IX) at VI-C, page 8; Ohio Dept. of Rehabilitation and Correction, Number 01-COM-11, Execution Policy (October 7, 2016) (Attachment I, Vol. IX) at page 12.

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Exhibits

Exhibit 1 Chris McDaniel, "Pharmacy That Mixed Executions Drugs Is Being Sold After Admitting Numerous Violations," Buzzfeed (April 21, 2016), available at https://www.buzzfeed.com/chrismcdaniel/pharmacy-that-mixed-execution-drugs-is-being-sold-after-disc?utm_term=.nymAQKDQ9#.dfyJ5bX5G

Exhibit 2 Oklahoma Dept. of Corrections, OP-040301, eff. June 30, 2015, Operating Procedure 040301, effective June 30, 2015 and Attachment D, available at (https://www.ok.gov/doc/documents/op040301.pdf and https://www.ok.gov/doc/documents/040301ad.pdf)

Exhibit 3 501 Ky. Admin. Regs 16:330, Lethal injection protocols.

Exhibit 4 Intravenous Medication Administration: What to Know," healthline.com, available at http://www.healthline.com/health/intravenous-medication-administration#standard-iv-lines3.

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EXHIBIT 1

https://www.buzzfeed.com/chrismcdaniel/pharmacy-that-mixed-execution-drugs-is-being-sold-after-disc?utm_term=.owlMeB6mJ#.jvrzj9ynE

Politics

Pharmacy That Mixed Executions Drugs Is Being Sold After Admitting Numerous Violations

A small compounding pharmacy in Oklahoma sold execution drugs for at least three Missouri executions. When investigators later inspected the pharmacy, they found “significant” problems, and it later defaulted on its bank loans.

Posted on April 21, 2016, at 7:45 p.m.

Chris McDaniel
BuzzFeed News Reporter

After admitting to more than a thousand pharmaceutical violations, a pharmacy that sold execution drugs to Missouri auctioned off its assets last week after it defaulted on its loans. The sale is expected to be finalized in the coming weeks.

The Apothecary Shoppe, based in Tulsa, Oklahoma, mixed execution drugs for at least three executions held in Missouri in 2013 and 2014. A year after its identity became public, the pharmacy faced investigations by state and federal regulators that revealed “significant” violations of pharmacy regulations, BuzzFeed News has learned.

The pharmacy issued a recall on some of the drugs it made, and was forced to shut down its mixing practice for a time. Its license is currently on probation.

In March 2015, a year after its role in selling lethal drugs had been revealed, the Food and Drug Administration inspected the pharmacy. Two investigators found questionable potency, disinfecting and sterilization practices. In response to a Freedom of Information Act request, an FDA official told BuzzFeed News in late February that the investigation is ongoing.

A month after the FDA inspection, however, investigators with the Oklahoma Board of Pharmacy arrived at the facility as part of a routine inspection. Over the next few months, the three investigators would find hundreds of violations of pharmacy guidelines at the facility.

While inspectors were there, they observed pharmacy techs wearing no masks or goggles while compounding drugs. Pharmacists were storing drugs in a blue Igloo cooler so they wouldn’t have to walk to the proper refrigeration unit in another room; regulators seized the blue cooler and the drugs it was storing. The pharmacy was extending the expiration date on its drugs without proper testing or documentation, and used questionable sterilization practices.

https://www.buzzfeed.com/chrismcdaniel/pharmacy-that-mixed-execution-drugs-is-being-sold-after-disc?utm_term=.owlMeB6mJ#.jvrzj9ynE

Compounding pharmacies, unlike drug manufacturers, mix drugs based on specific prescriptions. They are lightly regulated by the FDA, and the products they make have a significantly higher failure rate than manufactured drugs.

State regulators caught the Apothecary Shoppe making a testosterone injection without a legitimate medical need — and said the drug should have instead been made by manufacturers. The head pharmacist, David Kent Johnson, told the board regulators that he would stop making that drug immediately.

The investigators also discovered unexplained irregularities in a lab certification. In a complaint, the board noted that in the first certification report they received indicated the pharmacy was operating without its lab being certified for a time.

“Another copy of the report was given to [investigators] on June 9, 2015; this report appeared to have been altered,” the board wrote in a complaint against the pharmacy.

Investigators “were not able to ascertain if the documents were changed by the inspection company or by the pharmacy,” said Cindy Fain, Chief Compliance Officer for the board. “That’s why the statement is so vague in the Complaint.”

The regulators gave Johnson a letter on May 28, 2015, noting all of the violations, and asking the pharmacy to recall its drugs and stop making new drugs until it complied with regulations. They also asked for more documentation about the pharmacy’s practices.

Johnson responded with a letter the next day that regulators wrote was “inadequate, and the required documentation was not produced.” They returned to the pharmacy weeks later and found the pharmacy “in significant violation of [pharmacy] guidelines.”

The board of pharmacy subpoenaed the Apothecary Shoppe’s records and again asked for a recall and for it to stop its compounding. This time, the pharmacy acquiesced.

In total, the pharmacy admitted guilt to an astounding 1,892 violations of state pharmacy guidelines. Johnson agreed to guilt on 1,887 violations, and neither admitted nor denied violating the other five requirements.

The pharmacy declined to comment on the violations.

The licenses of the Apothecary Shoppe and Johnson were both placed on probation for five years. They also had to pay $50,000 in fines altogether, and Johnson will undergo additional training. The Oklahoma Board of Pharmacy said the fine has been paid and the pharmacy can continue to compound drugs while the licenses are on probation.

The pharmacy’s receiver, put in place by a court, said the potential buyers were all aware of the pharmacy’s regulation problems.

“The issues have all been cleared,” David Rhoades said. “It did not have anything to do with the financial troubles. It was disclosed to all potential purchasers.”

Many of these violations were similar to concerns raised years ago by death row inmates in Missouri, who questioned the qualifications of the drug maker that the state had tried to keep secret.

“Compounding-pharmacy products do not meet the requirements for identity, purity, potency, efficacy, and safety that pharmaceuticals produced under FDA regulation must meet,” the inmates argued in court. Among the possibilities they listed, were that the drug may not be sterile, may be less potent than it needs to be, or may be contaminated.

The state responded that their concerns were speculation.

“What the [inmates] allege, is that if the pharmacist makes a serious mistake in compounding the pentobarbital, or uses the wrong ingredients, and if the laboratory, which tests the chemical for purity, potency, and sterility, fails to catch the error through accident or incompetence, then something could go wrong with an execution,” the state wrote, arguing the lawsuit should be dismissed.

“[This] allegation does not make a plausible claim that Missouri’s execution procedure is sure or very likely to cause serious illness or needless suffering and give rise to sufficiently imminent dangers.”

Attorney General Chris Koster’s office did not respond to a request for comment about the Apothecary Shoppe’s inspections.

In November 2015, months after the Board of Pharmacy and the FDA investigated the facility, the pharmacy defaulted on its loans. The bank took the Apothecary Shoppe to court, placing a court-approved receiver in charge to run the business. Last week, an Oklahoma company called Marcain Properties bid the highest on the Apothecary Shoppe’s assets. The company is affiliated with other pharmacy businesses in the area.

According to the Apothecary Shoppe’s receiver, the plan is currently to keep on the pharmacy’s employees. The new owners may change the name, he said.

That a pharmacy with such questionable policies could be selected by the state to provide drugs for lethal injections happened, in part, because of the shroud of secrecy put in place just before the state decided to use the Apothecary Shoppe for its execution drugs.

In October 2013, Gov. Jay Nixon announced the Department of Corrections would be expanding secrecy around executions. For the first time in the state, the execution drug supplier would be confidential. Behind the scenes, a select few individuals in the Department of Corrections selected the Apothecary Shoppe which, at the time, was not licensed to sell in the state.

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Although Missouri attempted to keep the pharmacy's identity hidden, going so far as to pay the pharmacy more than $30,000 in cash, an un-redacted document from 2013 pointed to the Apothecary Shoppe. An email also indicates that the pharmacy offered to supply execution drugs to Louisiana.

The Apothecary Shoppe stopped selling execution drugs in February 2014, after death row inmates sued the pharmacy. In turn, the state found a new execution drug supplier and has withheld all information about the pharmacy. Earlier this year, a state judge ruled that the expanded secrecy violates state law.

Gov. Jay Nixon's office, as well as the Missouri Department of Corrections, which he oversees, did not respond to requests for comment.

Recently, other states have begun to employ the expanded execution secrecy like Missouri has. States that carry a lot of executions out like Texas, Oklahoma and Florida all attempt to keep their drug suppliers hidden.

Georgia also has a secret compounding pharmacy mix its lethal injection drugs. Last year, the state had to call off an execution after the syringe had particles floating in it.

Arkansas executions are currently on hold after a state judge found the state's secrecy law violated the state constitution. The issue is now before the Arkansas Supreme Court.

Texas and Arizona purchased illegal execution drugs from a supplier in India, and attempted to keep the purchase hidden. The FDA is currently detaining the shipment.

Virginia could be the next state to expand its secrecy. Last week, Gov. Terry McAuliffe called for more secrecy for its potential execution drug suppliers. His office did not respond when asked about the situation in Missouri.

Virginia Attorney General Mark Herring said in a legal opinion this week that McAuliffe's proposal would be legal. When approached with the problems Missouri has faced, his office said it is a policy decision for lawmakers and the governor to decide.

The "Attorney General's recent opinion just laid out his best evaluation of what the law allows and requires in this area, and it will be for the General Assembly to set the state's policy within those limits," a spokesperson said.

After Gov. McAuliffe called for the measure, the Virginia legislature approved on Wednesday a bill that would grant anonymity to its executioners. McAuliffe is expected to sign it.

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EXHIBIT 2

Section-04 Security	OP-040301	Page: 1	Effective Date: 06/30/2015
Execution Procedures	ACA Standards: 2-CO-1A-27-1		

Robert Patton, Director **Signature on File**
Oklahoma Department of Corrections

Execution of Offenders Sentenced to Death

The Oklahoma Department of Corrections (ODOC) establishes procedures for planning and carrying out the execution of a person convicted of a capital offense and sentenced to death. These procedures shall be followed as written unless deviation or adjustment is required, as determined by the director of Corrections or their designee (in the event of an absence). This procedure outlines the internal procedures and does not create any legally enforceable rights or obligations.

I. Definitions

A. Stay or Stop An Execution

1. Stay

An order by the governor or court of competent jurisdiction to reprieve or suspend the execution of the judgment of death.

2. Stop

Upon order by the director, all acts congruent to an execution shall immediately cease until the director orders the execution to continue or a stay is ordered by the governor or court of competent jurisdiction.

II. Responsibility

The ODOC ensures the execution of a person sentenced to death under state law by a court of competent authority and jurisdiction is carried out in keeping with statute, case law and professional practices.

A. The ODOC shall make every effort in the planning and preparation of an execution to ensure the execution process:

1. Faithfully adheres to constitutional mandates against cruel and unusual punishment, in accordance with Article II, Section 9 of the Oklahoma Constitution and the Eighth Amendment to the United States Constitution;

2. Is handled in a manner that minimizes its impact on the safety, security and operational integrity of the facility and the community in which it occurs;

3. Accommodates the public's right to obtain certain information concerning the execution;

4. Reasonably addresses the privacy interests as provided by law;

5. Provides contingency planning to identify and address unforeseen problems;

6. Allows for stays of execution, commutations and other exigencies;

7. Provides opportunity for citizens to exercise their First Amendment Rights to demonstrate for or against capital punishment in a lawful manner; and

8. Ensures there is an appropriate response to unlawful civil disobedience, trespass and other violations of the law by any person attempting to impact the execution or the operation of the facility.

B. The ODOC shall detain, seek the arrest and encourage prosecution of persons who:

1. Violate prohibitions against filming, taping, broadcasting or otherwise electronically documenting the execution of the offender;

2. Trespass and otherwise enter upon ODOC property without authorization;

3. Participate in unlawful demonstrations or unlawfully attempt to disrupt, prevent and otherwise interfere with the execution; and

4. Unlawfully threaten, intimidate and otherwise attempt to influence authorized persons involved in the execution process.

These prohibitions apply to the offender population, ODOC personnel and members of the general public engaging or attempting to engage in disruptive and other prohibited behaviors.

III. Conduct and Selection of Staff for Execution Teams

A. Conduct of Staff

1. Participating staff shall adhere to OP-110215 entitled “Rules Concerning the Individual Conduct of Employees” and guided principles evidenced by:

a. Appropriate levels of professionalism, restraint and courtesy when interacting with witnesses, demonstrators, attorneys, news media, state and local law enforcement and any other member of the public directly or indirectly involved with the imposition of the sentence of death;

b. All assigned duties are performed proficiently and professionally;

c. Their ability to exercise the option to withdraw from the process by the prescribed means at any time;

d. Conduct that appropriately reflects the solemnity of the activities in which they elect to engage and the duties they choose to perform;

e. Reserving public comment on any and all facets of the execution; and

f. Maintaining confidentiality of identifying information regarding any person who participates in or performs any function of an execution. As defined in Oklahoma State Statute Title 22, Section 1015, "The identity of all persons who participate in or administer the execution process and persons who supply the drugs, medical supplies or medical equipment for the execution shall be confidential and shall not be subject to discovery in any civil or criminal proceedings. The purchase of drugs, medical supplies or medical equipment necessary to carry out the execution shall not be subject to the provision of the Oklahoma Central Purchasing Act."

2. All team members serve on a strictly voluntary basis. At any point before, during, or after an execution any team member may decline to participate or participate further without additional notice and explanation or repercussion.

3. The associate director of Field Operations shall ensure all team members understand and comply with the provisions contained herein.

B. Selection of Staff for Execution Teams

1. The associate director of Field Operations coordinates the activities of the division managers of East and West Institutions and the wardens of Oklahoma State Penitentiary (OSP) and Mabel Bassett Correctional Center (MBCC) in activating the Execution Teams.

2. The OSP and MBCC wardens shall review the current teams' rosters and recommend retention and replacement of staff and alternates to the division manager of West Institutions.

3. The division manager of West Institutions shall evaluate the teams' composition and the wardens' recommendations to the director.

4. In the selection and retention of any staff for the teams, the division manager for West Institutions shall consider:

   a. Employees suspended or demoted in the past 12 months or currently under investigation shall not be selected;

   b. Special consideration may be given to staff with pertinent specialized training and qualifications;

   c. Staff shall only be assigned to one team in the overall execution process;

   d. Staff serving on any team shall not be related to the offender by blood or marriage or have any other legal relationship with the offender, the offender's family or the crime victims(s); and

   e. Staff participation in the execution process is strictly voluntary. ODOC staff is not required to attend or participate in an execution.

5. Any staff volunteers may withdraw from performing their assigned duties specific to the execution at any time by advising their team leader, advising a team member or advising their immediate chain of command.

IV. Execution Teams

A. Command Team

1. Provides overall coordination of execution procedures.

2. Consists of a minimum of three team members:

   a. Commander (division manager of East Institutions);

   b. Recorder;

   c. Telephone operator; and

d. Others as necessary.

3. The commander is selected by the director.

4. All other team members are selected by the division manager of East Institutions with the documented approval of the director.

B. H Unit Section Teams

1. The H Unit Section chief shall coordinate the activities of the H Unit Section Teams to ensure compliance with conditions of confinement and application of approved procedures.

2. The director shall select the H Unit Section chief.

3. The H Unit Section Teams shall be comprised of the Restraint Team and the Special Operations Team.

a. Restraint Team

(1) Provides continuous observation of the offender on the day of the execution and applies appropriate restraint procedures and offender management prior to, during, and after the execution.

(2) Consists of one team leader and six team members divided into two teams.

(3) The division manager of West Institutions shall select the team leader with the documented approval of the director.

(4) Team members are selected by the warden of OSP with the documented approval of the director.

b. Special Operations Team

(1) Implements the protocols associated with the administration of the chemicals for the execution (Attachment D, attached).

(2) Consists of a minimum of five team members:

(a) Team leader;

(b) Recorder; and

(c) Three additional team members.

(3) The team members and team leader are selected by the division manager of West Institutions with the documented approval of the director.

(4) The team leader shall designate functions of the team members.

C. Intravenous (IV) Team

1. The IV Team shall consist of a team leader and member(s) of any one or more of the following:

a. Physician(s).

b. Physician assistant(s).

c. Nurse(s).

d. Emergency medical technician(s) (EMT).

e. Paramedic(s).

f. Military corpsman or other certified or licensed personnel including those trained in the United States military.

2. The team leader and member(s) shall be currently certified or licensed within the United States.

3. The team leader and member(s) shall be selected by the director.

a. Selection of any team member shall include a review of the proposed team member's qualifications, training, experience, and/or any professional license(s) and certification(s) they may hold.

b. Licensing and criminal history reviews shall be conducted by the inspector general's office prior to assigning or retaining any team member and upon the issuance of an Order Setting Execution Date.

4. The division manager of West Institutions shall ensure the team leader and member(s) thoroughly understand all provisions contained herein as written and by practice.

5. Documentation of team members' qualifications, including training of the team members, shall be maintained by the director or his designee.

6. All information pertaining to the selection and review of the IV Team members shall remain confidential in accordance with O.S. 22 Section 1015 of Oklahoma State Statute.

D. Maintenance Response Team

1. Tests all H Unit equipment utilized to impose the sentence of death and ensures electrical, plumbing, heating and air conditioning units are in working order.

2. Consists of one team leader and three team members.

3. The team leader and members are selected by the warden of OSP.

4. Reports to the Command Team.

E. Critical Incident Management Team (CIMT)

1. Educates affected staff at all levels in the ODOC prior to, during, and after the execution regarding possible psychological responses and effective coping mechanisms as well as provides ongoing follow-up contact to staff.

2. Consists of one team leader and three team members.

   a. The team leader is the Employee Assistance Program coordinator or designee.

   b. Team members are CIMT responders and are selected by the Employee Assistance Program coordinator.

3. Reports to the Command Team.

F. Traffic Control Team

1. Supervises the movement of people and vehicles into and out of the facility before, during, and after the execution.

2. Consists of one team leader and eight team members.

3. Team members and the team leader are selected by the warden of OSP.

4. Reports to the Command Team.

G. Witness Escort Teams

1. Coordinates the movement of all pre-approved witnesses on and off facility grounds and within its perimeter.

    a. One (1) Witness Escort Team is assigned to escort and assist each group of pre-approved officials, victims, news media and offender family witnesses.

    b. Witness Escort Team members shall always remain with witnesses within established areas.

2. Consists of one team leader and eight team members divided into four teams.

3. Team members and the team leader are selected by the warden of OSP.

4. Reports to the Command Team.

H. Victim Services Team

1. Ensures victims of the crime that resulted in the imposition of death are informed of the execution date and their opportunity to witness the execution.

    a. The team explains the execution process.

    b. If the victim is interested in attending, the team submits the victim's name(s) for consideration to the director.

2. Consists of one team leader and one team member.

3. The team leader is the victim services coordinator.

4. The team member is selected by the victim services coordinator.

5. Reports to the Witness Escort Team leader.

V. Training

The agency will establish protocols and training to enable staff to function in a safe, effective and professional manner before, during and after an execution.

A. The division manager of West Institutions shall establish a training schedule and identify dates for periodic on-site practice by the H Unit Section Teams, to include ten training scenarios within the 12 months preceding the scheduled execution. Multiple training scenarios can be

accomplished on the same date, including but not limited to contingency plans for:

1. Issues with execution equipment or supplies;

2. Issues with offender IV access, including obtaining alternate IV access site(s);

3. Issues if offender is not rendered unconscious after administration of execution chemicals;

4. Unanticipated medical or other issues concerning the offender or an execution team member; and

5. Issues regarding order, security or facilities at OSP.

B. The H Unit Section Team shall initiate training sessions no less than once per week until the scheduled date of execution beginning 35 days prior to the execution date.

C. The H Unit Section Team shall conduct a minimum of two training sessions with multiple scenarios within two days prior to the scheduled execution.

D. The IV Team members shall participate in at least one training session with multiple scenarios, within seven days prior to the scheduled execution.

E. The Command Team leader shall conduct training of the following team members approximately seven days prior to the execution date.

1. Witness Escort Team

2. Maintenance Response Team

3. Critical Incident Management Team

4. Traffic Control Team

5. Victim Services Team

VI. Selection of Execution Witnesses

A. ODOC Staff Witnesses

The following staff shall be present at the execution:

1. Director or designee.

2. H Unit Section chief.

3. Other necessary correctional officials.

B. Law Enforcement Witnesses

The following persons may be present at the execution:

1. State Attorney General or designee.

2. Cabinet Secretary of Public Safety or designee.

3. Judge who presided during the trial.

4. Chief of police of the municipality in which the crime occurred.

5. District attorney or designee of the county of conviction.

6. Sheriff of the county of conviction.

7. Lead law enforcement officials from agencies that investigated the crime or testified in court or clemency proceedings related to the crime.

8. In the event the defendant has been sentenced to death in one or more criminal proceedings in this state, or has been sentenced to death in this state and by one or more courts of competent jurisdiction in another state (or pursuant to federal authority), or any combination thereof, and this state has priority to execute the defendant, the general counsel must invite the district attorney, the judge and the chief law enforcement official from each jurisdiction where any death sentence has been issued. The above mentioned officials shall be allowed to witness the execution or view the execution by closed circuit television as determined by the director.

9. The law enforcement witnesses authorized to be present at the execution shall receive a two-week prior written notice of the scheduled execution per Attachment A entitled “Notification Letter to Dignitaries/Law Enforcement (sample)” (attached).

C. Victim and Offender Witnesses

1. Victim and Offender witnesses may be subject to a criminal records check which will be conducted using the “Oklahoma Department of Corrections Request for Record” (DOC 090211B).

2. The division manager of West Institutions shall prioritize persons to view the execution, including: surviving victims; offender's immediate family members; individuals who served a close supporting role or professional role to the offender including, but not limited to, a minister or licensed counselor. The warden of OSP may set a limit on the number of viewers within occupancy limits.

3. The victim and offender witnesses authorized to be present at the execution shall receive a two-week prior written notice of the scheduled execution per Attachment B entitled "Notification Letter to Offender Witnesses (sample)" (attached).

   a. Victim Witnesses

      (1) Any surviving victim of the offender who is 18 years of age or older may view the execution if approved by the general counsel and the warden of OSP.

      (2) As used in this section, 'surviving victim' means any immediate family member of the deceased victim who, as a direct result of the crime, suffered serious harm or injury due to the criminal acts of the offender of which the offender has been convicted in a court of competent jurisdiction.

      (3) Immediate family is defined as the spouse, child by birth or adoption, stepchild, parent by birth or adoption, stepparent, grandparent, grandchild, sibling or stepsibling of each deceased victim or the spouse of any immediate family member specified in this section.

      (4) Any surviving victim approved to view the execution of the offender may request to have an accompanying support person who serves a close supporting role or professional role to the deceased victim or an immediate family member, including, but not limited to, a minister or licensed counselor. The warden of OSP and the director shall approve or disapprove such requests.

      (5) A representative from the Attorney General's Victim Services Unit and the ODOC Victim Services team

coordinator or designee shall be allowed to attend the execution.

b. Offender Witnesses

(1) Witnesses may include five persons, relatives or friends, and two qualified ministers who are 18 years of age or older, as selected by the offender and approved by the general counsel and the warden of OSP. If the offender is female, approval shall be received by the warden of MBCC in conjunction with the warden of OSP.

4. All witnesses shall be provided a summary detailing the execution process which shall include what to expect and rules of conduct throughout the execution.

D. News Media Witnesses

1. News media witness selection is contingent upon adherence to the provisions stipulated in the "News Media Statement After an Execution" (Attachment E, attached).

2. No more than five members of the news media may be selected to witness the execution. First preference will be given to a local media representative in the market where the crime was committed and to the associated press.

3. News media witnesses shall be held to the same standards for conduct as are all other official witnesses.

4. All witnesses shall be provided a written summary detailing the execution process which shall include what to expect and rules of conduct throughout the execution.

5. The Command Team may exclude any news media witness at any time if the media witness fails to abide by the provisions of this procedure.

a. News media witnesses are not permitted to bring unauthorized items into H Unit. Examples of unauthorized items include:

(1) Any electronic or mechanical recording device;

(2) Still, moving picture, or video tape camera;

(3) Tape recorders or similar devices; and

(4) Radio/television broadcasting devices.

b. Each news media witness shall be provided a tablet of paper and a pencil for taking notes once they have completed security screening.

c. News media not selected to witness the execution shall remain in the designated Media Room during the execution.

E. Persons Excluded from the Execution Process

1. The correctional officers, case manager and medical staff who attended to the offender while in isolation shall not participate in the execution process.

2. Minors shall not be permitted to witness an execution.

3. The director shall retain full discretion as to the selection of, and any change in, the witnesses selected for each scheduled execution.

VII. Timeline of Events for Executions

A. Receipt of Order Setting Execution Date

Upon receipt of the Order Setting Execution Date, the following staff shall initiate the protocols below.

1. General Counsel's Office

a. Notify the director and associate director of Field Operations.

b. Notify the division manager of West Institutions, the warden of OSP and, if a female offender, the warden of MBCC.

c. Forward the original Order Setting Execution Date to the warden of OSP or MBCC.

d. Notify the coordinator of the Victim Services Team who shall contact the victim(s) and inform them of the court's issuance of the Order Setting Execution Date.

e. Notify the appropriate government officials and law enforcement officials.

2. Director of Corrections

   a. Select the time of the execution and provide notice to the Oklahoma Court of Criminal Appeals.

   b. Under exigent circumstances, the director shall have the authority to change the timeframes established in this procedure.

3. Warden of OSP or MBCC

   a. Coordinate the monitoring and evaluation of offender activity at their facilities for any activity related to the execution or its impact on the facility operation.

   b. Direct the offender to complete the "35-Day Notification Packet" (Attachments F-1 thru F-5, attached (links in the reference section) and return it to the warden no later than 30 days prior to the scheduled execution date.

   c. Notify the offender that minors are prohibited from witnessing the execution pursuant to Oklahoma State Statute Title 22, Section 1015.

   d. Notify the offender's family members as indicated by the offender.

   e. Notify the offender that requests for ODOC or contract staff to attend the execution shall be denied.

   f. Notify the offender that requests for other offenders to attend the execution shall be denied.

   g. Notify the offender to review and update as necessary DOC 030120B entitled "Designation for Disposition of Property." The warden shall direct the offender to provide any changes no later than 14 days prior to the execution. If the offender does not provide instruction, the property and accounts shall be disposed of in accordance with OP-030120 entitled "Offender Property."

   h. Advise the offender that his/her body shall not be used for organ donation.

   i. Summarize the options available with the offender for release and disposition of his/her body.

1. The warden shall direct the offender to review the previously completed "Release of Remains and Burial Arrangements" form (Attachment C, attached) and update as necessary no later than 14 days prior to the execution.

2. If the offender provides no instruction or the information is insufficient or incorrect, the deceased shall be disposed of in accordance with OP-140111 entitled "Offender Death, Injury and Illness Notification and Procedures."

j. Summarize the options available to the offender for the release of medical information in accordance with HIPAA regulations.

k. Advise the offender he/she may request a last meal by completing the "Last Meal Request" (Attachment F-5, attached). Reasonable effort shall be made to accommodate the request which shall not exceed $25.00.

B. Thirty-Five (35) Days Prior to the Day of Execution

1. Facility

a. The warden or designee shall confirm in writing to the associate director of Field Operations that the following steps have been completed:

(1) Warrant has been read to the offender.

(2) An outline was provided to the offender how conditions of confinement shall be modified over the next 35 days with a brief description of the relevant aspects of the execution process. (Attachments F-1 thru F-5)

(3) The offender's medical condition shall be assessed in order to identify any necessary accommodations or contingencies that may arise from the offender's medical condition or history.

(a) Any medical condition or history that may affect the performance of the execution shall be communicated as soon as possible through the

chain of command to the director, who shall confer with others as necessary to plan such accommodations or contingencies.

(b) The facts of the assessment and any conclusions shall be documented in the offender's healthcare record.

(4) Any concerns for establishing or maintaining IV lines and any concerns or plans for medical accommodations or contingencies shall be communicated to the Special Operations Team in order that they may be discussed and addressed in execution trainings or rehearsals.

(5) An appropriate member of the mental health staff shall evaluate the offender approximately thirty-five (35) days prior to the execution to evaluate his or her stability and mental health in light of the scheduled execution.

(a) Any concerns or contingencies affecting the execution process shall be communicated through the chain of command to the director as soon as possible and documented in the offender's healthcare record.

(b) The director shall order the warden to notify the appropriate district attorney and the attorney general of any concerns or contingencies.

(6) Transfer the offender to the appropriate cell on Death Row at OSP (or MBCC when the offender is female). Before transferring the offender into the cell, the offender shall be strip searched, x-rayed, screened on the calibrated BOSS Chair and then issued a new set of clothes and shoes to wear.

(7) The assigned cell shall be thoroughly searched prior to placing the offender in the cell.

(8) Place the offender on 24-hour continuous observation and post staff to the offender's cell to maintain visual contact with the offender.

(9) Establish an observation log to chronicle staff's observations of the offender's activities and behavior until the sentence of death is imposed or a stay of execution is issued.

(10) The shift commander shall be responsible for ensuring the information recorded in the observation logs includes, but is not limited to:

(a) All statements or behaviors that could be detrimental to completing an execution;

(b) All meals provided to the offender and what portions of the meals the offender consumed or refused;

(c) All medications provided to the offender and the observations made by staff as to whether the offender ingested the medication as prescribed; and

(d) All liquids consumed by the offender.

(11) The warden shall be responsible for reviewing observation logs once every twenty-four hour period, excluding weekends and holidays.

(12) The warden will communicate any significant changes in the offender's medical and/or mental health to the health services administrator.

(13) In the instance where the offender is female, the 35 day protocols shall be implemented with the offender housed at MBCC.

b. Conditions of Confinement

(1) The warden shall:

(a) Ensure none of the offender's personal property is transferred with the offender, except as provided in this section;

(b) Have the offender's personal property inventoried in his/her presence before the

transfer of cells occurs and then have it boxed, sealed and removed from the cell;

(c) Store the offender's property pending receipt of written instruction by the offender regarding disposition of property, or otherwise dispose of the property as outlined in OP-030120 entitled "Offender Property;"

(d) Allow the offender to keep in the cell one (1) cubic foot each of legal and religious materials, a safety ink pen, paper, a book or periodical, family photographs and correspondence from family members;

(e) Issue the offender a new mattress, pillow and bedding;

(f) Provide the offender limited hygiene supplies, including a towel and washcloth and exchange these items on a daily basis;

(g) Ten calendar days after being placed on continuous observation, the warden may approve weekly canteen purchases of no more than $20.00 based on the offender's behavior;

(h) Ensure all offender medications are unit-dosed and issued in liquid form, when available. None of the offender's medication, including over-the-counter medications, shall be dispensed or maintained by the offender as keep-on-person (KOP);

(i) Ensure the offender has access to a ODOC television set that is secured inside the cell and does not have access to any other appliances; and

(j) Continue to provide outdoor exercise and showers, non-contact visits and phone calls per the current schedule for other death row offenders.

c. State and Local Law Enforcement Briefing

(1) The warden of OSP shall ensure state and local law enforcement is periodically briefed and adequately prepared for the execution.

d. Site Checks

(1) All of the equipment necessary to the administration of the execution shall be available on site and in good working order including:

(a) Transportation vehicles;

(b) Communication devices with inter-operability capability and restricted frequencies;

(c) Climate control;

(d) Tool control;

(e) Safety equipment;

(f) Audio/Visual equipment;

(g) Utility infrastructure;

(h) Key control/locking devices; and

(i) Medical emergency response capability

2. Division Manager of West Institutions

a. Identifies and assigns team leaders and members, with documented approval by the director, and upon approval shall activate the teams.

b. Ensures preventative maintenance in H Unit occurs and that an equipment inventory is completed. If deficiencies are noted, ensures appropriate and timely action is taken to correct the deficiency.

c. Directs the initiation of the continuous observation log commencing 35 days prior to the day of the execution. The log shall be maintained until the execution occurs or a stay of execution is issued.

d. Activates the training schedule ensuring staff participating in the execution receives adequate training, written instruction and practice, all of which is documented.

3. Division Manager of Correctional Health Services

a. Directs Health Services staff to conduct a medical records file review to identify any prescribed medication(s) and dosages the offender is currently or was recently taking. Health Services staff provider shall modify prescribed medication as may be necessary.

b. Directs Health Services staff to dispense all offender medications in unit doses and in liquid form, when available. No medication, including over-the-counter medication, shall be provided or maintained by the offender as KOP.

c. Ensures Health Services staff monitors the offender two times per day for significant changes in his/her medical and/or mental health. Reports findings immediately to the division manager of East Institutions and the general counsel.

4. Victim Services Office

a. Identifies and advises victims of the crime for which the offender has been sentenced to death of the issuance of the Order Setting Execution Date and the scheduled date and time of the execution.

C. Fourteen Days (14) Prior to the Day of Execution

1. Inspector General or Designee

a. Finalizes arrangements with the State Medical Examiner for the disposition of the body, security for the medical examiner's vehicle and the custodial transfer of the body.

b. Obtains a body bag and tag from the Medical Examiner's office.

2. General Counsel

a. Finalizes a list and documented approval of all witnesses for the director's review including official offender and victim

witnesses through coordination with the offices of Victim Services.

b. Upon documented approval, the director or designee shall prepare a written invitation to each chosen witness.

c. Sends the completed list of approved witnesses to the warden of OSP.

D. Two Days (2) Prior to the Day of Execution

1. Division Manager of West Institutions

a. Schedules and conducts on-site scenario training sessions, modifying practices as warranted.

b. Confirms adequate staffing and vehicles are in place for regular operations and the execution.

2. Warden of OSP

a. Confirms staff assigned to the Maintenance Response Team (MRT) are scheduled and shall be on-site eight (8) hours prior to the time scheduled for imposition of sentence.

b. Restricts access to H Unit to those with expressly assigned duties.

c. Verifies execution inventory and equipment checks are completed and open issues resolved in accordance with established protocols.

E. Twenty-Four (24) Hours Prior to the Day of Execution

1. Final preparation of the execution area is completed. Each room receives final evaluation specific to its functions including security, climate control, lighting, sound, sanitation, and ensures that separation screens and appropriate restraints are ready.

2. Detailed staff briefings detailing operational changes, security and intelligence information as well as protocol and checklist requirements are provided to facility staff through shift briefings, staff meetings, etc.

3. The offender’s telephone privileges shall be terminated at 2100 hours the day prior to the execution, excluding calls from the

offender's attorney of record and others as approved by the division manager of West Institutions.

4. The offender's visitation privileges shall be terminated at 2100 hours the day prior to the execution. The offender shall be permitted two hours of in-person visitation with no more than two attorneys of record, concluding two hours prior to the scheduled execution or earlier if necessary to begin preparing the offender for the execution.

5. The warden of OSP shall ensure the offender receives the last meal as requested in accordance with procedures. Every reasonable effort to accommodate the last meal request shall be made. All eating utensils and remaining food and beverage shall be removed upon completion of the meal.

6. The Traffic Control Team shall confer with state and local law enforcement agencies, establish check points and parameters for traffic control, and formulate inter-agency emergency response strategies. The team shall also coordinate the ingress/egress for ODOC and contract staff and other persons whose attendance is necessary. This process shall continue through the conclusion of the execution process.

F. Twelve Hours (12) Prior To and Through the Execution

1. Restricting Access to Institution Property

   a. During the final 12 hours prior to the execution, access to the Oklahoma State Penitentiary is limited to:

      1. On-duty personnel;

      2. On-duty contract workers;

      3. Volunteers deemed necessary by the warden;

      4. Law enforcement personnel on business-related matters; and

      5. Approved witnesses.

   b. Restriction to the facility shall remain in effect until normal operations are resumed after the execution or stay of execution is issued.

c. Any non-execution related visitation sessions or special visits shall be cancelled.

d. Approved witnesses are gathered and separated into pre-determined staging areas.

(1) One Witness Escort Team is assigned to escort and assist pre-approved officials, victims, news media witnesses and offender's witnesses.

(2) Witness Escort Teams shall remain with the assigned witnesses within established areas.

(3) The Victim Services Team coordinator shall meet with the victim(s) in the staging area and shall remain available to them throughout the process. The team shall provide support and advocacy as appropriate.

2. News Media Access

a. Reasonable efforts shall be made to accommodate the representatives of the news media before, during, and after a scheduled execution; however, the ODOC reserves the right to regulate media access to ensure the orderly and safe operations of its facility.

b. The Communications Office shall coordinate the release of information to news media outlets. All ODOC and contract staff is expressly prohibited from providing information not readily available in the public domain.

c. News media witnesses to the execution shall be limited to five representatives.

(1) One seat will be given to a local media representative in the market where the crime was committed.

(2) One seat will be given to the associated press.

(3) Three seats will be chosen from the remaining media representatives with preference given to Oklahoma-based media.

d. If more than one media representative meets criteria for the available seats, a lottery or lotteries shall be held.

e. The public information officer shall provide general information regarding the execution and the offender.

f. News media witnesses shall return to the Media Room after the execution to answer questions of all other media representatives concerning their observations during the execution, prior to filing or reporting their story.

3. Offender Preparation and Observation Log

a. The offender shall be escorted to medical to receive a full body x-ray.

b. All property in the assigned cell shall be removed and the cell thoroughly searched prior to the return of the offender from medical.

c. The offender shall be strip-searched and screened on the calibrated BOSS Chair before placement in the cell.

d. The offender shall be issued one pair each of pants, shirt, underwear and socks on the morning of the execution.

e. The cell shall be furnished with a mattress, pillow and pillowcase, one each top and bottom sheet, blanket, wash cloth, towel, and toilet paper.

f. The offender may have a safety ink pen and paper, religious items, a book or periodical and indigent-sized hygiene supplies (liquid soap, toothpaste) and a toothbrush and comb. These items may be made available only for the duration of the use and shall be removed immediately thereafter. Any other requested property shall require approval by the warden and shall be documented.

g. The Restraint Team shall take custody of the offender and the observation log. The Restraint Team members shall assume maintenance of the log until the execution is completed or a stay of execution is issued.

h. The offender shall remain on continuous watch. The Restraint Team members shall record observations and make entries every 15 minutes, or as incidents occur, in the observation log during the final four hours.

i. The warden will ensure the assigned cell is preserved and secured immediately after the offender is moved to the execution chamber. Entry will be limited to preservation of mission only and will be released by the inspector general once the execution is completed or a stay of execution is issued.

j. The offender may be offered a mild sedative.

k. No later than four hours prior to the execution the offender may be offered an additional mild sedative.

l. These time frames may be adjusted as necessary in the event of a stay of execution or other exigencies.

4. Notification to Proceed With Execution

a. Prior to moving the offender from the holding cell to the execution table, the director shall confer with the attorney general or designee and the governor or designee to confirm there is no legal impediment to proceeding with the lawful execution.

b. The H Unit Section chief shall direct the Restraint Team to prepare and escort the offender into the execution chamber.

c. The Restraint Team shall secure the offender on the execution table.

5. IV Site(s) Preparation and Establishment

a. The IV Team shall enter the Execution Room to prepare and insert a primary IV catheter and a backup IV catheter. The arm veins near the joint between the upper and lower arm shall be utilized as the preferred site for the IV injection.

b. The director, acting upon the advice of the IV Team leader, shall determine the catheter sites.

c. In the event that the IV Team is unable to establish an IV at a preferred site, the member(s) may establish an IV at an alternative site(s), including a central line, for use by the Special Operations Team when administering execution drugs.

d. The IV Team may utilize a non-invasive device to assist in locating a vein.

e. The IV Team shall be allowed as much time as is necessary to establish a viable IV site(s).

f. If the IV Team is unable to establish viable IV sites(s) the member(s) shall consult with the director.

g. The director shall consult with others as necessary for the purpose of determining whether or how long to continue efforts to establish viable IV sites(s).

h. After one hour of unsuccessful IV attempts, the director shall contact the governor or designee to advise of the status and potentially request a postponement of the execution.

i. A central line shall not be used unless the person placing the line is qualified to place a central line.

6. Confirming and Recording Establishment of IV Sites(s)

a. An IV Team member shall test the viability of the IV site with a low-pressure saline drip through IV tubing. If necessary, a heparin lock may be attached to the IV needle as an alternative to the saline drip.

b. The H Unit Section chief and IV Team leader shall both confirm the visibility of the IV sites.

c. The H Unit Section Team Recorder shall document in the Correctional Service Log the number of attempts to establish an IV site.

7. Using Alternative IV Sites

a. The H Unit Section Team chief shall observe the offender during the injection process to look for signs of swelling or infiltration at the IV site, blood in the catheter, and leakage from the lines and other unusual signs or symptoms.

b. The H Unit Section Team chief shall determine whether it is necessary to use an alternate IV site.

c. Whenever it is necessary to use alternate IV sites, the Special Operation Team shall administer a full dosage of the

execution drugs through the alternate site, using additional syringes as necessary, prepared in accordance with the terms of this procedure.

d. In the event the H Unit Section Team chief changes to another IV site, the Special Operation Team recorder shall capture that information on the Correctional Service Log.

8. Proceeding with the Execution

a. When the offender is secured on the execution table by the Restraint Team and readied by the IV Team, the H Unit Section Team chief shall advise the director and order the witnesses to their respective seating.

b. The director shall reconfirm with the attorney general or designee and the governor or designee that there is no legal impediment to proceeding. Upon oral confirmation that there are no legal impediments to proceeding with the execution, the director shall order the H Unit Section chief to proceed with the execution.

(1) If there is a legal impediment the director shall instruct the H Unit Section chief to stop the execution and to notify the offender witnesses that the execution has been stayed or delayed. The H Unit Section chief shall also notify the Command Team to notify the agency's public information officer in the Media Room.

c. The H Unit Section chief shall read aloud a summary of the Warrant of Execution.

d. The H Unit Section chief shall ask the offender if he wishes to make a last statement that is reasonable in length and does not contain vulgar language or intentionally offensive statements directed at the witnesses. The microphone shall remain on during the last statement, after which time it shall be turned off. The microphone may be turned off earlier in the event the offender uses vulgarity or makes intentionally offensive statements.

e. The director shall instruct the disbursement of chemicals to begin in accordance with Attachment D entitled "Preparation and Administration of Chemicals."

G. Pronouncement and Documentation of Death

1. The director or designee shall announce death has occurred.

2. The H Unit Section chief shall complete and sign the return of the Death Warrant. The H Unit Section chief is also responsible for coordinating with the general counsel's office for the filing of the document with the sentencing court and the Oklahoma Court of Criminal Appeals within five business days.

3. The State Medical Examiner's Office shall be given custody of the body in order to issue a Certificate of Death.

H. Stay of Execution

1. Upon receipt of notification that the court and/or governor has issued a Stay of Execution, the director shall advise the Command Team.

2. Upon receipt of the notification, the H Unit Section chief shall:

a. Instruct the Special Operations Team to stand down.

b. Direct the Restraint Team to remove the offender from the chamber and return to the assigned cell if the stay of execution is less than 35 days.

(1) Prior to moving the offender back to the assigned cell, the inspector general shall release the cell.

(2) The assigned cell shall be thoroughly searched prior to placing the offender in the cell.

c. Advise the witnesses a Stay of Execution has been issued.

d. The Command Team shall inform the following teams of the Stay of Execution:

(1) Traffic Control Team Leader.

(2) Critical Incident Management Team Leader.

(3) Communications Director.

(4) Victim Services Coordinator.

(5) Escort Team Leader.

e. The Traffic Control Team leader shall notify any protestors of the issuance of the Stay of Execution.

I. Post Execution/Stay of Execution

1. The Witness Escort Teams shall commence escorting witness groups from H Unit in the prescribed order from the facility.

2. Each group of witnesses shall continue to be kept separated from the other groups at all times.

3. News media witnesses shall return to the Media Room to participate in the media briefing.

4. Victim witnesses speaking with the media shall be escorted to the Media Room.

5. Media may remain on site in a designated location outside the secure perimeter for a limited time to complete live broadcasts.

6. The Victim Services team leader ensures the victim(s) receives follow up phone calls and support.

J. Site Clean Up and Recording of Execution Drugs

1. In accordance with OP-040109 entitled "Control of Contraband and Physical Evidence," the Special Operations Team leader shall properly dispose of any execution drugs that have not been utilized. The drugs will be inventoried on the form entitled "Oklahoma State Bureau of Investigation Inventory of Drugs Submitted for Destruction" (www.ok.gov/osbi/documents/LABdestructForm.pdf) and forwarded to the Oklahoma State Bureau of Investigation.

2. The warden of OSP shall witness the disposal of the unused execution drugs and document the disposal in accordance with procedure.

3. The Special Operations Team leader shall document the name, description, expiration date, and lot number of all execution drugs used.

4. The Special Operations Team Leader shall save any packaging of the used execution drugs or take photographs of such packaging of items.

5. Under supervision of a person designated by the warden, the execution room shall be cleaned and secured. Institutional staff trained in infectious diseases preventive practices shall utilize appropriate precautions.

K. Normal Operations

1. The Command Team shall determine when the prison shall resume normal operations.

2. ODOC staff shall be deactivated at the direction of the Command Team.

L. Execution Documentation

1. The division manager of West Institutions shall gather all documents pertaining to the executions and forward to the general counsel for archiving.

2. The division manager of West Institutions shall attach a copy of the death warrant and forward it to the general counsel, who shall then forward it to the court from which it was rendered, indicating the time and mode and manner of which it was accomplished. Copies of the report and log shall be sent to closed records department for filing. MBCC shall receive a copy for females that are executed.

M. After-Action Review

1. Immediately following an execution, all of the Execution Teams and the on-site administrators directly involved in the execution process shall meet to review the process of the execution.

2. Any unique or unusual events shall be discussed, as well as opportunities for improvement and successful procedures.

3. Actions and documentation of the events shall be reviewed to identify any discrepancies.

4. The review should serve as an opportunity for all involved personnel to voice their opinions, concerns, and/or recommendations.

5. The review shall be formally documented and retained for future reference.

N. Critical Incident Debriefing

1. The Command Team shall ensure that critical incident debriefings are available for the Execution Teams and staff participants immediately following the execution.

2. The Critical Incident Management Team shall conduct interviews in accordance with Critical Incident Program guidelines.

VIII. Quality Assurance Review

The director shall designate the division manager for Field Support to evaluate the performance of the execution process and report findings to the director.

a. The division manager shall review documentation and training to ensure compliance with the written procedure directive.

b. The division manager may utilize assistance as necessary to compile or assess the information, and may consult with others consistent with the confidentiality of the process.

c. Whenever appropriate, the division manager shall consult with a properly trained medical person when reviewing the medical aspects of the execution procedures.

d. The division manager shall provide consultation and advice concerning modifications in the written directive.

e. The division manager shall prepare a report to the director following each execution, with appropriate suggestions or recommendations as needed.

IX. References

Policy Statement No. P-040100 entitled “Security Standards for the Oklahoma Department of Corrections”

OP-030120 entitled “Offender Property”

OP-040109 entitled “Control of Contraband and Physical Evidence”

OP-110215 entitled “Rules Concerning the Individual Conduct of Employees”

OP-140111 entitled “Offender Deaths, Injury and Illness Notification and Procedures”

Robinson v. Maynard, 857 P.2d 817 (Okla. App. 1992)

21 O.S. § 142A-14

22 O.S. §1014 and 1015

X. Action

The wardens of Oklahoma State Penitentiary and Mabel Bassett Correctional Center are responsible for compliance with this procedure.

The associate director of Field Operations is responsible for the annual review and revisions.

Any exception to this procedure will require prior written approval from the director.

This procedure is effective as indicated.

Replaced: Operations Memorandum No. OP-040301 entitled "Procedures of the Execution of Offenders Sentenced to Death" dated September 30, 2014

Distribution: Policy and Operations Manual
Agency Website

Attachments	Title	Location
Attachment A	"Notification Letter to Dignitaries/Law Enforcement (sample)"	Attached
Attachment B	"Notification Letter to Offender Witnesses (sample)"	Attached
Attachment C	"Release of Remains and Burial Arrangements"	Attached
Attachment D	"Preparation and Administration of Chemicals"	Attached
Attachment E	"News Media Statement After an Execution"	Attached
Attachment F-1	"35 Day Information Packet"	Attached
Attachment F-2	"Summary of Rules and Procedures"	Attached
Attachment F-3	"Witnesses"	Attached
Attachment F-4	"Visitors"	Attached
Attachment F-5	"Last Meal"	Attached

Referenced Forms	Title	Location
DOC 030120B	"Designation for Disposition of Property"	OP-030120
DOC 090211B	"Oklahoma Department of Corrections Request for Record"	OP-090211
OSBI Form	"OSBI Inventory of Drugs Submitted for Destruction and/or Other Items in OSBI Custody for Destruction" http://www.ok.gov/osbi/documents/LABdestructForm.pdf	Website Link

PREPARATION AND ADMINISTRATION OF CHEMICALS

A. Obtaining Chemicals and Equipment

1. Upon receipt of the Order Setting Execution Date, the H Unit Section Chief shall:

   a. Confirm and ensure all equipment necessary to properly conduct the procedure is on site, immediately available for use and functioning properly.

   b. Ensure all medical equipment, including a backup electrocardiograph, is on site, immediately available for use and functioning properly.

   c. Ensure the chemicals are ordered, arrive as scheduled and are properly stored. The chemicals shall be under the direct control of the H Unit Section Chief and stored in a secured, locked area and monitored to ensure compliance with manufacturer specifications.

B. Preparation of Chemicals

1. At the appropriate time, the H Unit Section Chief shall transfer custody of the chemicals to the Special Operations Team to begin the chemical(s) and syringe preparation in the chemical room, under the direct supervision by the Intravenous (IV) Team leader.

2. The Special Operations Team leader shall assign a team member(s) to assist preparing each chemical and the corresponding syringe under the supervision of the IV Team leader. The IV Team leader, with the assistance of the Special Operations Team members, shall prepare the designated chemical and syringes for a total of one (1) complete set of chemicals. One (1) full set of syringes is used in the implementation of the death sentence and an additional complete set of the necessary chemicals shall be obtained and kept available in the chemical room.

3. The IV Team leader, with the assistance of a Special Operations Team member, shall be responsible for preparing and labeling the assigned sterile syringes in a distinctive manner. The specific chemical contained in each syringe will be identified with the following information as set forth in the chemical charts:

   a. Assigned number

   b. Chemical name

   c. Chemical amount

   d. Designated color

This information shall be pre-printed on a label, with one label affixed to each syringe to ensure the label remains visible.

C. Chemical Charts

1. CHART A: One (1) Drug Protocol with Pentobarbital

CHEMICAL CHART	
Syringe No.	**Label**
1A	2.5 gm pentobarbital **GREEN**
2A	2.5 gm pentobarbital **GREEN**
3A	60 ml heparin/saline, **BLACK**

a. Syringes 1A and 2A shall each have a dose of 2.5 grams of pentobarbital for a total of 5 grams. Each syringe containing pentobarbital shall have a **GREEN** label which contains the name of the chemical, chemical amount and the designated syringe number.

b. Syringe 3A shall contain 60 milliliter of heparin/saline solution at a concentration of 10 units of heparin per milliliter. The syringe shall have a **BLACK** label which contains the name of the chemical, chemical amount and the designated syringe number.

2. CHART B: One (1) Drug Protocol with Sodium Pentothal

CHEMICAL CHART	
Syringe No.	**Label**
1A	1.25 gm sodium pentothal, **GREEN**
2A	1.25 gm sodium pentothal, **GREEN**
3A	1.25 gm sodium pentothal, **GREEN**
4A	1.25 gm sodium pentothal, **GREEN**
5A	60 ml heparin/saline, **BLACK**

a. Syringes 1A, 2A, 3A, and 4A shall each contain 1.25 grams/50 milliliter of sodium pentothal in 50 milliliter of sterile water in four (4) syringes for a total dose of 5 grams of sodium pentothal. Each syringe containing sodium pentothal shall have a **GREEN** label which contains the name of the chemical, the chemical amount and the designated syringe number.

b. Syringe 5A shall contain 60 milliliter of heparin/saline solution at a concentration of 10 units of heparin per milliliter. The syringe shall have a **BLACK** label which contains the name of the chemical, chemical amount and the designated syringe number.

3. CHART C: Reserved

4. CHART D: Three (3) Drug Protocol with Midazolam, Vecuronium Bromide and Potassium Chloride

CHEMICAL CHART	
Syringe No.	**Label**
1A	250 mg midazolam, **GREEN**
2A	250 mg midazolam, **GREEN**
3A	60 ml heparin/saline, **BLACK**
4A	50 mg vecuronium bromide, **YELLOW**
5A	50 mg vecuronium bromide, **YELLOW**
6A	60 ml heparin/saline, **BLACK**
7A	120 mEq potassium chloride, **RED**
8A	120 mEq potassium chloride, **RED**
9A	60 ml heparin/saline, **BLACK**

a. Syringes 1A and 2A shall each have a dose of 250 milligrams midazolam for a total dose of 500 milligrams. Each syringe containing midazolam shall have a **GREEN** label which contains the name of each chemical, the chemical amounts and the designated syringe number.

b. Syringes 4A and 5A shall each have a dose of 50 milligrams vecuronium bromide or 50 milligrams pancuronium bromide or 50 milligrams rocuronium bromide, for a total dose of 100 milligrams. Each syringe containing the selected bromide shall have a **YELLOW** label which contains the name of each chemical, the chemical amounts and the designated syringe number.

c. Syringes 7A and 8A shall each contain 120 milliequivalents potassium chloride for a total dose of 240 milliequivalents. Each syringe containing potassium chloride shall have a **RED** label which contains the name of each chemical, the chemical amounts and the designated syringe number.

d. Syringes 3A, 6A, and 9A shall each contain 60 milliliter of heparin/saline solution at a concentration of 10 units of heparin per milliliter. Each syringe shall have a **BLACK** label which contains the name of the chemical, chemical amount and the designated syringe number.

D. Choice of Chemicals

1. The director shall have the sole discretion as to which chemicals shall be used for the scheduled execution. This decision shall be provided to the offender in writing ten (10) calendar days prior to the scheduled execution date.

2. Any compounded drug used shall be obtained from a certified or licensed compounding pharmacist or compounding pharmacy in good standing with their licensing board. Licensing certification and criminal history reviews shall be conducted by the Inspector General's office prior to obtaining the compounded drug. A qualitative analysis of the compounded drug to be used in the execution shall be performed no more than thirty (30) calendar days prior to the execution date. The decision to use compounded drugs shall be provided to the offender in writing no less than ten (10) calendar days prior to the scheduled execution.

3. After the IV Team prepares all required syringes with the proper chemicals and labels as provided in the Chemical Chart, the IV Team leader shall attach one complete set of the prepared and labeled syringes to a 3-Gang, 2-Way Manifold in the order in which the chemicals are to be administered. The syringes shall be attached to the 3-Gang, 2-Way Manifold in a manner to ensure there is no crowding, with each syringe resting in its corresponding place in the shadow board which is labeled with the name of the chemical, color, chemical amount and the designated syringe number.

4. The syringes shall be affixed in such a manner to ensure the syringe labels are clearly visible. Prior to attaching the syringes to the 3-Gang, 2-Way Manifold, the flow of each gauge on the manifold shall be checked by the IV Team leader running the Heparin/Saline solution through the line to confirm there is no obstruction.

5. After all syringes are prepared and affixed to the 3-Gang, 2-Way Manifold in proper order, the Special Operations Team leader shall confirm that all syringes are properly labeled and attached to the manifold in the order in which the chemicals are to be administered as designated by the Chemical Chart. Each chemical shall be administered in the predetermined order in which the syringes are affixed to the manifold.

6. The quantities and types of chemicals prepared and administered may not be changed in any manner without prior documented approval of the director.

7. All prepared chemicals shall be utilized or properly disposed of in a timely manner after the time designated for the execution to occur.

8. The chemical amounts as set forth in the Chemical Chart are designated for the execution of persons weighing 500 pound or less. The chemical amounts shall be reviewed and may be revised as necessary for an offender exceeding this body weight.

9. The Special Operations Team Recorder is responsible for completing the Correctional Service Log. The Recorder shall document on the form the amount of each chemical administered and confirm that it was

administered in the order set forth in the Chemical Chart. Any deviation from the written procedure shall be noted and explained on the form.

E. Movement and Monitoring of Offender

1. Prior to moving the offender from the holding cell to the execution table, the director shall confer with the attorney general or designee and the governor or designee to confirm there is no legal impediment to proceeding with the lawful execution.

2. The offender may be offered a mild sedative based on the offender's need. The sedative shall be provided to the offender no later than four (4) hours prior to the execution, unless it is determined medically necessary.

3. At the designated time, the offender shall be brought into the execution room and secured on the table by the prescribed means with the offender's arms positioned at an angle away from the offender's side.

4. The offender shall be positioned to enable the IV Team or the Special Operations Team leader and the H Unit Section Chief to directly observe the offender and/or to monitor the offender with the aid of a high resolution color camera and a high resolution color monitor.

5. After the offender has been secured to the execution table, the Restraint Team leader shall personally check the restraints which secure the offender to the table to ensure they are not so restrictive as to impede the offender's circulation, yet sufficient to prevent the offender from manipulating the catheter and IV lines.

6. A microphone shall be affixed to the offender's shirt to enable the IV Team, or the Special Operations Team leader, to hear any utterances or noises made by the offender throughout the procedure. The Special Operations Team leader shall confirm the microphone is functioning properly, and that the offender can be heard in the chemical room.

7. The Restraint Team members shall attach the leads from the electrocardiograph to the offender's chest once the offender is secured. The IV Team leader shall confirm that the electrocardiograph is functioning properly. A backup electrocardiograph shall be on site and readily available if necessary. Prior to and on the day of the execution both electrocardiograph instruments shall be checked to confirm they are functioning properly.

8. An IV Team member shall be assigned to monitor the electrocardiograph at the commencement and completion of the administration of the chemicals.

9. Throughout the procedure, the IV Team leader shall monitor the offender's level of consciousness and electrocardiograph readings utilizing direct observation, audio equipment, camera and monitor as well as any other medically approved method(s) deemed necessary by the IV Team leader. The IV Team leader shall be responsible for monitoring the offender's level of consciousness.

F. Intravenous Lines

1. The director, acting upon the advice of the IV Team leader, shall determine the catheter sites. A central line shall only be used if the person inserting the line is qualified to insert a central line. The IV Team members shall insert a primary IV catheter and a backup IV catheter.

2. After one hour of unsuccessful IV attempts, the director shall contact the governor or designee to advise of the status and potentially request a postponement of the execution.

3. The IV Team leader shall ensure the catheters are properly secured and properly connected to the IV lines and out of reach of the offender's hands. A flow of heparin/saline shall be started in each line and administered at a slow rate to keep the lines open.

4. The primary IV catheter shall be used to administer the chemicals and the backup catheter shall be reserved in the event of the failure of the first line. Any failure of a venous access line shall be immediately reported to the director.

5. The IV catheter in use shall remain visible to the H Unit Section Chief throughout the procedures.

6. The H Unit Section Chief shall physically remain in the room with the offender throughout the administration of the chemicals in a position sufficient to clearly observe the offender and the primary and backup IV sites for any potential problems and shall immediately notify the IV Team leader and director should any issue occur. Upon receipt of such notification, the director may stop the proceedings and take all steps necessary in consultation with the IV Team leader prior to proceeding further with the execution.

7. Should the use of the backup IV catheter be determined to be necessary, a set of backup chemicals should be administered in the backup IV site.

G. Administration of Chemicals – Charts A and B

1. At the time the execution is to commence and prior to administering the chemicals, the director shall reconfirm with the attorney general or designee and the governor or designee that there is no legal impediment

to proceeding with the execution. Upon receipt of oral confirmation that there is no legal impediment, the director shall order the administration of the chemicals to begin.

2. Upon receipt of the director's order and under observation of the IV Team leader, the Special Operations Team leader shall instruct the assigned Special Operations Team member(s) to begin dispensing the chemicals in the order they appear in the corresponding chart.

3. Upon direction from the Special Operations Team Leader, the assigned Special Operations Team member shall visually and orally confirm the chemical name on the syringe and then administer the full dose of the chemicals immediately followed by the heparin/saline flush.

4. When five (5) minutes has elapsed since commencing the administration of the chemicals, the IV Team leader, dressed in a manner to preserve their anonymity, shall enter into the room where the section chief and offender are located to physically confirm the offender is unconscious by using all necessary and medically-appropriate methods. The IV Team leader shall also confirm that the IV line remains affixed and functioning properly.

5. If, after five (5) minutes the offender remains conscious, the IV Team shall communicate this information to the director, along with all IV Team input. The director shall determine how to proceed or, if necessary, to start the procedure over at a later time or stop. The director may order the curtains to the witness viewing room be closed, and if necessary, for witnesses to be removed from the facility.

6. If deemed appropriate, the director may instruct the Special Operations Team to administer additional doses of the chemical(s) followed by the heparin/saline flush.

7. Upon administering the chemical(s) and heparin/saline from a backup set, the IV Team shall confirm the offender is unconscious by sight and sound, utilizing the audio equipment, camera and monitor. The IV Team leader shall again physically confirm the offender is unconscious using proper medical procedures and verbally advise the director of the same.

8. When all electrical activity of the heart has ceased as shown by the electrocardiograph, the IV Team leader shall confirm the offender is deceased and the offender's death shall be announced by the director.

9. The Special Operations Team Recorder shall document on the Correctional Service Log the start and the ending times of the administration of the chemical(s).

10. Throughout the entire procedure, the IV Team members, the Special Operations Team members and the H Unit Section Chief shall continually monitor the offender using all available means to ensure that the offender remains unconscious and that there are no complications.

H. Administration of Chemicals – Chart D

1. At the time the execution is to commence and prior to administering the chemicals, the director shall reconfirm with the attorney general or designee and the governor or designee that there is no legal impediment to proceeding with the execution. Upon receipt of oral confirmation that there is no legal impediment, the director shall order the administration of the chemicals to begin.

2. Upon receipt of the director's order and under observation of the IV Team leader, the Special Operations Team leader shall instruct the assigned Special Operations Team member(s) to begin dispensing the chemicals in syringe numbers 1A, 2A, and 3A.

3. Upon direction from the Special Operations Team Leader, the assigned Special Operations Team member shall visually and orally confirm the chemical name on the syringe and then administer the full dose of the chemicals in syringe numbers 1A, 2A, and 3A.

4. When five (5) minutes has elapsed since commencing the administration of the first chemical, the IV Team leader, dressed in a manner to preserve their anonymity, shall enter into the room where the section chief and offender are located to physically confirm the offender is unconscious by using all necessary and medically-appropriate methods. The IV Team leader shall also confirm that the IV line remains affixed and functioning properly.

5. If confirmed the offender is unconscious, an announcement will be made and the director will order the remaining chemicals be dispensed in the order they appear in the chart.

6. Upon direction from the Special Operations Team Leader, the assigned Special Operations Team member shall visually and orally confirm the chemical name on the syringe and then administer the full dose of the remaining chemicals in the order they appear in the chart.

7. If the offender remains conscious after five (5) minutes, the IV Team shall communicate this information to the director, along with all IV Team input. The director shall determine how to proceed or, if necessary, to start the procedure over at a later time or stop the execution. The director may order the curtains to the witness viewing room be closed, and if necessary, for witnesses to be removed from the facility.

8. If deemed appropriate, the director may instruct the Special Operations Team to administer additional doses of the chemical(s) followed by the heparin/saline flush.

9. Upon administering the chemical(s) and heparin/saline from a backup set, the IV Team shall confirm the offender is unconscious by sight and sound, utilizing the audio equipment, camera and monitor. The IV Team leader shall again physically confirm the offender is unconscious using proper medical procedures and verbally advise the director of the same.

10. When all electrical activity of the heart has ceased as shown by the electrocardiograph, the IV Team leader shall confirm the offender is deceased and the offender's death shall be announced by the director.

11. The Special Operations Team Recorder shall document on the Correctional Service Log the start and the ending times of the administration of the chemical(s).

12. Throughout the entire procedure, the IV Team members, the Special Operations Team members and the H Unit Section Chief shall continually monitor the offender using all available means to ensure that the offender remains unconscious and that there are no complications.

I. Post Execution Procedures

1. Upon the pronouncement of death, the director shall notify the governor or designee and the attorney general or designee via telephone that the sentence has been carried out and the time that death occurred.

2. An IV Team member shall clamp and cut the IV lines leaving them connected to the offender for examination by a medical examiner.

3. An investigator with the Inspector General's office and a medical examiner shall take photos of the offender's body:

   a. While in restraints prior to being placed in the body bag;

   b. Without restraints prior to being placed in the body bag;

   c. Sealed in the body bag; and

   d. A photo of the seal in place on the bag.

4. The offender's body shall be placed on a medical examiner's gurney and released into the custody of a medical examiner's office.

5. Once the offender's body is placed in a medical examiner's transport vehicle, it shall be escorted off the premises. The examiner's office shall

take the offender's body to the medical examiner's office designated by the county.

J. Documentation of Stay Prior to Execution

1. In the event that a pending stay results in more than a two (2) hour delay, the catheters shall be removed, if applicable, and the offender shall be returned to the holding cell until further notice.

2. The Correctional Service Log and the list of identifiers shall be submitted to the general counsel for review and storage.

K. Contingency Procedure

1. An Automated External Defibrillator (AED) shall be readily available on site in the event that the offender goes into cardiac arrest at any time prior to dispensing the chemicals. Trained medical staff shall make every effort to revive the offender should this occur.

2. Trained medical personnel and emergency transportation, neither of which is involved in the execution process, shall be available in proximity to respond should any medical emergency arise.

3. If at any point any team member determines that any part of the execution process is not going according to procedure, they shall advise the IV Team leader who shall immediately notify the director. The director may consult with persons deemed appropriate and shall determine to go forward with the procedure, start the procedure over at a later time within the twenty-four (24) hour day, or stop the execution.

4. There shall be no deviation from the procedures as set forth herein, without prior consent from the director.

L. Debrief and Policy Review

1. The IV and Special Operations Teams shall participate in an informal debriefing immediately upon completion of the event.

2. Upon an assignment to a team, team members shall review OP-040301 entitled "Execution of Offenders Sentenced to Death."

3. Periodically, and in the discretion of the director, a review of OP-040301 entitled "Execution of Offenders Sentenced to Death," along with this attachment may be reviewed to confirm it remains consistent with the law. The general counsel shall advise the director immediately upon any change that may impact these procedures.

EXHIBIT 3

501 KAR 16:330. Lethal injection protocols.

RELATES TO: KRS 196.030, 196.070, 196.180, 431.213 – 431.270
STATUTORY AUTHORITY: KRS 196.035, 197.020, 431.218, 431.220, 431.224, 431.240, 431.250, 431.260, 431.270
NECESSITY, FUNCTION, AND CONFORMITY: KRS 196.035 and 197.020 authorize the Justice and Public Safety Cabinet and Department of Corrections to promulgate administrative regulations necessary and suitable for the proper administration of the Cabinet or any of its divisions. KRS 431.220 establishes requirements for the execution of the death penalty. This administrative regulation establishes the protocols for execution by lethal injection.

Section 1. Procurement, Storage, and Accountability of Substances. (1) Upon receipt of an execution order, the warden shall check the supply of substances and their expiration dates. If additional substances are needed, the warden shall place an order to obtain the necessary substances for the lethal injection protocols listed in Section 3 of this administrative regulation.

(2) The substances shall be stored according to the manufacturer's instructions, if applicable, and placed in a secured area of the penitentiary in locked containers. The warden shall maintain control of the keys to the secured areas and containers.

(3) A log shall be maintained in the storage containers which shall record:

(a) New supplies of substances received and added to inventory;

(b) Substances removed for use;

(c) Disposal of substances due to expiration; and

(d) Any other reason that a substance is removed or deducted from inventory.

Section 2. Preliminary Steps. (1) The condemned person shall be executed by using the One Drug Protocol in Section 3(2) of this administrative regulation. If the necessary substance or quantity of the substance for the One Drug Protocol is not in the warden's possession by seven (7) days prior to the execution, the condemned person shall be executed by using the Two Drug Protocol in Section 3(3) of this administrative regulation. The commissioner shall notify the condemned person at least seven (7) days prior to the execution of the protocol to be used.

(2) The penitentiary shall have a minimum of two (2) phone lines available for communication with the courts and counsel on the day of execution. The phones shall be checked to determine if they are operational prior to the execution.

(3) If the condemned person is to be executed by lethal injection:

(a) If male, his chest shall be shaved by a designated member of the execution team for heart monitor leads on the day of execution; and

(b) The IV team shall complete an examination of the condemned person's veins within twenty-four (24) hours prior to the execution to determine possible locations of the IV sites.

(4) On the day of execution the warden shall provide to the IV team sufficient amounts of each substance listed in Section 3 of this administrative regulation to prepare two (2) syringes for the drug protocol selected to be used. One (1) syringe shall serve as the primary syringe. The other syringe shall be a back-up.

(5) At the execution building, each substance shall be prepared in accordance with the manufacturer's instructions, if applicable, and drawn into the two (2) syringes by one (1) member of the IV team designated by the warden. The other member of the IV team shall observe preparation of the substances and verify that the instructions and procedures have been carried out correctly.

(6) Any syringes that are loaded with lethal injection substances that are not used during the execution shall be destroyed and documented in the log maintained in accordance with Section 1(3) of this administrative regulation.

(7) Any unused substances that were not prepared for the lethal injection shall be:

(a) Returned to the warden;

(b) Locked in the storage container; and

(c) Documented in the log maintained in accordance with Section 1(3) of this administrative regulation.

(8) A member of the IV team shall determine the appropriate size needle based on the examination of the condemned person's veins within the five (5) hours prior to the execution.

(9) The warden shall order the condemned person escorted to the execution chamber and strapped to the gurney.

(10) The IV team shall run the IV lines to the condemned person by the following:

(a) Site and insert one (1) primary IV line; and

(b) Site and insert one (1) backup IV line.

(11) The location of the IV sites on the body of the condemned person shall be determined by the IV team members. The insertion site of preference shall be the following order:

(a) Arms;

(b) Hands;

(c) Ankles; or

(d) Feet.

(12) To best ensure that a needle is inserted properly into a vein, the IV team members shall look for the presence of blood in the valve of the sited needle.

(13) If the IV team cannot secure two (2) IV sites within one (1) hour, the Commissioner shall contact the Governor's Office and request that the execution be scheduled for a later date.

(14) If the IV team is able to establish the two IV lines, the team shall start a saline flow.

(15) The execution team shall:

(a) Securely connect the electrodes of the cardiac monitor to the condemned person; and

(b) Ensure the equipment is functioning.

(16) Counsel assigned by the cabinet and counsel assigned by the office of the Attorney General shall be asked whether any stays, orders, pardons, or commutations of sentence have been received.

(17) The viewing curtain shall be opened.

(18) The warden shall announce the execution to the witnesses.

(19) The warden shall ask the condemned person if he wants to make a final statement and provide a brief opportunity of not less than two (2) minutes for him to do so. The warden may impose reasonable restrictions on the content and length of the statement. The warden may also terminate a statement that he or she believes is intentionally offensive to the witnesses. The witnesses shall be allowed to hear the condemned person's statement.

(20) The warden shall order the execution to proceed.

Section 3. Protocols and Sequence of Substances. (1) The lethal injection protocols shall be as follows.

(2) One Drug Protocol.

(a) A designated execution team member shall inject via IV three (3) gm of Sodium Thiopental (60 ml of a 50mg/ml solution) or five (5) gm of Pentobarbital (100 ml of a 50 mg/ml solution) under whatever generic or trade names they may be known or sold.

(b) If it appears to the warden based on his visual inspection that the condemned person is not unconscious within sixty (60) seconds of his command to proceed, the warden shall stop the flow of the Sodium Thiopental or Pentobarbital in the primary site and order that the backup IV be used with a new flow of the substance.

(c) A designated execution team member shall start a stopwatch once the lethal injection is complete.

(d) A designated execution team member shall:

1. Observe the heart monitor; and

2. Advise the coroner and physician when electrical activity of the heart has ceased as indicated by a flat line on the heart monitor.

(e) The viewing curtain shall be drawn before the:

1. Coroner enters the chamber to declare death; and

2. Physician enters the chamber to certify the cause of death.

(f) An additional injection of the substance in the same dose and concentration listed in paragraph (a) of this subsection shall be used if the:

1. Heart monitor does not indicate a flat line after ten (10) minutes;

2. Coroner is not able to declare death; and

3. Physician is unable to certify the cause of death after the ten (10) minute period.

(g) The injections shall continue until death has occurred.

(h) During the execution by lethal injection the warden and deputy warden shall watch the primary IV site for failure, leakage, the catheter coming out of a vein, or any other problem. If an IV fails or leaks, the catheter comes out of the vein, or any other problem arises, the execution team shall be instructed to switch to the backup IV.

(3) Two Drug Protocol.

(a) A designated execution team member shall inject via IV ten (10) mg of midazolam (5mg/ml concentration) and 40 mg of hydromorphone (10 mg/ml concentration) under whatever generic or trade names they may be known or sold.

(b) If it appears to the warden based on his visual inspection that the condemned person is not unconscious within sixty (60) seconds of his command to proceed, the warden shall stop the flow of midazolam and hydromorphone in the primary site and order that the backup IV be used with a new flow of the substances listed for this protocol in paragraph (a) of this subsection.

(c) A designated execution team member shall start a stopwatch once the lethal injection is complete.
(d) A designated execution team member shall:
1. Observe the heart monitor; and
2. Advise the coroner and physician when electrical activity of the heart has ceased as indicated by a flat line on the heart monitor.
(e) The viewing curtain shall be drawn before the:
1. Coroner enters the chamber to declare death; and
2. Physician enters the chamber to certify the cause of death.
(f) Except as described in paragraph (g) of this subsection, an additional injection of the lethal substances in the same doses and concentrations listed in paragraph (a) of this subsection shall be used if the:
1. Heart monitor does not indicate a flat line after ten (10) minutes;
2. Coroner is not able to declare death; and
3. Physician is unable to certify the cause of death after the ten (10) minute period.
(g) Any additional injections after the initial and second injections shall be sixty (60) mg of hydromorphone (10 mg/ml concentration). The injections shall continue until death has occurred.
(h) During the execution by lethal injection the warden and deputy warden shall watch the primary IV site for failure, leakage, the catheter coming out of a vein, or any other problem. If an IV fails or leaks, the catheter comes out of the vein, or any other problem arises, the execution team shall be instructed to switch to the backup IV.

Section 4. Post Lethal Injection Steps. (1) If the Coroner declares death, the warden shall announce the completion of the execution to the witnesses. The viewing curtain shall be open during the warden's announcement.
(2) The witnesses shall be escorted out of the witness room.

Section 5. Stabilization Procedure. (1) Before an execution commences:
(a) The warden shall arrange for an ambulance and staff to be present on penitentiary property during the execution; and
(b) A medical crash cart and defibrillator shall be located in the execution building.
(2) If at any time during the execution process the Governor grants a pardon or commutes the sentence of the condemned person or if a court of competent jurisdiction issues a stay after an execution has commenced:
(a) The execution team shall stop the execution; and
(b) The medical staff on site shall attempt to stabilize the condemned person with the equipment and personnel listed in subsection (1) of this section.

Section 6. Volunteer. (1) If a condemned person, who is a volunteer, tells department staff that he does not wish to continue with the execution process, the staff shall tell the warden.
(2) If the execution is in process:
(a) The execution team shall stop the execution; and
(b) If any of the substances have been injected, the medical staff on site shall attempt to stabilize the condemned person with the equipment and personnel listed in Section 5(1) of this administrative regulation.
(3) The warden shall allow the condemned person to contact his attorney.
(4) The warden shall notify the commissioner.
(5) The commissioner shall notify the Governor's Office or court issuing the mandate. (36 Ky.R. 1566; Am. 2096-M; 2042-A; eff. 5-7-2010; 39 Ky.R. 609; 1204; eff. 2-1-2013.)

EXHIBIT 4

Intravenous Medication Administration: What to Know

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Introduction

Some medications must be given by an intravenous (IV) injection or infusion. This means they're sent directly into your vein using a needle or tube. In fact, the term "intravenous" means "into the vein."

With IV administration, a thin plastic tube called an IV catheter is inserted into your vein. The catheter allows your healthcare provider to give you multiple safe doses of medication without needing to poke you with a needle each time.

In most cases, you won't give yourself an intravenous medication. While you can take some infusion medications yourself at home, you'll likely receive your therapy from a healthcare provider. Read on to learn about the two main tools used for IV administration — standard IV lines and central venous catheters — including why they're used and what the risks are.

Uses

Uses of IV medications

IV medication is often used because of the control it provides over dosage. For instance, in some situations, people must receive medication very quickly. This includes emergencies, such as a heart attack, stroke, or poisoning. In these instances, taking pills or liquids by mouth may not be fast enough to get these drugs into the bloodstream. IV administration, on the other hand, quickly sends a medication directly into the bloodstream.

Other times, medications may need to be given slowly but constantly. IV administration can also be a controlled way to give drugs over time.

Certain drugs may be given by IV administration because if you took them orally (by mouth), enzymes in your stomach or liver would break them down. This would prevent the drugs from working well when they're finally sent to your bloodstream. Therefore, these drugs would be much more effective if sent directly into your bloodstream by IV administration.

Standard IV lines

About standard IV lines

Standard IV lines are typically used for short-term needs. For instance, they may be used during a short hospital stay to administer medication during surgery or to give pain medications, nausea medications, or antibiotics. A standard IV line can typically be used for up to four days.

With standard IV administration, a needle is usually inserted into a vein in your wrist, elbow, or the back of your hand. The catheter is then pushed over the needle. The needle is removed, and the catheter remains in your vein. All IV catheters are typically given in a hospital or clinic.

A standard IV catheter is used for two kinds of IV medication administration:

IV push

An IV "push" or "bolus" is a rapid injection of medication. A syringe is inserted into your catheter to quickly send a one-time dose of drug into your bloodstream.

IV infusion

An IV infusion is a controlled administration of medication into your bloodstream over time. The two main methods of IV infusion use either gravity or a pump to send medication into your catheter:

Pump infusion: In the United States, a pump infusion is the most common method used. The pump is attached to your IV line and sends medication and a solution, such as sterile saline, into your catheter in a slow, steady manner. Pumps may be used when the medication dosage must be precise and controlled.

Drip infusion: This method uses gravity to deliver a constant amount of medication over a set period of time. With a drip, the medication and solution drip from a bag through a tube and into your catheter.

Central venous catheters

Types of central venous catheters

Long-term medication treatment, such as chemotherapy or total parenteral nutrition, usually requires a central venous catheter (CVC) instead of a standard IV catheter. A CVC is inserted into a vein in your neck, chest, arm, or groin area.

CVCs can be used for a longer period of time than a standard IV line. A CVC can stay in place for several weeks or even months.

The three main types of CVCs include:

Peripherally inserted central catheter (PICC)

A PICC has a long line that sends medication from the area of insertion, through your blood vessels, all the way to a vein near your heart. A PICC is typically placed in a vein above your elbow in your upper arm.

Tunneled catheter

With a tunneled catheter, medication can be sent directly into blood vessels in the heart. One end of the catheter is placed into a vein in the neck or chest during a short surgical procedure. The rest of the catheter is tunneled through the body, with the other end coming out through the skin. Medications can then be given into that end of the catheter.

Implanted port

Like a tunneled catheter, an implanted port inserts a catheter into a vein in the neck or chest. This device is also placed during a short surgical procedure. But unlike a tunneled catheter, an implanted port is located completely beneath the skin. To use this device, a healthcare provider injects medication through the skin into the port, which sends the medication into the bloodstream.

IV drugs

Drugs typically given by IV

Many different types of medications can be given by IV. Some of the drugs more commonly given by this method include:

- chemotherapy drugs such as doxorubicin, vincristine, cisplatin, and paclitaxel
- antibiotics such as vancomycin, meropenem, and gentamicin
- antifungal drugs such as micafungin and amphotericin
- pain medications such as hydromorphone and morphine
- drugs for low blood pressure such as dopamine, epinephrine, norepinephrine, and dobutamine
- immunoglobulin medications (IVIG)

Side effects

Side effects

While IV medication use is generally safe, it can cause both mild and dangerous side effects. Medications given intravenously act on the body very quickly, so side effects, allergic reactions, and other effects can happen fast. In most cases, a healthcare provider will observe you throughout your infusion and sometimes for a period afterward. Examples of IV side effects include:

Infection

Infection can occur at the injection site. To help prevent infection, the administration process must be done carefully using sterile (germ-free) equipment. An infection from the injection site can also travel into the bloodstream. This can cause a severe infection throughout the body.

Infection symptoms can include fever and chills, as well as redness, pain, and swelling at the injection site. If you have any symptoms of infection, call your doctor right away.

Damage to blood vessels and injection site

A vein can be damaged during injection or by the use of an IV catheter line. This can cause infiltration. When this occurs, medication leaks into surrounding tissue instead of going into the bloodstream. Infiltration can cause tissue damage.

IV administration can also cause phlebitis, or inflammation of the veins. Symptoms of both infiltration and phlebitis include warmth, pain, and swelling at the injection site. Call your doctor right away if you have any of these symptoms.

Air embolism

If air gets into the syringe or the IV medication bag and the line runs dry, air bubbles can enter your vein. These air bubbles can then travel to your heart or lungs and block your blood flow. An air embolism can cause severe problems such as heart attack or stroke.

Blood clots

IV therapy can cause blood clots to form. Clots can block important blood vessels and cause problems such as tissue damage or death. Deep vein thrombosis is one type of dangerous blood clot that IV treatment can cause.

Takeaway

Talk with your doctor

IV drug administration is a fast, effective way to send medication into your bloodstream. If your doctor has prescribed it for you, they will likely explain the purpose and the process for your treatment. But if you have questions, be sure to ask. Your questions may include:

- How long will I need to have my IV treatment?
- Am I at high risk of any side effects?
- Can I receive my IV medication at home? Can I give it to myself?

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