U.S. Department of Justice
Drug Enforcement Administration
FOI/Records Management Section
8701 Morrissette Drive
Springfield, Virginia 22152

OCT 07 2011

Case Number: 11-00322-F (1st Release)

Subject: DEA FORM 236 AND RELATED RECORDS, RECORDS RELATED TO U.S. DOJ CONFERENCE CALL WITH STATES, SUPPLEMENTAL RECORDS IN RESPONSE TO FOIA REQUEST CASE NUMBER 11-00133-F ETC.

Natasha Minsker
Death Penalty Policy Director
American Civil Liberties Union
of Northern California
39 Drumm Street
San Francisco, California 94111

Dear Ms. Minsker:

This letter responds to your Freedom of Information/Privacy Act (FOI/PA) request dated June 28, 2011, addressed to the Drug Enforcement Administration (DEA), Freedom of Information/Privacy Act Unit (SARF), seeking access to information regarding the above subject.

With regard to your request pertaining to DEA records regarding to the June, 2011 teleconference with State Attorney General's, we have located records responsive to your request. The processing of your request identified certain materials that will be released to you. Portions not released are being withheld pursuant to the Freedom of Information Act, 5 U.S.C. § 552, and/or the Privacy Act, 5 U.S.C. § 552a. Please refer to the list enclosed with this letter that identifies the authority for withholding the deleted material, which is indicated by a mark appearing in the block next to the exemption. An additional enclosure with this letter explains these exemptions in more detail. The documents are being forwarded to you with this letter.

Certain DEA documents contained information furnished by other government agencies. DEA is in the process of consulting with these government agencies before granting access to the documents in accordance with 28. C.F.R. 16.4 and/or 16.42. You will be notified if more material is available for release pending results from the consultations.

Further, certain DEA files contain information that was furnished by another government agency. That information and a copy of your request have been referred for a decision as to access and the agency involved will respond directly to you in accordance with 28 C.F.R § 16.4 and/or 16.42.

Additionally, the remaining portion of your request will be processed expeditiously. Upon completion, all releasable information will be provided to you.

If you wish to appeal any denial of your request, you must make your appeal in writing and it must be received by the Office of Information Policy within sixty (60) days of the date of this letter pursuant to 28 C.F.R. § 16.9. The appeal should be sent to the following address, with the envelope marked "FOIA Appeal":

DEPARTMENT OF JUSTICE
OFFICE OF INFORMATION POLICY
NYAV BUILDING, 11TH FLOOR
WASHINGTON, D.C. 20530

If you have any questions regarding this letter, you may contact FOI Specialist Rita A. Cuellar on 202-307-7610.

Sincerely,

Katherine Myrick

Katherine L. Myrick, Chief
Freedom of Information/Privacy Act Unit
FOI/Records Management Section

Enclosures

Number of pages withheld: 58

Number of pages released: 36

Number of pages referred: 6

Number of pages consulted: 11

APPLICABLE SECTIONS OF THE FREEDOM OF INFORMATION AND/OR PRIVACY ACT:

Freedom of Information Act 5 U.S.C. 552			**Privacy Act 5 U.S.C. 552a**	
[ ] (b)(1)	[X] (b)(5)	[ ] (b)(7)(C)	[ ] (d)(5)	[ ] (k)(2)
[ ] (b)(2)	[X] (b)(6)	[ ] (b)(7)(D)	[ ] (j)(2)	[ ] (k)(5)
[ ] (b)(3)	[ ] (b)(7)(A)	[ ] (b)(7)(E)	[ ] (k)(1)	[ ] (k)(6)
[ ] (b)(4)	[ ] (b)(7)(B)	[ ] (b)(7)(F)		

FREEDOM OF INFORMATION ACT
SUBSECTIONS OF TITLE 5, UNITED STATES CODE, SECTION 552

(b)(1) Information which is currently and properly classified pursuant to Executive Order in the interest of the national defense or foreign policy.

(b)(2) Materials related solely to the internal rules and practices of DEA.

(b)(3) Information specifically exempted from disclosure by another federal statute.

(b)(4) Privileged or confidential information obtained from a person, usually involving commercial or financial matters.

(b)(5) Inter-agency or intra-agency documents which are subject to a privilege, such as documents the disclosure of which would have an inhibitive effect upon the development of policy and administrative direction, or which represent the work product of an attorney, or which reflect confidential communications between a client and an attorney.

(b)(6) Materials contained in sensitive records such as personnel or medical files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(b)(7) Records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information (A) could reasonably be expected to interfere with enforcement proceedings; (B) would deprive a person of a right to a fair trial or an impartial adjudication; (C) could reasonably be expected to constitute an unwarranted invasion of personal privacy; (D) could reasonably be expected to disclose the identity of a confidential source, including a State, local or foreign agency or authority or any private institution which furnished information on a confidential basis; and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source; (E) would disclose techniques and procedures for law enforcement investigations or prosecutions or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law, or (F) could reasonably be expected to endanger the life or physical safety of any individual.

PRIVACY ACT
SUBSECTIONS OF TITLE 5, UNITED STATES CODE, SECTION 552a

(d)(5) Materials compiled in reasonable anticipation of a civil action or proceeding.

(j)(2) Material reporting investigative efforts pertaining to the enforcement of criminal law including efforts to prevent, control, or reduce crime or apprehend criminals.

(k)(1) Information which is currently and properly classified pursuant to Executive Order in the interest of the national defense or foreign policy.

(k)(2) Material compiled during civil investigations for law enforcement purposes.

(k)(5) Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment or for access to classified information, the disclosure of which would reveal the identity of the person who furnished information pursuant to an express promise that his identity would be held in confidence, or pursuant to an implied promise of confidentiality if such information was furnished prior to September 27, 1975.

(k)(6) The substance of tests used to determine individual qualifications for appointment or promotion in Federal Government Service.

(b)(6)

From: Gleason, Robert (Chris)
Sent: Wednesday, May 25, 2011 8:36 AM
To: Goggin, Wendy H.; (b)(6)
Subject: Draft Outline for State AG Talk

Importance: High

Folks,

Release
36 Pages

Attached for review is a draft outline for next week's telecc you please review and comment – I am interested in comments on form and flow as w like input on questions we can anticipate. It needs to go to Joe, too, but I wanted an in

(b)(5),(b)(6)

State AG Discussion.doc

Prison Wardens CSA-Reg Trainin...

Tracking:

(b)(6)

From: (b)(6)
Sent: Wednesday, May 25, 2011 10:14 AM
To: Gleason, Robert (Chris)
Cc: (b)(6)
Subject: RE: Draft Outline for State AG Talk

Chris: In response to your question (b)(5) I didn't see anything else yet, but I'll take another look and, if I have any other suggested edits, I'll let you know. Thanks.

-- Dan

From: Gleason, Robert (Chris)
Sent: Wednesday, May 25, 2011 8:36 AM
To: Goggin, Wendy H.; (b)(6)
Subject: Draft Outline for State AG Talk
Importance: High

Folks,

Attached for review is a draft outline for next week's teleconference with the State AG's. Can you please review and comment – I am interested in comments on form and flow as well as in substance. Also, I would like input on questions we can anticipate. It needs to go to Joe, too, but I wanted an internal CC review first.

(b)(5),(b)(6)

<< File: State AG Discussion.doc >> << File: Prison Wardens CSA-Reg Training 5-23-2011.doc >>

(b)(6)

From: Gleason, Robert (Chris)
Sent: Thursday, May 26, 2011 9:21 AM
To: (b)(6)
Subject: RE: State AG Discussion 2.doc

Importance: High

Thanks (b)(6) I've incorporated most of your suggestions, but do have some questions. I'd like to discuss ASAP once you've had a chance to re-review. I need to get this through OD and to DOJ.

From: (b)(6)
Sent: Wednesday, May 25, 2011 4:54 PM
To: Gleason, Robert (Chris)
Subject: State AG Discussion 2.doc

<< File: State AG Discussion 2.doc >>

In the interest of time, I wanted to get you our initial comments. I would like to review again in the morning.

Tracking:

(b)(6)

From: (b)(6)
Sent: Wednesday, May 25, 2011 12:20 PM
To: (b)(6)
Subject: RE: Draft Outline for State AG Talk

My comments, etc., are in track changes.

(b)(5),(b)(6)

State AG
Discussion RKM.doc

From: (b)(6)
Sent: Wednesday, May 25, 2011 9:22 AM
To: (b)(6)
Subject: FW: Draft Outline for State AG Talk
Importance: High

I will review. Can you review too? Thanks.

From: Gleason, Robert (Chris)
Sent: Wednesday, May 25, 2011 8:36 AM
To: Goggin, Wendy H.; (b)(6)
Subject: Draft Outline for State AG Talk
Importance: High

Folks,

Attached for review is a draft outline for next week's teleconference with the State AG's. Can you please review and comment – I am interested in comments on form and flow as well as in substance. Also, I would like input on questions we can anticipate. It needs to go to Joe, too, but I wanted an internal CC review first.

(b)(5),(b)(6)

<< File: State AG Discussion.doc >> << File: Prison Wardens CSA-Reg Training 5-23-2011.doc >>

(b)(6)

From: (b)(6)
Sent: Thursday, May 26, 2011 9:35 AM
To: (b)(6)
Subject: RE: State AG Discussion 2.doc

My changes are tracked on top of your changes in the attachment – they should show in a different color.

(b)(5)

State AG Discussion 2.doc

From: (b)(6)
Sent: Wednesday, May 25, 2011 5:09 PM
To: (b)(6)
Subject: FW: State AG Discussion 2.doc

Thanks.

From: (b)(6)
Sent: Wednesday, May 25, 2011 4:54 PM
To: Gleason, Robert (Chris)
Subject: State AG Discussion 2.doc

<< File: State AG Discussion 2.doc >>

In the interest of time, I wanted to get you our initial comments. I would like to review again in the morning.

(b)(6)

From: Gleason, Robert (Chris)
Sent: Thursday, May 26, 2011 9:38 AM
To: (b)(6)
Subject: RE: State AG Discussion 2.doc

10:00 is fine.

From: (b)(6)
Sent: Thursday, May 26, 2011 9:38 AM
To: Gleason, Robert (Chris)
Subject: FW: State AG Discussion 2.doc

Hi Chris. (b)(6) made a few edits. Here they are. Could we meet at 10:00 or 10:15?

From: (b)(6)
Sent: Thursday, May 26, 2011 9:35 AM
To: (b)(6)
Subject: RE: State AG Discussion 2.doc

My changes are tracked on top of your changes in the attachment – they should show in a different color.

(b)(5)

<< File: State AG Discussion 2.doc >>

From: (b)(6)
Sent: Wednesday, May 25, 2011 4:54 PM
To: Gleason, Robert (Chris)
Subject: State AG Discussion 2.doc

<< File: State AG Discussion 2.doc >>

In the interest of time, I wanted to get you our initial comments. I would like to review again in the morning.

Tracking:

(b)(6)

From: (b)(6)
Sent: Friday, May 27, 2011 9:27 AM
To: Gleason, Robert (Chris)
Subject: FW: Talk for State AGs

Hi Chris --

I thought we noted these cites, but they may have slipped through on one of the reworked drafts.

p. 2 – in V.b.1. – cite should be to 1301.13(e)(1)
p. 4 – in VII.c.i. – cite should be to 822(e)

Minor fixes on page 4 VII.b.ii. (your DoC instead of you DoC) and on page 5 XI.a. space between to and another.

From (b)(6)
Sent: Thursday, May 26, 2011 3:34 PM
To: (b)(6)
Subject: FW: Talk for State AGs

From: Gleason, Robert (Chris)
Sent: Thursday, May 26, 2011 11:57 AM
To (b)(6)
Subject: FW: Talk for State AGs

FYI – here's the current version.

From: Gleason, Robert (Chris)
Sent: Thursday, May 26, 2011 11:45 AM
To: Rannazzisi, Joseph T.
Subject: Talk for State AGs

PREDECISIONAL ATTORNEY-CLIENT COMMUNICATION

Joe,

Attached for your review is a draft outline for next week's teleconference with the State AGs.

(b)(5)

(b)(5)

<< File: State AG Discussion 2.doc >>

(b)(6)

From: (b)(6)
Sent: Friday, May 27, 2011 11:55 AM
To: Gleason, Robert (Chris)
Cc: Rannazzisi, Joseph T.; Boggs, Gary
Subject: AG talking points

Chris,
Joe is on leave today, but he cleared the attached TPs (just minor edits). Thanks for your help. (b)(6)

(b)(6) Executive Assistant | Office of the Deputy Assistant Administrator |
Office of Diversion Control | Drug Enforcement Administration |
(b)(6)

State AG
Discussion 2.doc

(b)(6)

From: Goggin, Wendy H.
Sent: Tuesday, May 31, 2011 11:27 AM
To: Rannazzisi, Joseph T.
Cc: Gleason, Robert (Chris)
Subject: POC for sodium thiopental issues

Have you selected some person to be the DEA POC? We should probably have that person's contact info ready to give to the state AG's next Thursday.
W

Wendy Goggin
Chief Counsel
Drug Enforcement Administration
(b)(6)

(b)(6)

From: Goggin, Wendy H.
Sent: Tuesday, May 31, 2011 5:09 PM
To: Gleason, Robert (Chris)
Subject: RE: Outline for AG Telecon - with Security & Recordkeeping Added

This looks fine to me. I sent an email to Joe soliciting POC nominations. No response. (b)(6)
(b)(6)

From: Gleason, Robert (Chris)
Sent: Tuesday, May 31, 2011 2:11 PM
To: (b)(6)
Cc: Goggin, Wendy H.; Rannazzisi, Joseph T.
Subject: Outline for AG Telecon - with Security & Recordkeeping Added

(b)(5)

I am forwarding it for your review and comment. (b)(5)

<< File: State AG Discussion.doc >>

(b)(6)

Subject: State AG Telecon
Location: Chris' Office

Start: Wed 6/1/2011 3:30 PM
End: Wed 6/1/2011 4:30 PM
Show Time As: Tentative

Recurrence: (none)

Meeting Status: Not yet responded

Organizer: Gleason, Robert (Chris)
Required Attendees: (b)(6)

To discuss possible Q&As.

(b)(6)

From: Goggin, Wendy H.
Sent: Wednesday, June 01, 2011 3:58 PM
To: (b)(6) Gleason, Robert (Chris)
Subject: RE: State AG Conference Call Tomorrow

Thanks.

From: (b)(6)
Sent: Wednesday, June 01, 2011 3:53 PM
To: Gleason, Robert (Chris); Goggin, Wendy H.
Subject: FW: State AG Conference Call Tomorrow

Wendy and Chris,

Below is the response from OD regarding the conference call tomorrow and a POC for sodium thiopental registration issues.

(b)(6)

From: Boggs, Gary
Sent: Wednesday, June 01, 2011 3:43 PM
To: (b)(6)
Subject: Re: State AG Conference Call Tomorrow

We will be on the call tomorrow and (b)(6) will be the POC for registration questions and Joe will be the POC for other related questions.

From (b)(6)
Sent: Wednesday, June 01, 2011 02:54 PM
To: Boggs, Gary
Subject: State AG Conference Call Tomorrow

Gary,

I was in a meeting with Wendy and Chris and they wanted me to find out if you or Joe were planning to participate in the conference call tomorrow with the State Attorney Generals. It is scheduled to begin at 1:00 p.m.

Also, I was asked to see if you have a Diversion POC for sodium thiopental registration questions. This is in response to DOJ advising that they want DEA to be able to respond to questions from registrants/states regarding this issue within 48 hours.

Thanks,

(b)(6)
Executive Assistant
DEA Office of Chief Counsel
(b)(6)

(b)(6)

From: Goggin, Wendy H.
Sent: Wednesday, June 01, 2011 4:40 PM
To: Rannazzisi, Joseph T.; Boggs, Gary
Cc: Gleason, Robert (Chris)
Subject: fun conference call with state AGs tomorrow

Do you want to join Chris and me in his office for this conference call?

Wendy Goggin
Chief Counsel
Drug Enforcement Administration
(b)(6)

(b)(6)

From: (b)(6)
Sent: Monday, June 06, 2011 10:56 AM
To: (b)(6) (b)(6)
Subject: FW: CSA Overview

Can you review? Thanks.

From: Gleason, Robert (Chris)
Sent: Friday, June 03, 2011 4:07 PM
To: (b)(6) Rannazzisi, Joseph T.
Subject: CSA Overview

Folks,

I've received a half dozen or so requests for the notes from the talk with the AG Offices yesterday. I have modified my notes, and here I what I propose to send out. Can you review and give me your thoughts?

CSA Overview.doc

(b)(6)

From: (b)(6)
Sent: Friday, June 03, 2011 4:20 PM
To: Gleason, Robert (Chris)
Subject: RE: CSA Overview

Looks fine to me.

From: Gleason, Robert (Chris)
Sent: Friday, June 03, 2011 4:07 PM
To: Murphy, (b)(6) Rannazzisi, Joseph T.
Subject: CSA Overview

Folks,

I've received a half dozen or so requests for the notes from the talk with the AG Offices yesterday. I have modified my notes, and here I what I propose to send out. Can you review and give me your thoughts?

<< File: CSA Overview.doc >>

(b)(6)

From: (b)(6)
Sent: Monday, June 06, 2011 3:37 PM
To: Gleason, Robert (Chris)
Cc: (b)(6)
Subject: CSA Overview (b)(6) docx

CSA Overview (b)(6) docx

Hi Chris. Here are our comments. (b)(6)

(b)(6)

From: Gleason, Robert (Chris)
Sent: Tuesday, June 07, 2011 8:44 AM
To: 'Mark Hudson'
Subject: RE: Conference Call re DEA Regulation pertaining to Sodium thiopental
Attachments: CSA Overview.docx

As requested.

From: Mark Hudson (b)(6)
Sent: Thursday, June 02, 2011 1:45 PM
To: Gleason, Robert (Chris)
Subject: Conference Call re DEA Regulation pertaining to Sodium thiopental

Please reply with any information you have to supplement the discussion during the conference call regarding obtaining and dispensing sodium thiopental.

Thank you.

Mark A. Hudson
Senior Counsel
Office of the Attorney General and Reporter
State of Tennessee
(b)(6)

Overview of the "Closed System" Established by the Federal CSA

I. The primary diversion control mechanism of the federal Controlled Substances Act (CSA) is the "closed system" it establishes. Generally speaking, any activity involving a controlled substance that is not specifically authorized by the CSA is prohibited. The CSA establishes and enforces this closed system through three general mechanisms
   a. Registration requirements
   b. Recordkeeping requirements
   c. Security requirements

II. Registration Basics
   a. Every entity that handles a controlled substance must register with the Drug Enforcement Administration (DEA). Furthermore, 21 U.S.C. § 822(b) says that registrants are authorized to possess, manufacture, distribute or dispense controlled substances *to the extent authorized by their registration.*
      i. There are different kinds of DEA registrations that authorize different kinds of activities. See 21 C.F.R. § 1301.13(e)
      ii. Registrations can be limited by drug schedule
      iii. Registrations are tied to a particular physical location. 21 U.S.C. § 822(e); 21 C.F.R. § 1301.12.
      iv. Simply having a DEA registration may not be sufficient. The registration must authorize the particular activity you want to engage in *and* it must include the particular drug class or drug schedule that you're dealing with *and* it must be issued for the location where the particular activity is being carried out.

III. Legitimate sources for obtaining a controlled substance.
   a. One option: Acquiring it directly on the international market. In other words, "importing" it.
      i. In order to do that, an individual or entity would need to be registered as an "importer."
      ii. Registration to import required by 21 U.S.C. §§ 957, 958; 21 C.F.R. § 1301.11
      iii. An entity with a valid importer registration can lawfully import a controlled substance under the CSA, provided their import registration includes the schedule of the drug being imported.
      iv. Additional requirements apply before actually importing the controlled substance. Those requirements depend on what schedule of controlled substance is being imported.
         1. Before importing a schedule III non-narcotic, for example, an importer must notify DEA 15 days in advance under 21 U.S.C. § 952 and 21 C.F.R. § 1312.18(b). This is done via a form DEA 236.

2. Before importing a schedule II drug, an entity must apply for and receive an import permit from DEA under 21 U.S.C. § 952 and 21 C.F.R. § 1312.11.

v. The forms for these steps are found on the DEA website at www.deadiversion.gov.

b. If the controlled substance is available domestically, there are several options

i. Acquire it from a DEA registered importer who has imported or will import it. Section 1301.13(e)(1) of 21 C.F.R. allows registered importers to distribute a controlled substance. So if an entity has a valid registration to import, that importer can distribute it to another properly registered entity.

ii. Acquire it from a DEA registered manufacturer.
   1. Registration to manufacture required by 21 U.S.C. §822(a)(1) and 21 C.F.R. § 1301.11
   2. Under 21 C.F.R. § 1301.13(e)(1), a manufacturer is also allowed to distribute a controlled substance.
   3. So if there's a registered domestic manufacturer, a properly registered entity can acquire it from them.

iii. Acquire it from a registered "distributor."
   1. Registration to distribute required by 21 U.S.C. § 822(a)(1) and 21 C.F.R. § 1301.11
   2. "Distribute" defined by 21 U.S.C. § 802(11).
   3. There will often be a manufacturer and one or more distributors in the supply chain before a controlled substance comes to a pharmacy or hospital/clinic from which it will be dispensed. Generally speaking, within the closed system established by the CSA, a "distribution" is what occurs when controlled substances move through that chain. The CSA calls the transfer of a controlled substance from one DEA registrant to another a "distribution."

iv. An entity with a DEA registration to "dispense" controlled substances (See Sections IV and V below) ordinarily is not permitted to "distribute" a controlled substance to another registrant. There is a limited exception in 21 C.F.R. § 1307.11, however, that allows an entity with a valid DEA registration to *dispense* a controlled substance to *distribute* it to another entity if
   1. The entity that is receiving the controlled substance is also registered with DEA to dispense,
   2. Records of the transaction are kept, and
   3. The total amount transferred does not exceed 5% of the total dosage units of controlled substances dispensed by the transferring entity within that calendar year.

IV. The next question is what does an entity need to do in order to be a legitimate buyer? In other words, what kind of registration is necessary?

a. The type of registration an entity needs is tied to the activity in which it wants to engage.

b. In order to give a controlled substance to an "ultimate user," that is, an individual who is not a registrant, an entity would need a registration that permits "dispensing."

i. Requirement for registration to dispense found in 21 U.S.C. § 822(a)(2); 21 C.F.R. § 1301.11.

ii. "Dispense" defined by 21 U.S.C. § 802(10) – as delivering a controlled substance to an ultimate user or research subject pursuant to the lawful order of a practitioner. "Distribution" goes from a registrant to another registrant. "Dispensing" goes from registrant to an "ultimate user," who is not a registrant. A registration authorizing dispensing is required in order to give a controlled substance to an ultimate user.

c. A DEA registration to import, manufacture or distribute carries with it implicit authority to possess, but none of those registrations authorize a registrant to dispense. Consequently, in order to give a controlled substance to a patient, research subject, or other ultimate user, an entity that has a registration to import, manufacture, or distribute also would need an additional registration that authorizes dispensing.

V. "Dispensing" registrations are subdivided into different categories.

a. Types of dispensers

i. Individual Practitioner. These are *individuals* who are authorized by states to handle controlled substances – Typically doctors, dentists, veterinarians, and so forth. 21 C.F.R. § 1300.01(b)(17)

ii. Hospital/Clinic/Institutional Practitioner. In this case, the institution itself is registered, and the institution itself orders and possesses controlled substances. 21 C.F.R. § 1300.01(b)(18). In some circumstances, individual practitioners who work in the facility can use controlled substances out of the institution's stock. See Section VIII.b.ii below.

iii. Pharmacy.

b. With respect to institutions, the type of DEA registration an entity will hold (i.e., hospital/clinic/institutional practitioner or pharmacy) will depend largely on the law of the state in which the entity is located. DEA registers entities and individuals to the extent authorized by state law. 21 U.S.C. § 823(f).

c. An entity with a valid DEA registration either as a hospital/clinic/institutional practitioner or as a pharmacy may lawfully possess and dispense a controlled substance [here's an important caveat] *at its registered location*.

i. 21 U.S.C. § 822(e) and 21 C.F.R. § 1301.12 require a separate registration at each principal place of business where controlled

substances are manufactured, distributed, or dispensed. So registration is keyed to an address.

ii. If an institution has multiple locations where controlled substances may be used or stored, it may be necessary to obtain a DEA registration for each location and to implement additional procedures regarding the storage and movement of the controlled substances.

VI. Final question is what is required for an institution to actually dispense a controlled substance. The answer differs depending on whether the institution is registered as a pharmacy or as a hospital/clinic/institutional practitioner.

VII. If registered as a pharmacy

a. Controlled substances can only be dispensed pursuant to a prescription
   i. Requirement found in 21 U.S.C. § 829(a) & 21 C.F.R. § 1306.11 for schedule II.
   ii. Requirement found in 21 U.S.C. § 829(b) & 21 C.F.R. § 1306.21 for schedules III – IV.
b. Who can write a prescription? Under 21 C.F.R. § 1306.03, any individual practitioner one who is authorized to do so by the state in which he or she practices and who himself/herself has a DEA registration.
c. Requirements for a valid prescription found in 21 C.F.R. §§ 1306.04 & 1306.05

VIII. If registered as a hospital/clinic

a. Can dispense pursuant to a prescription (see above) *or* pursuant to an order of an individual practitioner for the immediate administration to the ultimate user.
   i. Requirement found in 21 C.F.R. § 1306.11(c) for schedule II
   ii. Requirement found in 21 C.F.R. § 1306.21(c) for schedules III-V.
b. Who can issue an order?
   i. Just like with a prescription, any registered practitioner can.
   ii. Also, under 21 C.F.R. § 1301.22(c), an individual practitioner who is an agent or employee of the institution can dispense, administer or prescribe a controlled substance under the *institution's DEA registration* – i.e., he or she doesn't need his or her own registration - if
      1. It's done in usual course of professional practice,
      2. The jurisdiction in which he or she is located permits it,
      3. The institution permits it,
      4. The person is acting in the scope of employment,
      5. The institution has an internal designator for agents or employees with this authority, and
      6. The institution will make a list of these designations available to law enforcement upon request.

IX. Security and recordkeeping requirements

a. Along with Registration, Security and Recordkeeping are key components of enforcing the closed system.

b. Security

i. Under 21 C.F.R. § 1301.71(a) – a registrant must provide effective controls and procedures to guard against diversion.

ii. 21 C.F.R. §§ 1301.72 through 1301.76 detail the necessary standards.

iii. Under 21 C.F.R. § 1301.71(b), the DEA Administrator has discretion to find "substantial compliance" with these standards acceptable based on the overall security system.

iv. Under 21 C.F.R. § 1301.71(d), a registrant may send details of their security protocol to the local DEA SAC or to the Registration Unit at DEA Headquarters to determine adequacy of security.

c. Recordkeeping

i. Under 21 U.S.C. § 827 and 21 C.F.R. § 1304.04, registrants must keep complete records of all transactions involving controlled substances.

1. Records need to accurately reflect each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. 21 C.F.R. § 1304.21(a).
2. The information that records must contain is defined at 21 C.F.R. § 1304.22.
3. No specific format is required, except that transactions involving schedule II controlled substances must be recorded on a DEA Form 222 ("Order Form"). 21 C.F.R. § 1305.03.
4. Records need to be kept for two years. 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(a).

ii. There is also a requirement for an inventory which must be taken every two years of all controlled substances on hand. Must keep a copy of the inventory for two years, as well. 21 C.F.R. § 1304.11.

(b)(6)

From: Gleason, Robert (Chris)
Sent: Tuesday, June 07, 2011 8:48 AM
To: 'Spillane, Mike'
Subject: RE: 6-2-2011 call
Attachments: CSA Overview.docx

I am glad that you found the discussion useful. I was concerned that, given the subject matter and format, it would be excruciatingly boring! Here is the synopsis that we discussed.

Sincerely,

Chris Gleason
Deputy Chief Counsel

From: Spillane, Mike (b)(6)
Sent: Thursday, June 02, 2011 2:08 PM
To: Gleason, Robert (Chris)
Subject: 6-2-2011 call

Sir, that was an extremely informative presentation. I was hoping that when you prepare the synopsis of the relevant statutory and regulatory sections that you mentioned, you would please e-mail me a copy. Also I will give our DOC's general counsel your e-mail address as she may have questions on identifying proper suppliers. Thanks again sir. Great job!

Mike Spillane
Assistant Attorney General
Missouri

(b)(6)

From: Gleason, Robert (Chris)
Sent: Tuesday, June 07, 2011 8:49 AM
To: 'Zapp, Amy'
Subject: RE: Today's Conference Call
Attachments: CSA Overview.docx

Ms. Zapp:

Attached is the summary we discussed. Thank you for participating in the call.

Sincerely,

Chris Gleason
Deputy Chief Counsel

From: Zapp, Amy (b)(6)
Sent: Thursday, June 02, 2011 3:37 PM
To: Gleason, Robert (Chris)
Subject: Today's Conference Call

Mr. Gleason,

At your convenience, would you please forward to me the summary you are preparing of the information provided during today's conference call about the Controlled Substances Act? Thank you.

Amy Zapp
Chief Deputy Attorney General
Special Litigation Section
Criminal Law Division
PA OFFICE OF ATTORNEY GENERAL
16th Floor – Strawberry Square
Harrisburg, PA 17120
(b)(6)
E-Mail: (b)(6)

(b)(6)

From: Gleason, Robert (Chris)
Sent: Tuesday, June 07, 2011 8:50 AM
To: 'Joe Cordi'
Subject: RE: Statutes and Regulations Regarding Lethal Injection
Attachments: CSA Overview.docx

Dear Mr. Cordi:

Attached is the synopsis we discussed. Thank you for participating in the call.

Sincerely,

Chris Gleason
Deputy Chief Counsel

-----Original Message-----
From: Joe Cordi (b)(6)
Sent: Thursday, June 02, 2011 6:24 PM
To: Gleason, Robert (Chris)
Cc (b)(6)
Subject: Statutes and Regulations Regarding Lethal Injection

Dear Mr. Gleason,

Thank you for the information that you provided during today's conference call concerning federal statutes and regulations as they relate to capital punishment by means of lethal injection. As I mentioned at the end of the call, it would be helpful if you would please send me a list of the statutes and regulations that you discussed. Thank you.

Best regards,

Joe Cordi
Assistant Attorney General
323 Center Street, Suite 200
Little Rock, AR 72201
(b)(6)

(b)(6)

From: Gleason, Robert (Chris)
Sent: Tuesday, June 07, 2011 8:47 AM
To: 'Lang, Timothy (ATG)'
Subject: RE: Teleconference today
Attachments: CSA Overview.docx

I am glad you found the discussion helpful. Attached is the promised list of citations. With respect to registered importers, the best point of contact for you is (b)(6) who is the Chief of DEA's Registration Unit. He can be reached at (b)(6)

Sincerely,

Chris Gleason
Deputy Chief Counsel

From: Lang, Timothy (ATG) (b)(6)
Sent: Thursday, June 02, 2011 1:52 PM
To: Gleason, Robert (Chris)
Subject: Teleconference today

Chris,

Thank you for the informative discussion today about the laws and procedures regarding the acquisition of sodium thiopental and other substances used by state departments of corrections in administering capital punishment.

You offered to provide a list of pertinent citations to the Controlled Substances act and applicable DEA rules. I would appreciate a copy when you create the list, along with any other information you can share about the identity of registered importers of thiopental.

Thank you very much.

Tim Lang

Sr. Assistant Attorney General

Washington Attorney General's Office

Corrections Division

(b)(6)

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(b)(6)

From: Gleason, Robert (Chris)
Sent: Wednesday, June 08, 2011 7:22 AM
To: 'David Tatarsky'
Subject: RE: chemicals for lethal injection
Attachments: CSA Overview.docx

Good morning, Mr. Tatarsky:

Attached is the summary we discussed during the telephone conference. Thank you for participating.

Sincerely,

Chris Gleason
Deputy Chief Counsel

From: David Tatarsky (b)(6)
Sent: Tuesday, June 07, 2011 5:36 PM
To: Gleason, Robert (Chris)
Cc: (b)(6)
Subject: chemicals for lethal injection

Mr. Gleason:

Thanks to you and the other DEA staff for the telephone presentation to Departments of Correction/Attorneys General on how to legally obtain chemicals used for lethal injection purposes. I believe you agreed that you would provide a printout of the citations to the various statutes and regulations referenced in you presentation. Please email a copy to me at your earliest convenience. Thanks.

David M. Tatarsky
General Counsel
S.C. Dept. of Corrections
P.O. Box 21787
Columbia, SC 29221-1787

(b)(6)

Registration Issues

I. Introduction

II. I've been asked to talk to you all about the basic framework of the Federal Controlled Substances Act (CSA) and how it relates to a state Department of Corrections (DoC) obtaining, maintaining and dispensing a controlled substance. Many different specific scenarios, and this will necessarily be somewhat generic, but my hope is to give an overview of basic requirements.

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   a. The CSA requirements apply to controlled substances in all situations – so what we'll discuss applies to a pharmacy or a hospital just as it would a medical clinic in a prison. And they apply whether the prison clinic is obtaining it for an execution or for administration to sick inmates.
   b. Approach that I think would make the most sense is a step by step approach
      i. What's needed to acquire a controlled substance.
      ii. What's required in order to maintain it until it's needed.
      iii. What's required in order to dispense it and
      iv. What's required to transfer a controlled substance to another entity.
   c. To do this we need to cover a bit of the CSA first for context.

III. Primary diversion control mechanism of the CSA is the "closed system" it establishes. Generally speaking, any activity involving a controlled substance that is not specifically authorized is prohibited. CSA establishes and enforces this closed system through three general mechanisms
   a. Registration requirements
   b. Recordkeeping, inventory & inspection requirements
   c. Security requirements

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IV. Of those three, we're going to focus on the registration requirement today.

   a. From importers, manufactures, wholesalers, retailers, through those who dispense to ultimate user, every entity that handles a controlled substance must register with DEA, and that registration must authorize the activities in which the entity seeks to engage and must include the specific schedules for the controlled substances used by the registrant. 21 U.S.C. § 822(b) says registrants are authorized to possess, manufacture, distribute or dispense *to the extent authorized by their registration.*
      i. So there are different kinds of DEA registrations that authorize different kinds of activities
      ii. Similarly, registrations can be limited by drug schedule
      iii. Also, registrations are tied to a particular physical location.
      iv. Simply having a DEA registration is not sufficient. The registration must authorize the particular activity you want to engage in *and* it must include the particular drug class or drug

schedule that you're dealing with *and* it must be issued for the location where the particular activity is being carried out.

b. So, as you follow controlled substances through the process need to ask "Are we registered for this activity, for this drug schedule, and at this location?"

V. With that background in mind, let's talk about first step in the process, which would be how should a DoC acquire a needed controlled substance. First step is to identify a legitimate source for acquiring a controlled substance. Several different options.

a. One option: Acquiring it directly on the international market. In other words, "importing" it.

i. In order to do that, a Department of Corrections (DoC) would need to be registered as an "importer."

ii. Registration to import required by 21 U.S.C. §§ 957, 958; 21 C.F.R. § 1301.11

iii. A DoC with a valid importer registration can lawfully import a controlled substance under the CSA, provided their import registration includes the schedule of the drug being imported.

iv. There are a number of registered importers. We can provide a list if it would help. Also, we are aware of at least one registered importer who is making arrangements to import sodium thiopental.

v. Additional requirements apply before you actually import the controlled substance. Those requirements depend on what schedule of controlled substance you're importing.

1. If you're importing a schedule III non-narcotic, for example, you must notify DEA 15 days in advance under 21 U.S.C. § 952 and 21 C.F.R. § 1312.18(b). This is done via a form DEA 236.
2. If you're importing a schedule II drug, you must apply for and receive an import permit from DEA before importing under 21 U.S.C. § 952 and 21 C.F.R. § 1312.11.

vi. The forms for these steps are found on website at www.deadiversion.gov.

b. If it's available and you want to acquire it domestically, there are a couple of options

1. Acquire it from a DEA registered importer. Section 1301.13(e)(1) of 21 C.F.R. allows registered importers to distribute a controlled substance. So if an entity has a valid registration to import, that entity can distribute it to another properly registered entity..
2. Acquire it from a DEA registered manufacturer.
   a. Registration to manufacture required by 21 U.S.C. §822(a)(1) and 21 C.F.R. § 1301.11
   b. Under 21 C.F.R. § 1301.13(e)(1), a manufacturer is also allowed to distribute a controlled substance.

c. So if there's a registered domestic manufacturer, a properly registered entity can acquire it from them.

3. Acquire it from a registered "distributor."
   a. Registration to distribute required by 21 U.S.C. § 822(a)(1) and 21 C.F.R. § 1301.11
   b. "Distribution" defined by 21 U.S.C. § 802(11).
   c. Basically, within the closed system, the act of distribution typically is what occurs when controlled substances move through the chain from manufacturer to pharmacy. Distribution goes from one DEA registrant to another. Will often be a manufacturer and one or more distributors in the chain before it comes to the pharmacy.
   d. This presupposes that the distributor is in lawful possession. That is, a distributor registration does not permit importation. So if a registered distributor unlawfully imported a controlled substance, that would not be a legitimate source.
4. We've gotten some questions about the possibility of acquiring it from another state that has a supply. In certain limited circumstances, that is possible. I will explain that, but I think it would be helpful to move on to the next point and then circle back.

VI. We've talked about legitimate sellers. Next question is what does a DoC need to do in order to be a legitimate buyer? In other words, what kind of registration is necessary?
   a. Remember, the type of registration you need is tied to the activity in which you want to engage.
   b. In this instance, the DoC wants the controlled substances to be able to give them to inmates.
      i. For purposes of the CSA, that act is called "dispensing."
      ii. Requirement for registration to dispense found in 21 U.S.C. § 822(a)(2); 21 C.F.R. § 1301.11.
      iii. "Dispense" defined by 21 U.S.C. § 802(10) – as delivering a controlled substance to an ultimate user or research subject pursuant to the lawful order of a practitioner. "Distribution" goes from a registrant to another registrant. "Dispensing" goes from registrant to an "ultimate user," who is not a registrant. Need a registration authorizing dispensing to do that.
   c. A DEA registration to import, manufacture or distribute carries with it implicit authority to possess, but none of those registrations authorize a registrant to dispense. Consequently, DoC needs a registration that authorizes dispensing in order to give it to an inmate.

VII. "Dispensing" registrations subdivided into different categories. So next question is "what kind of dispenser does a DoC want/need to be?"

a. Relevant types of dispensers
   i. Individual Practitioner – These are *individuals* who are authorized by states to handle controlled substances – Doctors, dentists, veterinarians. [Practitioner defined at 21 U.S.C. § 802(21)]
   ii. Hospital/Clinic/Institutional Practitioner. In this case, the institution itself is registered, and the institution itself orders and possesses controlled substances. In some circumstances, individual practitioners who work in the facility can use controlled substances out of the institution's stock, as I'll discuss in a few minutes.
   iii. Pharmacy

b. What type of DEA registration your DoC will hold will depend on your state's requirements and how you are set up. DEA registers entities and individuals to the extent authorized by state law. 21 U.S.C. § 823(f).
   i. So, your state law will dictate whether DoC is registered as an institution (i.e., hospital/clinic) or as a pharmacy.
   ii. If your state considers your DoC a pharmacy, DEA will register it as a pharmacy. If your state considers your DoC to be a hospital/clinic, DEA will register it as a hospital/clinic.

c. However that is accomplished, a DoC with a valid registration may lawfully possess a controlled substance [here's an important caveat] *at their registered location*.
   i. 21 U.S.C. § 822(e) and 21 C.F.R. § 1301.12 require a separate registration at each principal place of business where controlled substances are manufactured, distributed, or dispensed. So registration is keyed to an address.
   ii. I bring this up because some of you may have multiple complexes spread throughout the state.
   iii. A single prison compound would probably be a single principal place of business.
   iv. But if you have multiple locations, you may need to review your procedures regarding where you store the controlled substance or you may need to get multiple registrations.
   v. DEA registration section can work with you on an individual basis to get that straight.

VIII. So, now the DoC has appropriately obtained it and appropriately possesses it. Next (and last) question is what is required to actually dispense it. Answer different depending on whether registered as a pharmacy or as a hospital/clinic

IX. If registered as a pharmacy,

a. Controlled substances can only be dispensed pursuant to a prescription

i. Requirement found in 21 U.S.C. § 829(a) & 21 C.F.R. § 1306.11 for schedule II.
ii. Requirement found in 21 U.S.C. § 829(b) & 21 C.F.R. § 1306.21 for schedules III – IV

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X. If registered as a hospital/clinic
   a. Can dispense pursuant to a prescription *or* pursuant to an order of an individual practitioner which is dispensed for the immediate administration to the ultimate user.
      i. Requirement found in 21 C.F.R. § 1306.11(c) for schedule II
      ii. Requirement found in 21 C.F.R. § 1306.21(c) for schedules III-V

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      ii. Under 21 C.F.R. § 1301.22(c), an individual practitioner who is agent or employee of the institution can dispense, administer or prescribe a controlled substance under *institution's DEA registration* – i.e., doesn't need his or her own registration

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XI. I said I would circle back to discuss how a state DoC could obtain a controlled substance from another state DoC. Two ways to do that:
   a. First, as I said before, a DoC with a proper DEA registration can lawfully obtain a controlled substance from a registered importer. So, if one DoC is registered as an importer, that DoC can then distribute the imported controlled substance to another appropriately registered DoC.
   b. Second, under 21 C.F.R. § 1307.11, a DoC who is registered to dispense in state 1 can distribute a controlled substance to another DEA registered practitioner in state 2 for the purpose of dispensing to an ultimate user if

i. The registered practitioner who is receiving the controlled substance is registered with DEA to dispense
ii. Records must be kept
iii. Total amount transferred does not exceed 5% of the total dosage units of controlled substances dispensed by the transferring DoC within that calendar year.

XII. Finally, want to cover briefly security and recordkeeping requirements
a. Mentioned earlier that, along with Registration, Security and Recordkeeping are key components of enforcing the closed system.
b. Security
i. Under 21 C.F.R. § 1301.71(a) – must provide effective controls and procedures to guard against diversion.
ii. 21 C.F.R. §§ 1301.72 through 1301.76 detail the necessary standards. Won't further bore you with those details.
1. Need to know they need to be locked up with controlled access.
2. Standards for schedule II controlled substances are higher than for schedule III through V controlled substances.
iii. Will point out that 21 C.F.R. § 1301.71(b) points out that DEA Administrator has discretion to find substantial compliance with the standards acceptable based on the overall security system.
1. Under 21 C.F.R. § 1301.71(d) says you can send details to the local DEA SAC or to the Registration Unit at DEA HQ to determine adequacy of security.
c. Recordkeeping
i. Under 21 U.S.C. § 827 and 21 C.F.R. § 1304.04, must keep complete records of all transactions involving controlled substances.
1. Records need to accurately reflect each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. 21 C.F.R. § 1304.21(a).
2. Information records required to contain found at 21 C.F.R. § 1304.22.
3. No specific format required except that transactions involving schedule II controlled substances must be recorded on a DEA Form 222 ("Order Form"). 21 C.F.R. § 1305.03.
4. Records need to be kept for two years. 21 U.S.C. § 827(b); 21 C.F.R. § 1304.04(a).
ii. There is also a requirement for an inventory which must be taken every two years of all controlled substances on hand. Must maintain inventory for two years, as well. 21 C.F.R. § 1304.11.

XIII. Provide contact information

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XIV. Questions?

From: Spillane, Mike (b)(6)
Sent: Tuesday, August 16, 2011 11:20 AM
To: Gleason, Robert (Chris)
Subject: RE: 6-2-2011 call

Sir I was wondering if you had a phone number I could give to our Department of Corrections, as they may have some questions for you. Thanks

From: Gleason, Robert (Chris) (b)(6)
Sent: Tuesday, June 07, 2011 7:48 AM
To: Spillane, Mike
Subject: RE: 6-2-2011 call

I am glad that you found the discussion useful. I was concerned that, given the subject matter and format, it would be excruciatingly boring! Here is the synopsis that we discussed.

Sincerely,

Chris Gleason
Deputy Chief Counsel

From: Spillane, Mike (b)(6)
Sent: Thursday, June 02, 2011 2:08 PM
To: Gleason, Robert (Chris)
Subject: 6-2-2011 call

Sir, that was an extremely informative presentation. I was hoping that when you prepare the synopsis of the relevant statutory and regulatory sections that you mentioned, you would please e-mail me a copy. Also I will give our DOC's general counsel your e-mail address as she may have questions on identifying proper suppliers. Thanks again sir. Great

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