Respondent's blatant disregard for fundamental record-keeping requirements, among other violations, to be significantly at odds with the public interest.

Accordingly I find by a preponderance of the evidence that Respondent unlawfully failed to make, keep or furnish required records relating to her handling of controlled substances, during the time period from November 2008 to May 2011, in violation of applicable federal law.[47]

3. Respondent's Issuance of Prescriptions Without Required Information

Pursuant to 21 CFR 1306.05(a), ''[a]ll prescriptions for controlled substances shall * * * bear the full name and address of the patient * * * [and] directions for use * * *.'' The evidence of record included approximately eleven prescriptions issued by Respondent for various controlled substances to a single patient covering the time period August to November 2006. (Tr. 219–20; Gov't Ex. 7.) Each of the eleven prescriptions was deficient by failing to include the patient's address. (Tr. 220–21; *see* Gov't Ex. 7.)

Additionally, the Government introduced testimony by DI Kresnak that he reviewed approximately twelve prescriptions seized from a Portsmouth, Ohio pharmacy that Respondent had issued for controlled substances to more than one patient between 2005 and 2006. Of the twelve reviewed, DI Kresnak testified that eleven lacked a patient address. (Tr. 53–55, 123–24.) None of these prescriptions were introduced by the Government at hearing, and DI Kresnak was uncertain if any of the prescriptions he recalled reviewing from the Portsmouth, Ohio pharmacy were the same as those identified in Government Exhibit 7. Nor could DI Kresnak recall any of the patient names from memory without reviewing copies of the prescriptions.[48] (Tr. 118.) In light of this testimony, I give little overall weight to the testimony offered by the Government with regard to the eleven prescriptions seized from the Portsmouth, Ohio pharmacy, since those prescriptions may or may not be the same as those contained within Government Exhibit 7. ''Speculation is, of course, no substitute for evidence, and a decision based on speculation is not supported by substantial evidence.'' *White ex rel. Smith* v. *Apfel,* 167 F.3d 369, 375 (7th Cir. 1999) (citing *Erhardt* v. *Sec'y, DHS,* 969 F.2d 534, 538 (7th Cir. 1992)).

Accordingly, I find by a preponderance of the evidence that Respondent issued approximately eleven prescriptions between August and November 2006 for controlled substances without providing a patient address, in violation of applicable federal regulations.

All of the above findings regarding Respondent's violation of applicable law and regulation as it pertains to her prescribing practices, record-keeping, and dispensing from an unregistered location weigh heavily against a finding under Factors Two and Four of 21 U.S.C. 823(f) that Respondent's continued registration would be consistent with the public interest.

Factor 5: Such Other Conduct Which May Threaten the Public Health and Safety

Under Factor Five, the Administrator is authorized to consider ''other conduct which may threaten the public health and safety.'' 5 U.S.C. 823(f)(5). The Agency has accordingly held that ''where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for his or her actions and demonstrate that he or she will not engage in future misconduct. *Patrick W. Stodola,* 74 FR 20,727, 20,734 (DEA 2009).[49] A ''[r]espondent's lack of candor and inconsistent explanations'' may serve as a basis for denial of a registration. *John Stanford Noell, M.D.,* 59 FR 47,359, 47,361 (DEA 1994).

In this case Respondent was called by the Government to testify, but refused to answer questions by invoking her Fifth Amendment privilege. ''It is well established that the Agency may draw an adverse inference from a respondent's failure 'to testify in response to probative evidence offered against' [her].'' *Surinder Dang, M.D.,* 76 FR 51,417, 51,422 (DEA 2011) (citing *Baxter* v. *Palmigiano,* 425 U.S. 308, 318 (1976)). I find it appropriate on the facts of this case to draw an adverse inference against Respondent where the Government presented evidence of misconduct involving Respondent's prescribing, dispensing, and record-keeping practices, yet Respondent failed to testify and respond to this evidence. Additionally, Respondent presented no evidence of acceptance of responsibility for past misconduct, nor any evidence demonstrating that she will not engage in future misconduct, which weighs heavily against a finding under Factor Five of 21 U.S.C. 823(f) that Respondent's continued registration would be consistent with the public interest.

V. Conclusion and Recommendation

After balancing the foregoing public interest factors, I find that the Government has established by substantial evidence a prima facie case in support of revoking Respondent's DEA COR BT5598214, based on Factors Two, Four and Five of 21 U.S.C. 823(f). Once DEA has made its prima facie case for revocation or denial, the burden shifts to the respondent to show that, given the totality of the facts and circumstances in the record, revoking or denying the registration would not be appropriate. *See Morall* v. *DEA,* 412 F.3d 165, 174 (D.C. Cir. 2005); *Humphreys* v. *DEA,* 96 F.3d 658, 661 (3d Cir. 1996); *Shatz* v. *United States Dep't of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 FR 72,311 (DEA 1980). The record reveals that Respondent has not sustained her burden in this regard. In light of the foregoing, Respondent's evidence as a whole fails to sustain her burden to accept responsibility for her misconduct and demonstrate that she will not engage in future misconduct.

I recommend revocation of Respondent's DEA COR BT5598214 as a practitioner, and denial of any pending applications for renewal or modification, on the grounds that Respondent's continued registration would be fully inconsistent with the public interest as that term is used in 21 U.S.C. 824(a)(4) and 823(f).

Dated: December 15, 2011.

Timothy D. Wing,

Administrative Law Judge.

[FR Doc. 2012–18749 Filed 7–31–12; 8:45 am]

BILLING CODE 4410–09–P

[47] *See* 21 U.S.C. 827(a), 842(a)(5); 13 CFR 1304.11 (b) and (c), 1305.13(e).

[48] The Government did not seek to refresh DI Kresnak's recollection with any documents, nor were the prescriptions at issue introduced at hearing. *See supra* note 9.

[49] *See also Hoxie* v. *DEA,* 419 F.3d 477, 484 (6th Cir. 2005) (decision to revoke registration ''consistent with the DEA's view of the importance of physician candor and cooperation'').

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–364]

Electronic Prescriptions for Controlled Substances Notice of Approved Certification Process

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice.

SUMMARY: DEA is announcing a new DEA-approved certification process for Electronic Prescriptions for Controlled

Substances (EPCS). Certifying organizations with a certification process approved by DEA pursuant to 21 Code of Federal Regulations (CFR) 1311.300(e) are posted on DEA's Web site once approved.

FOR FURTHER INFORMATION CONTACT: Alan G. Santos, Associate Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 307–7165.

SUPPLEMENTARY INFORMATION:

Background

The Drug Enforcement Administration (DEA) is a component of the Department of Justice and is the primary agency responsible for coordinating the drug law enforcement activities of the United States. DEA also assists in the implementation of the President's National Drug Control Strategy. The Diversion Control Program (DCP) is a strategic component of the DEA's law enforcement mission. It is primarily the DCP within DEA that implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 801–971), as amended (hereinafter, ''CSA'').[1] DEA drafts and publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to 1321. The CSA together with these regulations are designed to establish a closed system for controlled substances and to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring a sufficient supply of controlled substances and listed chemicals for legitimate medical, scientific, research, and industrial purposes.

The CSA and DEA's implementing regulations establish the legal requirements for possession and dispensing of controlled substances, most notably pursuant to a prescription issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. ''The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.'' 21 CFR 1306.04(a). A prescription serves both as a record of the practitioner's determination of the legitimate medical need for the drug to be dispensed, and as a record of the dispensing, providing the pharmacy with the legal justification and authority to dispense the medication prescribed by the practitioner. The prescription also provides a record of the actual dispensing of the controlled substance to the ultimate user (the patient) and, therefore, is critical to documenting that controlled substances held by a pharmacy have been dispensed legally. The maintenance by pharmacies of complete and accurate prescription records is an essential part of the overall CSA regulatory scheme established by Congress.

Electronic Prescriptions for Controlled Substances (EPCS)

Historically, where federal law required that a prescription for a controlled substance be issued in writing, that requirement could only be satisfied through the issuance of a paper prescription. Given advancements in technology and security capabilities for electronic applications, DEA recently amended its regulations to provide practitioners with the option of issuing electronic prescriptions for controlled substances (EPCS) in lieu of paper prescriptions. Efforts to develop EPCS have been underway for a number of years. DEA's Interim Final Rule for Electronic Prescriptions for Controlled Substances was published on March 31, 2010, at 75 FR 16236–16319, and became effective on June 1, 2010. While these regulations have paved the way for controlled substance prescriptions to be issued electronically, not all states have authorized electronic prescriptions for controlled substances, particularly Schedule II controlled substances, which have a significant potential for abuse.

Update

All certifying organizations with a certification process approved by DEA pursuant to 21 CFR 1311.300(e) are posted on DEA's Web site once approved.

As noted above, the Interim Final Rule provides that, as an alternative to the audit requirements of 21 CFR 1311(b) through (d), an electronic prescription or pharmacy application may be verified and certified as meeting the requirements of 21 CFR part 1311 by a certifying organization whose certification process has been approved by DEA. The preamble to the Interim Final Rule further indicated that, once a qualified certifying organization's certification process has been approved by DEA in accordance with 21 CFR 1311.300(e), such information will be posted on DEA's Web site. 75 FR 16243, March 31, 2010. On May 22, 2012, DEA approved the certification processes developed by Drummond Group and by iBeta LLC. iBeta's approved certification process is limited to the certification of the biometrics subsystem, including its interfaces, to the requirements of the overall regulations and specifically to those in 1311.116. Relevant information has been posted on DEA's Web site at *http://www.DEAdiversion.usdoj.gov*.

Dated: July 25, 2012.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 2012–18748 Filed 7–31–12; 8:45 am]

BILLING CODE 4410–09–P

[1] The Attorney General's delegation of authority to DEA may be found at 28 CFR 0.100.

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; The 1,2-Dibromo-3-Chloropropane Standard

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Occupational Safety and Health Administration (OSHA) sponsored information collection request (ICR) titled, ''The 1,2-Dibromo-3-Chloropropane Standard,'' to the Office of Management and Budget (OMB) for review and approval for continued use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 et seq.).

DATES: Submit comments on or before August 31, 2012.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site, *http://www.reginfo.gov/public/do/PRAMain,* on the day following publication of this notice or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OSHA, Office of Management and Budget, Room 10235, 725 17th Street, NW., Washington, DC 20503, Telephone: 202–395–6929/Fax: 202–395–6881 (these are not toll-free numbers), email: *OIRA_submission@omb.eop.gov.*