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Karen S. Dworkin,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2014–00436 Filed 1–13–14; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

James Clopton, M.D.; Decision and Order

On March 22, 2012, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to James Clopton, M.D. (hereinafter, Applicant), of El Dorado Hills, California. GX 2. The Show Cause Order proposed the denial of Applicant's application for a DEA Certificate of Registration as a practitioner, on the ground that his registration would be inconsistent with the public interest. *Id.* (citing 21 U.S.C. 823(f)).

The Show Cause Order alleged that on May 22, 2009 and July 8, 2009, Applicant "illegally distributed OxyContin, a schedule II controlled substance," to an undercover law enforcement officer, "for other than a legitimate medical purpose and outside

the usual course of professional practice." *Id.* (citing 21 U.S.C. 841(a)(1)). Specifically, the Show Cause Order alleged that Applicant failed to conduct a physical examination prior to prescribing the controlled substances to the undercover officer. *Id.*

Next, the Show Cause Order alleged that on February 10, 2010, Applicant illegally distributed Norco, a schedule III hydrocodone combination product, and Xanax, a schedule IV controlled substance, to the same undercover officer under similar circumstances. *Id.* at 2. Finally, the Show Cause Order alleged that Applicant "failed to maintain an inventory of controlled substances, records of receipt of controlled substances, failed to retain copy 3 of DEA form 222, and failed to maintain dispensing records." *Id.* (citing 21 CFR 1304.11, 1304.22, 1305.17).

The Show Cause Order also notified Applicant of his right to request a hearing on the allegations or to submit a written statement regarding the allegations while waiving his right to a hearing. *Id.* at 2. However, the Order then notified Applicant that "[s]hould [he] fail to respond to this official correspondence by exercising [his] rights . . . [his] application shall be deemed withdrawn pursuant to 21 CFR § 1301.16(b)." *Id.*

On April 2, 2012, the Government personally served the Show Cause Order on Respondent. Request for Final Agency Action, Attachment 2, at 5. Thereafter, Applicant neither filed a request for a hearing nor submitted a written statement in lieu of a hearing. Request for Final Agency Action, at 2.

On November 5, 2012, the Government forwarded a Request for Final Agency Action to this Office. *Id.* at 1. Therein, the Government noted that since the date of service of the Show Cause Order, Applicant had not requested a hearing. *Id.* at 2. The Government thus contended that Applicant had waived his right to a hearing and requested the issuance of a final order denying the application. *Id.* at 2–9.

On review, the Administrator found that the Government had failed to provide fair notice to Applicant regarding the consequences of his failure to request a hearing or to submit a written statement in lieu of a hearing. Order, at 1. Specifically, the Administrator found that the Government had not notified Applicant that the consequence of failing to request a hearing or to submit a written statement "would be that it would then seek a final order denying his application." *Id.* at 2. Rather, the Administrator found that the

Government "specifically notified Applicant that the only consequence of his failure to request a hearing or to submit a written statement in lieu of a hearing would be that his application would be deemed withdrawn." *Id.* (citing 21 CFR 1301.16(b)).¹ The Administrator further explained that "were a final order issued denying the application, Applicant would be required to disclose the existence of such an order on any subsequent application, under the threat of criminal prosecution if he failed to do so." *Id.* at 2–3. Finally, the Administrator explained that the findings of the final order "would be entitled to preclusive effect in a subsequent DEA proceeding." *Id.* at 3 (citing *Jose G. Zavaleta*, 78 FR 27431, 27434 (2013)).

Accordingly, the Administrator instructed the Government that if it intended to seek a final order denying the application, it must serve a corrected Show Cause Order, which "properly notif[ie]d Applicant of the consequences of failing to either request a hearing or submit a written statement in lieu of a hearing." *Id.* The Administrator further directed the Government to notify her Office, within thirty days, if it intended to do so. *Id.* The Government subsequently complied with the Order. Second Request for Final Agency Action, Attachment 2, at 1.

On July 29, 2013, the Deputy Assistant Administrator issued a new Show Cause Order, which re-alleged the charges of the previous Show Cause Order. The second Show Cause Order again advised Applicant that he had the right to request a hearing or to submit a written statement while waiving his right to a hearing and the procedure for electing either option. Most importantly, the Order properly advised Applicant that "[s]hould you decline to file a request for a hearing . . . you shall be deemed to have waived the right to a

¹ This regulation provides, in relevant part, that "[a]fter an application has been accepted for filing . . . the failure of the applicant to respond to official correspondence regarding the application, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application." 21 CFR 1301.16(b). In her Order, the Administrator explained that once the Government files an Order Show Cause, the consequence of an applicant's or registrant's failure to respond to the Order is specifically addressed by 21 CFR 1301.43(d), which provides that if "[i]f any person entitled to a hearing . . . fails to file a request for a hearing . . . such person shall be deemed to have waived the opportunity for a hearing . . . unless such person shows good cause for such failure." See also 21 CFR 1301.43(e) ("If all persons entitled to a hearing . . . are deemed to waive their opportunity for the hearing . . . the Administrator may cancel the hearing, if scheduled, and issue his/her final order pursuant to § 1301.46 without a hearing.").

hearing and the Administrator may . . . issue a final order in this matter without a hearing based upon the evidence presented to her.” Show Cause Order (II), at 2 (citing 21 CFR 1301.43(d) & (e); *id.* § 1301.46). On August 23, 2013, the Show Cause Order was personally served on Applicant by the lead Diversion Investigator. Second Request for Final Agency Action, Attachment 4.

On October 2, 2013, the Government submitted a Second Request for Final Agency Action. Therein, the Government noted that since the date of service of the Second Show Cause Order, Applicant had not requested a hearing. *Id.* at 2. The Government thus contends that Applicant has waived his right to a hearing and requests the issuance of a final order denying the application. *Id.*

Based on the Government’s submission, I find that since the date of service of the Second Order to Show Cause, neither Applicant, nor anyone purporting to represent him, has either requested a hearing on the allegations or submitted a written statement in lieu of a hearing. See 21 CFR 1301.43(a) & (c). Accordingly, I find that Applicant has waived his right to a hearing or to submit a written statement. *Id.* § 1301.43(c) & (d). I therefore issue this Decision and Final Order based on the Investigative Record submitted by the Government. *Id.* § 1301.43(e). I make the following findings of fact.

Findings

Applicant is a psychiatrist, who previously held DEA Certificate of Registration BC2559219, which authorized him to dispense controlled substances, as a practitioner, in schedules II–V. GX 1, at 4. On January 26, 2011, Applicant surrendered this registration for cause, “after which date no controlled substances could be obtained, stored, administered, prescribed, or dispensed under” his registration. *Id.* at 1. However, on June 8, 2011, Applicant submitted an application for a new registration. *Id.* at 3.

In February 2009, DEA first became interested in Applicant after a Diversion Investigator (DI) received a letter from a pharmacist in Cameron Park, California. GX 3, at 1; GX 6. In the letter, the pharmacist expressed her “concerns about [Applicant’s] prescribing” practices. GX 6. Specifically, the pharmacist opined that Applicant was writing methadone prescriptions to treat drug withdrawal, that he was prescribing excessive amounts of methadone, and that in 2007, one of his patients died from a drug overdose. *Id.*

Subsequently, the DI teamed up with the West El Dorado Narcotics Enforcement Team to conduct several undercover operations involving Applicant. GX 3, at 1. Specifically, on May 22, 2009, July 8, 2009, and February 10, 2010, the team conducted three undercover visits, during which a West El Dorado Detective, using the alias of “Tony Cruz,” visited Applicant for the purpose of obtaining controlled substances. *Id.*

On May 22, 2009, the Detective arrived at Applicant’s medical clinic and paid \$250 before seeing him. GX 4, at 2. Upon meeting Applicant, the Detective told him that he was taking “Oxy,” but because his wallet had been stolen he had borrowed some pills from a friend. *Id.* at 3–4. The following exchange ensued:

Applicant: What’s the medical problem?
Det: Um you know I started a while ago and you know.

Applicant: Ok, so you are trying to get off of them at this point?
Id. at 4.

Applicant then recognized that the Detective’s use of OxyContin was “recreational” and that “there’s not a medical problem.” *Id.* at 4–5. The Detective further told Applicant that he “liked to stay more on the right side you know I mean I like to have a prescription instead of hitting somebody up.” *Id.* at 10.

Applicant then stated: “You see, the only problem is unless we have an actual pain diagnosis psychiatrists can’t write for it. So have you ever been diagnosed with a disk problem or anything?” *Id.* The Detective replied: “I mean um if I just gotta say I got something.” *Id.* Applicant then stated “ok[,] what I can do is probably write it for a couple of months,” but then warned that “after that it’s got to be more of a primary care or the urgent care because you know again without the pain diagnosis that’s where we get nailed.” *Id.* at 10–11.

Applicant did not perform a physical examination during the visit, which lasted thirteen minutes. Nonetheless, Applicant issued the Detective a prescription for 120 tablets of OxyContin 80mg. GX 5, at 1. On the prescription, Applicant wrote: “Dx 722.1.” *Id.* According to the DI, this is an insurance code “describing displacement of thoracic or lumbar intervertebral [sic] disc without myelopathy.” GX 4, at 13.

On July 8, 2009, the Detective returned to Applicant’s clinic. *Id.* During the visit, Applicant asked the Detective what kind of pain he felt, and if it was back pain. *Id.* at 14. The

Detective answered, “um, that’s what you uh told me you put on there before.” *Id.* Applicant replied, “Ok. Ok. Good luck.” *Id.*

Applicant’s interaction with the Detective lasted all of two minutes, during which Applicant did not perform a physical examination. GX 4, at 14–15. He did, however, issue to the Detective another prescription for 120 tablets of OxyContin 80mg. GX 5.

On February 10, 2010, the Detective returned again to Applicant’s clinic. *Id.* at 15. Upon meeting Applicant, the Detective again asked for “Oxy.” *Id.* at 16. However, Applicant stated that “they won’t let us,” and added that “[t]he Drug Enforcement Agency has basically told physicians that if you don’t give a physical exam you can’t prescribe opiates.” *Id.* at 16–17.

Applicant then stated that “[p]sychiatrists don’t do physical exams and so [we are] specifically forbidden from doing that.” *Id.* at 17. Applicant added that “they will not let us do . . . the Schedule II’s like the Oxy [and] the Percocet . . . they will let us do the Schedule III’s which are the Norcos.” *Id.*

After Applicant discussed with the Detective where he could get Schedule II drugs, the Detective asked if he would “still be able to” get Norcos.² *Id.* at 18. Applicant replied, “I can write Norco, yeah.” *Id.*

Applicant then asked “[i]s this for your back?” *Id.* The Detective answered: “You know yeah that’s well last time you told me to it was my back yeah.” *Id.* Continuing, Applicant asked, “[i]s it more help out your mood or what’s it do for you?” *Id.* The Detective answered that he did “concrete all day long” and was “working with people and stuff like that,” and that after coming home, the drug “helps [to] unwind.” *Id.* To this, Applicant stated: “Ok[,] that one they’ll let us do.” *Id.*

Next, the Detective asked if Applicant had “anything that will help sleep”; Applicant replied in the affirmative. *Id.* The Detective then said that someone had told him about a drug that was “spelt weird,” and that he couldn’t remember the drug’s name but that it “had two X’s.” Applicant then said “Xanax?” and the Detective agreed. *Id.*

Applicant issued to the Detective two prescriptions: One for 120 tablets of Norco 10/325mg and one for 30 tablets of Xanax 1mg. GX 5, at 3–4. Applicant’s interaction with the Detective lasted three minutes, during which Applicant again failed to perform a physical exam. GX 4, at 15–18.

² Norco (hydrocodone/acetaminophen) is a schedule III narcotic. See 21 CFR 1308.13(e)(1).

On January 25, 2011, DEA Investigators, including the DI, executed a federal search warrant at Applicant's clinic. GX 3, at 2. During the execution of the warrant, Applicant admitted to the DI "that he did not maintain any records of acquisition or dispensation" of controlled substances and that he "did not document the dispensation in the patient's chart." *Id.* He also admitted that he "frequently would not perform physical examinations on patients." *Id.*

During the search, DEA seized various schedule IV controlled substances including alprazolam (Xanax), zolpidem (Ambien), and eszopiclone (Lunesta). GX 7; see 21 CFR 1308.14(c). That same day, Applicant surrendered his DEA Certificate of Registration. GX 3.

Discussion

Section 303(f) of the Controlled Substances Act (CSA) provides that an application for a practitioner's registration may be denied "if the Attorney General determines that the issuance of such registration . . . would be inconsistent with the public interest." 21 U.S.C. 823(f). In making this determination, Congress directed that the following factors be considered:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing . . . controlled substances.
- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

Id.

"These factors are . . . considered in the disjunctive." *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). I "may rely on any one or a combination of factors and may give each factor the weight . . . [I] deem [] appropriate in determining whether . . . an application for registration [should be] denied." *Id.*; see also *Kevin Dennis, M.D.*, 78 FR 52787, 52794 (2013); *MacKay v. DEA*, 664 F.3d 808, 816 (10th Cir. 2011).

The Government has the burden of proving, by substantial evidence, that the requirements for a denial of an application, pursuant to 21 U.S.C. 823(f), are met. 21 CFR 1301.44(e). This is so even in a non-contested case. *Gabriel Sanchez, M.D.*, 78 FR 59060, 59063 (2013). Having considered all of the factors,³ I conclude that the

Government's evidence with respect to factors two and four establishes, *prima facie*, that the issuance of a DEA certificate of registration to Applicant "would be inconsistent with the public interest." See 21 U.S.C. 823(f).

Factors Two and Four—The Applicant's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

Under a longstanding Agency regulation, "[a] prescription for a controlled substance [is not] effective [unless it is] issued for a legitimate medical purpose by an individual practitioner acting in the usual course of [his] professional practice." 21 CFR 1306.04(a). This regulation further provides that "an order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Id.*

As the Supreme Court recently explained, "the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006) (citing *United States v. Moore*, 423 U.S. 122, 135, 143 (1975)); *United States v. Alerre*, 430 F.3d 681, 691 (4th Cir. 2005), *cert. denied*, 547 U.S. 1113 (2006) (holding that the CSA's prescription requirement stands as a proscription against doctors acting not "as a healer[,] but as a seller of wares.").

Under the CSA, it is fundamental that a practitioner establish and maintain a legitimate doctor-patient relationship in

professional disciplinary authority, or any other evidence as to the status of Applicant's state license. See 21 U.S.C. 823(f)(1). However, even assuming that Applicant currently possesses state authority to dispense controlled substances and thus meets this requirement for obtaining a practitioner's registration, see *id.* sections 802(21) and 823(f), this is only one of the five factors which the Agency considers in making the public interest determination and is therefore not dispositive. See *Joseph Gaudio*, 74 FR 10083, 10090 n.25 (2009); *Mortimer B. Levin*, 55 FR 8209, 8210 (1990).

There is also no evidence in the record that Applicant has been convicted of an offense related to the manufacture, distribution or dispensing of controlled substances. See 21 U.S.C. 823(f)(3). However, as the Agency has held, there are a number of reasons why a person who has committed misconduct may not have been convicted, let alone prosecuted for such an offense. Accordingly, the absence of such a conviction is not dispositive.

order to act "in the usual course of . . . professional practice" and to issue a prescription for a "legitimate medical purpose." *Paul H. Volkman*, 73 FR 30629, 30642 (2008), *pet. for rev. denied*, 567 F.3d 215, 223–24 (6th Cir. 2009). The CSA generally looks to state law and state medical practice standards to determine whether a legitimate doctor-patient relationship has been established. *Id.*

Under California law, a physician "may prescribe for, or dispense or administer to, a person under his or her treatment for a medical condition . . . prescription controlled substances for the treatment of pain or a condition causing pain." Cal. Bus. & Prof. Code section 2241.5(a). However, under California law, in order to legally prescribe a controlled substance, a physician must conduct an "appropriate prior examination." Cal. Bus. & Prof. Code section 2242(a) ("Prescribing, dispensing, or furnishing dangerous drugs . . . without an appropriate prior examination and a medical indication, constitutes unprofessional conduct."); see also *People v. Gandotra*, 14 Cal. Rptr. 2d 896, 899–900 (Cal. Ct. App. 1992) ("A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.") (quoting Cal. Health & Safety Code section 11153(a)).

Here, the Government has presented evidence that on multiple occasions, Applicant acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed highly abused controlled substances including OxyContin (oxycodone), hydrocodone, and alprazolam to the Detective, without conducting a prior physical examination as required by state law. See 21 CFR 1306.04(a). More specifically, the evidence shows that Applicant did not perform a physical examination of the Detective at any of the visits and that the Detective did not even complain of any symptoms that would warrant medical treatment, let alone the issuance of controlled substance prescriptions. Indeed, Respondent issued prescriptions to the Detective notwithstanding that he clearly knew that the latter (in his undercover persona) was seeking drugs to abuse them.

As found above, during his first visit, the Detective openly stated that he had borrowed some pills from a friend and Applicant acknowledged that the Detective's use of OxyContin was "recreational" and that "there's not a medical problem." Moreover, after the

³ The record contains no evidence regarding any recommendation of the state licensing board or

Detective stated that he would like to get “a prescription instead of hitting somebody up.” Applicant acknowledged that “the only problem is unless we have an actual pain diagnosis psychiatrists can’t write for it” and then asked the Detective if he had “ever been diagnosed with a disk problem or anything?” GX 4, at 10. Even then, the Detective did not identify any pain problem, and said: “I mean . . . if I just gotta say I got something.” *Id.* Applicant thus clearly knew that the Detective did not have a legitimate pain condition.

Moreover, Applicant did not perform a physical exam at either the Detective’s second or third visit, each of which lasted two to three minutes. Indeed, at the second visit, Applicant merely asked “what kind of pain is it? Is it back pain or?” to which the Detective replied: “That’s what you . . . told me you put on there before.” *Id.* at 14. Here again, Applicant issued the Detective an additional prescription for OxyContin and did so notwithstanding that he knew that the Detective did not have any pain.

So too, at the Detective’s third visit, Applicant’s inquiry into the former’s need for controlled substances involved him asking, “[i]s this for your back?” with the Detective answering: “You know yeah that’s well last time you told me to it was my back yeah.” *Id.* at 18. Applicant then asked “[i]s it more help out your mood or what’s it do for you?” to which the Detective answered that he did “concrete all day long” and was “working with people and stuff like that,” and that after coming home, “it helps unwind.” Respondent then stated: “Ok that one they’ll let us do.” *Id.* Applicant then agreed to write the Detective a prescription for Norco, a schedule III combination drug which contains hydrocodone. *Id.* Moreover, he also wrote the Detective a prescription for Xanax based solely on the Detective’s asking him if he had anything for sleep and did not ask him a single question about his sleep patterns. *Id.*

As the evidence shows, at each of the above visits, Applicant knew that the Detective was not seeking the drugs for the purpose of treating a legitimate medical condition, but rather, for the purpose of abusing them. He also did not perform a physical examination. Applicant nonetheless issued the four prescriptions to the Detective. Given the evidence, expert testimony is not necessary to conclude that Applicant acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing each of the four prescriptions. 21 CFR 1306.04(a); *see also T.J. McNichol*, 77

FR 57133, 57147–48 (2012), *pet. for rev. denied McNichol v. DEA*, No. 12–15292, Slip. Op. at 4 (11th Cir. Oct. 17, 2013).

Indeed, these were outright drug deals. *See Moore*, 423 U.S. at 142–43 (noting that evidence established that physician “exceeded the bounds of professional practice,” when, *inter alia*, “he gave inadequate physical examinations or none at all” and ignored signs of diversion); Cal. Bus. & Prof. Code section 2242(a) (requiring a “prior examination” before prescribing medication); *Gabriel Sanchez, M.D.*, 78 FR 59060, 59063–64 (2013) (finding that a doctor acted outside the usual course of professional practice by not conducting an adequate physical examination before prescribing controlled substances). These findings alone support the conclusion that granting Applicant’s application for a new registration “would be inconsistent with the public interest.” 21 U.S.C. 823(f).

While these findings provide reason alone to deny his application, the evidence further shows that Applicant violated several recordkeeping requirements. *See Volkman*, 73 FR at 30644 (“Recordkeeping is one of the CSA’s central features; a registrant’s accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.”). As found above, at the time of the search, Respondent possessed various controlled substances including Ambien (zolpidem), Lunesta (eszopiclone), and Xanax (alprazolam). Applicant, however, admitted to the DI that he “did not maintain any records of acquisition or dispensation” of controlled substances and that he “did not document the dispensation in the patient’s chart.” GX 3, at 2.

Under the CSA, a “registered individual practitioner is required to maintain records of controlled substances in Schedules II–V that are dispensed and received, including the number of dosage units, the date of receipt or disposal, and the name, address, and registration number of the distributor.” *Richard A. Herbert*, 76 FR 53942, 53958 (2011) (citing 21 CFR 1304.03(b), 1304.22(c)); *see also* 21 U.S.C. 827(a) & (c). Thus, by his own admission, Applicant violated federal law by failing to maintain CSA-required records. *See Volkman*, 73 FR at 30644; *see also* Cal. Bus. & Prof. Code section 2241.5(c)(5) (subjecting physician to discipline for failing to “keep complete and accurate records of purchases and disposals of . . . controlled substances scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act

of 1970”). This finding provides an additional basis for denying Applicant’s application.

I therefore conclude that the Government has met its *prima facie* burden of showing that the issuance of a registration to Applicant “would be inconsistent with the public interest.” 21 U.S.C. 823(f). Because Applicant neither requested a hearing nor submitted a written statement regarding the allegations of the Order to Show Cause, there is no evidence to the contrary. *Patrick K. Chau*, 77 FR 36003, 36008 (2012). Accordingly, I will order that Applicant’s application be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b) and 0.104, I hereby order that the application of James Clopton, M.D., for a DEA Certificate of Registration be, and it hereby is, denied. This order is effective immediately.

Dated: January 6, 2014.

Thomas M. Harrigan,
Deputy Administrator.

[FR Doc. 2014–00524 Filed 1–13–14; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Executive Office for Immigration Review

[OMB Number 1125–NEW]

Agency Information Collection Activities: Proposed Collection; Comments Requested; Request by Organization for Accreditation of Non-Attorney Representative (Form EOIR–31A)

ACTION: 30-Day notice.

The Department of Justice (DOJ), Executive Office for Immigration Review (EOIR) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register**, 78 FR 66382, November 5, 2013, allowing for a 60-day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until February 13, 2014. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this