recordkeeping activities. (See 5 CFR 1320.8 (d) and 1320.12(a)).

As required at 5 CFR 1320.8(d), the BLM published a 60-day notice in the **Federal Register** on June 15, 2016 (81 FR 39064), and the comment period ended August 15, 2016. The BLM received no comments in response to the notice.

The BLM now invites comments on the following subjects:

1. Whether the collection of information is necessary for the proper functioning of the BLM, including whether the information will have practical utility;

2. The accuracy of the BLM's estimate of the burden of collecting the information, including the validity of the methodology and assumptions used;

3. The quality, utility and clarity of the information to be collected; and

4. How to minimize the information collection burden on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other forms of information technology.

Please send comments as instructed under the headings **DATES** and **ADDRESSES**, above. Please refer to OMB Control Number 1004–0119 in your correspondence. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

The following information is provided for the information collection:

Title: Permits for Recreation on Public Lands (43 CFR part 2930).

Forms: Form 2930–1, Special Recreation Permit Application.

OMB Control Number: 1004–0119.

Summary: This collection pertains to the management of recreation on public lands. The BLM is required to manage commercial, competitive and organized group recreational uses of the public lands, and individual use of special areas. This information allows the BLM to collect the required information to authorize and collect fees for recreation use on public lands. The currently approved information collection consists of the collection in accordance with 43 CFR part 2930, and Form 2930–1 (Special Recreation Permit Application and Permit).

Frequency of Collection: On occasion.

Estimated Annual Responses: 1,376.

Estimated Annual Burden Hours: 5,504.

Estimated Annual Non-hour Burden Cost: None.

Jean Sonneman,

Bureau of Land Management, Information Collection Clearance Officer.

[FR Doc. 2016–25277 Filed 10–18–16; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–D–COS–POL–22111; PPWODIREP0] [PPMPSPD1Y.YM0000]

Notice of Availability and Request for Comments on Draft Director's Order #100 Resource Stewardship for the 21st Century

AGENCY: National Park Service, Interior.

ACTION: Notice of availability and request for comments.

SUMMARY: The National Park Service (NPS), under its authority at 54 U.S.C. 100101(a) *et seq.*, has prepared a new Director's Order setting forth the policies and procedures that will guide resource stewardship in the 21st century. This guidance will form a new framework for stewardship decision making within the NPS based upon an overarching resource stewardship goal described in the Order.

DATES: Written comments will be accepted until November 18, 2016.

ADDRESSES: Draft Director's Order #100 is available online at: *http://parkplanning.nps.gov/DO100* where readers may submit comments electronically.

FOR FURTHER INFORMATION CONTACT: Megan McKenna, Director's Order #100 Implementation Coordinator, National Park Service, at *megan_f_mckenna@nps.gov*, or by telephone at (970) 267–2123.

SUPPLEMENTARY INFORMATION: The NPS is updating its current system of internal written instructions. When these documents contain new policy or procedural requirements that may affect parties outside the NPS, they are first made available for public review and comment before being adopted. Director's Order #100 and a reference manual (subsequent to the Director's Order) will be issued. The draft Director's Order covers topics such as resource stewardship, Service-wide training, and decision making.

Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2016–25283 Filed 10–18–16; 8:45 am]

BILLING CODE 4312–52–P

JUDICIAL CONFERENCE OF THE UNITED STATES

Meeting of the Judicial Conference Advisory; Committee on Rules of Civil Procedure

AGENCY: Judicial Conference of the United States.

ACTION: Notice of open meeting.

SUMMARY: The Advisory Committee on Rules of Civil Procedure will hold a meeting on November 3, 2016, which will continue the morning of November 4, 2016, if necessary. The meeting will be open to public observation but not participation. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: *http://www.uscourts.gov/rules-policies/records-and-archives-rules-committees/agenda-books.*

DATES: November 3–4, 2016.

Time:

November 3, 2016: 1:30–5:00 p.m.

November 4, 2016 (if necessary): 9:00 a.m.–12:00 p.m.

ADDRESSES: Thurgood Marshall Federal Judiciary Building, Mecham Conference Center, Administrative Office of the United States Courts, One Columbus Circle NE., Washington, DC 20544.

FOR FURTHER INFORMATION CONTACT: Rebecca A. Womeldorf, Rules Committee Secretary, Rules Committee Support Office, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 502–1820.

Dated: October 13, 2016.

Rebecca A. Womeldorf,

Rules Committee Secretary.

[FR Doc. 2016–25258 Filed 10–18–16; 8:45 am]

BILLING CODE 2210–55–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Edge Pharmacy; Decision and Order

On October 8, 2014, the Deputy Assistant Administrator, Office of

Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Edge Pharmacy (hereinafter, Respondent), which proposed the revocation of its DEA Certificate of Registration FE1512501, pursuant to which it was authorized to dispense controlled substances in schedules II through V, as a retail pharmacy, at the registered location of 2039 E. Edgewood Drive, Lakeland, Florida. GE 1, at 1. As ground for the proposed actions, which also include the denial of any pending applications, the Show Cause Order alleged that Respondent's ''continued registration is inconsistent with the public interest.'' GE 1, at 1 (citing 21 U.S.C. 824(a)(4) and 823(f)).

More specifically, the Show Cause Order alleged that Respondent's ''pharmacists repeatedly failed to exercise their corresponding responsibility to ensure that controlled substances they dispensed were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting within the usual course of their professional practice'' and that its ''pharmacists ignored readily identifiable red flags that [the] controlled substances prescribed were being diverted and dispensed despite unresolved red flags.'' *Id.* (citing 21 CFR 1306.04(a); *Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195,* 77 FR 62315, 62319 (2012)). The Show Cause Order further alleged that Respondent's ''pharmacists dispensed controlled substances when they knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose, including circumstances where the pharmacist knew or should have known that the controlled substances were abused and/or diverted by the customer.'' *Id.* at 2.

The Show Cause Order then alleged that Respondent's ''pharmacists filled numerous controlled substance prescriptions despite customers exhibiting multiple 'red flags' of . . . diversion that were never resolved before dispensing.'' *Id.* The Order alleged that these ''red flags''' included: (1) ''Multiple individuals presenting prescriptions for the same drugs in the same quantities from the same doctor''; (2) ''individuals presenting prescriptions for controlled substances known to be highly abused, such as oxycodone and hydromorphone''; (3) ''individuals paying high prices . . . for controlled substance [prescriptions] with cash''; and (4) ''individuals residing long distances from the pharmacy.'' *Id.*

As more specific examples, the Show Cause Order alleged that ''[o]n January 10, 2011, one or more . . . pharmacists dispensed large and substantially similar quantities of'' oxycodone 30 mg tablets ''to at least nine persons, including one customer who resided more than four hundred (400) miles from [it], two customers who resided more than one hundred fifty (150) miles from [it], and six customers who resided more than ninety (90) miles from'' it. *Id.* The Order further alleged that these ''customers were all prescribed thirty milligram tablets of oxycodone by the same doctor in quantities ranging from 168 to 224 tablets'' and that each of the prescriptions was ''facially invalid'' because it did not contain the patient's address. *Id.*

The Show Cause Order also alleged that ''[f]rom January 6 through January 7[,] 2011, one or more . . . pharmacists dispensed large and substantially similar quantities of'' oxycodone 30 mg tablets ''to at least sixteen persons, including eight customers who resided more than one hundred fifty (150) miles from [it], and four customers who resided more than one hundred (100) miles from'' it. *Id.* The Order further alleged that ''these customers were all prescribed thirty milligram tablets of oxycodone by the same doctor in quantities ranging from 168 to 224 tablets'' and that each of the prescriptions was ''facially invalid'' because it did not contain the patient's address. *Id.*

Next, the Show Cause Order alleged that ''[f]rom October 7 through October 28[,] 2011, one or more . . . pharmacists dispensed large and substantially similar quantities of hydromorphone to seventeen [persons], ten of whom resided more than one hundred (100) miles from'' it, and ''two of whom resided more than four hundred (400) miles away.'' *Id.* The Order alleged that ''sixteen'' of these prescriptions ''were written by the same doctor and only one . . . contained a patient address.'' *Id.* The Order then alleged that ''at least four'' of the hydromorphone prescriptions were ''in dosage amounts that, if taken as directed, far exceeded the recommended dosages of hydromorphone that should be taken on a daily basis'' and that ''[t]hese prescriptions were dispensed on October 21 and 27[,] 2011'' and July 5–6, 2012. *Id.*

The Show Cause Order also alleged that ''[f]rom January 4 through 23[,] 2013, one or more . . . pharmacists dispensed large quantities of'' of oxycodone 30 mg ''to at least'' 19 persons, 15 ''of whom resided more than 90 miles from [it] and eight of whom resided more than [150] miles away.'' *Id.* at 3. The Order alleged that ''[a]ll of these prescriptions were issued by the same doctor, and were purchased with cash by individuals willing to pay as much as eight dollars per tablet.'' *Id.* The Order also alleged that these prescriptions were facially invalid because they lacked the patient's address. *Id.*

The Show Cause Order then alleged that Respondent's ''pharmacists knew or should have known that the vast increase of customers seeking controlled substance prescriptions and the large number of customers residing long distances from [its] location and/or their respective physicians created a suspicious situation requiring increased scrutiny, and nonetheless failed in carrying out their responsibilities as a DEA registrant.'' *Id.* Continuing, the Order alleged that Respondent's ''pharmacists failed to exercise their corresponding responsibility'' under 21 CFR 1306.04(a) in dispensing controlled substances and either ''knew, or should have known, that a large number of the prescriptions for controlled substances that it filled were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice.'' [1] *Id.* (citing cases).

Next, the Show Cause Order alleged that following the execution of an Administrative Inspection Warrant, DEA had obtained various records from

[1] In its Prehearing Statement, the Government provided notice that its expert witness in pharmacy practice would identify various red flags of diversion that were presented by the prescriptions ''and that there is no evidence that any of the red flags were resolved prior to distributing the controlled substances to the customers.'' Gov. Prehearing Statement, at 5. Subsequently, in its Supplemental Prehearing Statement, the Government provided notice that its Expert ''will opine on 127 additional prescriptions which the Government provided to Respondent's counsel'' and ''that the prescriptions were issued to individuals residing long distances both from Respondent's pharmacy and/or the physician who issued the prescriptions.'' Gov. Supplemental Prehearing Statement, at 3.

After identifing various cities where the patients resided, the Government provided notice that its Expert ''will testify that this type of red flag, with only a few exceptions, is not resolvable and the prescription should not be dispensed by a pharmacist exercising the appropriate standard of care and fulfilling his or her corresponding responsibility to ensure that a prescription for a controlled substances is issued for a legitimate medical purpose.'' *Id.* at 3–4. The Government also provided notice that its Expert will testify that ''exceptions'' [sic] that would make such a prescription resolvable were ''if a patient were travelling to a specialist of great renown, such as a physician working in a nationally recognized cancer treatment facility.'' *Id.* at 3 n.4. The Government then provided that its Expert ''will testify that he is unaware that any of the physicians prescribing the controlled substances at issue in this matter remotely fit that profile.'' *Id.*

Respondent and determined that it ''failed to create and maintain accurate records in violation of 21 U.S.C. 842(a)(5).'' *Id.* at 3. More specifically, the Order alleged that:

(1) Respondent's schedule II order forms did not contain the ''receipt date or quantity received in violation of 21 U.S.C. 827(b) and 21 CFR 1305.13(e)'';

(2) it ''failed to retain Copy 3 of'' its schedule II order forms ''as required by 21 CFR 1305.13(a) and 1305.17(a) and 21 U.S.C. 827(b)'';

(3) it ''failed to create a record of the quantity of each item received and the date received'' for controlled substances it ordered using the Controlled Substances Ordering System and ''also failed to electronically archive and link these records to the original order,'' both being required by 21 CFR 1305.22(g);

(4) that ''as supplier of controlled substances, [it] failed to forward Copy 2 of'' schedule II order forms to the Special Agent in Charge of the field division in which it is located, as ''required by 21 CFR 1305.13(d)''; and

(5) it also ''failed to record the date and quantity shipped'' on schedule II order forms, ''in violation of 21 CFR 1305.13(b).'' *Id.* at 3–4.

Finally, the Show Cause Order alleged that DEA conducted an audit of Respondent's handling of various schedule II drugs for ''the period [of] June 10, 2011, through February 4, 2013.'' *Id.* at 4. The Order then alleged that the audit found overages of the following drugs and amounts: 71,084 oxycodone 30 mg; 19,322 hydromorphone 8 mg; 10,460 methadone 10 mg; 5,542 morphine 60 mg; 4,451 hydromorphone 4 mg; 3,033 morphine 100 mg; and 1,338 morphine 30 mg. *Id.*

On November 14, 2014, Respondent filed a timely hearing request with the Office of Administrative Law Judges. Thereafter, the matter was assigned to Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, CALJ), who proceeded to conduct extensive pre-hearing procedures. On February 19, 2015, Respondent's original counsel withdrew and new counsel entered an appearance. The same day, Respondent's new counsel informed the ALJ's law clerk that Respondent would be ''filing a waiver of hearing along with a written position on the matters of fact and law in accordance with 21 CFR 1316.49.'' GE 1, at 10.

Subsequently, on February 26, 2015, the Government filed a motion *in limine* to preclude Respondent from offering any of its evidence at the hearing. Respondent did not oppose the motion, and on March 3, 2016, the ALJ granted the motion. Letter from CALJ to the former Administrator (Mar. 23, 2015) (hereinafter, CALJ Ltr.). The same day, Respondent's counsel telephoned the CALJ's staff and stated that he would be filing its waiver of hearing by March 9, 2015, and that if he ''was unable to file the Hearing Waiver by that date, he would file a motion to allow a waiver of hearing with a subsequent filing of position.'' *Id.* However, on March 10, 2015, after Respondent failed to file the waiver or otherwise notify the ALJ as to why he had not done so, the CALJ's staff contacted Respondent's counsel to seek clarification. *Id.*

On March 12, 2015, before the evidentiary hearing was to be conducted, Respondent's counsel emailed the CALJ's staff stating that he had not filed the hearing waiver because he had been unable to complete the written statement ''[d]ue to several unforeseen matters in'' another DEA proceeding in which he was involved. Email from Respondent's Counsel to CALJ's Law Clerk, at 1 (Mar. 12, 2015). Respondent's counsel further advised that he had not sought leave to file the waiver immediately and the statement of position later because the Government's counsel would not consent. *Id.* Respondent's counsel further represented that while he intended to file the waiver prior to the scheduled date of the hearing, he would not file the waiver until he was ready to file Respondent's written statement of position. *Id.*

On March 16, 2015, the CALJ conducted a status conference after which Respondent's counsel filed a pleading in which Respondent waived its right to a hearing while seeking leave to file a written statement no later than March 21, 2015. CALJ Ltr., at 2. The CALJ then issued an order terminating the proceeding effective on March 21, 2015 while granting Respondent leave to file its written statement prior to that date. *Id.*

On March 20, 2015, Respondent filed its Statement of Position. In his March 23, 2015 letter to the former Administrator regarding the status of the proceeding, the CALJ noted that under the plain language of the Agency's regulation which allows a respondent to file a written statement of position, the time period for filing a written statement had expired as Respondent had not requested an extension of the time for filing a response to the Order Show Cause. *Id.* at 3. Moreover, because Respondent did not oppose the Government's Motion in Limine, ''it is foreclosed from offering hearing evidence.'' *Id.*

The CALJ then explained that ''strict adherence to the regulations, because of the procedural choices made by the Respondent in the course of this litigation, would result in either a non-hearing decision without the option of filing a statement of position, or hearing procedures where it was precluded (by its own tactical choices) of presenting evidence in its defense.'' *Id.* Continuing, the ALJ reasoned that:

> [a]lthough the Agency . . . has not been reticent in holding respondents responsible for the procedural omissions of their counsel, justice here will be better served by applying principles of reasonableness. In the interests of justice, I *sua sponte* find good cause to extend the Respondent's ability to respond to the Order to Show Cause in accordance with 21 CFR 1316.47(b), accept its Statement of Position on the Agency's behalf, and herein forward it to you for whatever consideration or actions (if any) you deem appropriate in this matter.

Id. (footnotes omitted).

Thereafter, the Government filed a motion in which it sought to clarify its obligations prior to submitting its Request for Final Agency Action. More specifically, the Government sought clarification as to whether, in light of Respondent's waiver of its right to a hearing, it was required to serve any further pleadings on Respondent's counsel. Motion for Clarification, at 1. It also sought clarification as to whether Respondent was ''entitled to continue to litigate this matter'' given the waiver. *Id.* at 1–2.

Respondent objected to the Government's motion. Resp. Objection to Motion for Clarification. In its objection, Respondent argued that while it had waived its right to a hearing, it was entitled to otherwise participate in the proceeding which was ongoing and to receive copies of any filings submitted by the Government and respond to them. *Id.* at 2–3.

Respondent also asserted that while ''the Government was similarly entitled to participate in the proceeding, it chose not to do so and opted to sit in silence when Respondent submitted its evidence and [written] position . . . [and] when the ALJ unambiguously announced his intention to terminate the proceeding upon receipt of Respondent's position.'' *Id.* at 3–4. In Respondent's view, the Government was entitled to participate in the hearing and ''could have objected [sic] cancellation of the hearing'' or ''could have presented its evidence in writing.'' *Id.* at 8. Respondent further maintained that the Government, by failing to present its evidence to the CALJ, ''allow[ed] the record before the ALJ to close without presenting [its] case.'' *Id.* Respondent also argued that this Decision and Order ''must be based on [the] record''

submitted by the CALJ and that because that record contains no evidence to support the allegations, the Government had not met its burden of proof. *Id.* at 9–10.

On review, I determined that it was unnecessary to decide whether either the Administrative Procedure Act or the Due Process Clause requires the Government to submit copies of any subsequent filings to Respondent. Order, at 3 (July 29, 2015). Rather, I exercised my discretion and directed the Government to provide a copy of its Request for Final Agency Action and the record submitted in support of its Request to Respondent. *Id.* at 3–4. Based on Respondent's waiver of its right to hearing, I concluded that Respondent had waived its right to submit evidence in refutation of the Government's case. *Id.* at 4. However, I again exercised my discretion and provided that Respondent could file a brief raising arguments challenging the sufficiency of the evidence, the Government's positions on matters of law, and the appropriate sanction. *Id.*

However, I rejected Respondent's contention that the Government was not allowed to continue litigating the matter because it chose to forgo making a record before the ALJ.[2] *Id.* at 4 n.2. Moreover, finding the reasons proffered by the CALJ insufficient to support a finding to excuse the untimely submission of its Statement of Position, I directed Respondent to address ''why there is good cause to excuse the untimeliness of its filing, paying particular attention as to why there is good cause to excuse the untimely submission of the attached affidavits.'' *Id.* And because the CALJ had issued an order terminating the proceeding effective March 21, 2015 and the CALJ did not rule on whether there was good cause to admit Respondent's Statement of Position until March 23, 2015 (after his jurisdiction had terminated pursuant to his own order), I directed Respondent to ''address whether, given the effective date of the ALJ's termination order, the ALJ had authority to admit its Statement of Position.'' *Id.*

Thereafter, Respondent filed a letter responding to my Order. Letter from Resp's. Counsel to the Acting Administrator (Aug. 7, 2015). Therein, Respondent asserted that it had faxed its Written Statement of Position on March 20, 1015, which is borne out by the fax cover sheet.[3] *Id.* at 1–2. As for whether there was good cause to accept its Written Statement of Position, Respondent argues that the CALJ erred in relying on 21 CFR 1301.43 when he concluded that it was foreclosed from filing its written statement of position because the time period for filing its hearing request had passed. *Id.* at 3. Respondent argues that after it filed its hearing request under 21 CFR 1301.43(a), the provisions of part 1301 no longer apply and the provisions of part D of 21 CFR part 1316 are controlling. *Id.* It further argues that 21 CFR 1316.49, the provision of Subpart D which applies to the waiver of a hearing, ''contains no provision for cancellation of the hearing'' and that ''no provision in Subpart D . . . indicat[es] the time period within which [it] may waive its opportunity to participate in the hearing and file its written statement.'' *Id.* In Respondent's view, it has been denied ''fair notice'' that ''having requested a hearing, it had to waive its opportunity to participate in a hearing and file its Statement . . . within 30 days of being served with the'' Show Cause Order. *Id.* And Respondent argues that the requirement that it file its written statement within 30 days of the date on which it was served with the Show Cause Order ''does not apply to a waiver and written statement filed after requesting a hearing.'' *Id.*

I reject these contentions because Respondent is simply trying to re-write the Agency's procedural rules to suit its own purpose. Under the Agency's rules, a person served with a Show Cause Order has two options for responding to it.[4] First, it can, ''within 30 days after the date of receipt of the order to show cause,'' file a request for a hearing as Respondent initially did. 21 CFR 1301.43(a). Alternatively, it can, ''within the period permitted for filing a request for a hearing, file with the Administrator a waiver of an opportunity for a hearing . . . together with a written statement regarding such person's position on the matters of fact and law involved in such hearing.'' *Id.* § 1301.43(c). *See also id.* § 1316.49 (''Any person entitled to a hearing may, within the period permitted for filing a request for a hearing . . . waiver of an opportunity for a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing.'').[5]

Contrary to Respondent's contention, both the procedural rules found in 21 CFR part 1301 and Part 1316 apply to hearings conducted under 21 U.S.C. 823 and 824. *See* 21 CFR 1301.41(a) (''In any case where the Administrator shall hold a hearing on any registration or application therefore, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559), and specifically by [21 U.S.C. 823–24], by §§ 1301.42–1301.46 of this part, and by the procedures for administrative hearings . . . set forth in §§ 1316.41–1316.67 of this chapter.'').[6] Thus, while Respondent argues that no regulation in part 1316 provides for the cancellation of a hearing, Part 1301 contains a provision which states that ''[i]f all persons entitled to a hearing . . . waive or 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.'' 21 CFR 1301.43(e). Thus, contrary to Respondent's understanding, this provision applies to its waiver, notwithstanding that it had previously requested a hearing. In any event, given that a hearing is only held on request of ''a person entitled to a hearing'' and is held ''for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation or suspension of any registration,'' 21 CFR 1301.42, it is indisputable that a hearing can be cancelled when a respondent initially requests a hearing but then decides to waive its right to it.

Nor am I persuaded by Respondent's contention that it has been denied fair notice because once it requested a hearing, no provision in Subpart D sets forth the time period in which it was required to file its written statement if it subsequently decided to waive its right to a hearing. Resp's. Ltr., at 3. The Agency's regulations grant the right to file a written statement only when a hearing waiver is filed within the 30-day period or where a respondent establishes ''good cause'' for the

[2] I also rejected Respondent's contention that the Government had no procedural basis for requesting clarification and that I had no authority to respond to that motion. I did not, however, set forth my reasoning for rejecting these contentions.

[3] In his letter, Respondent devoted considerable argument to discussing why portions of the fax were date stamped after the deadline imposed by the CALJ. That, however, was not the issue, and was not mentioned in my July 29, 2015 Order.

[4] Of course, a person served with a Show Cause Order can also choose to not respond.

[5] While the wording of this provision clearly reflects a scrivener's error in that it is missing language to the effect that the person ''may file a'' waiver and written statement, it has never been construed as creating a right to file a written statement at any time thereafter.

[6] *See also* 21 CFR 1316.41 (''Procedures in any administrative hearing held under the Act are governed generally by the rule making and/or adjudication procedures set forth in the [APA] and specifically by the procedures set forth in this subpart, except where more specific regulations [set forth in other parts including parts 1301] apply.'').

untimely filing. 21 CFR 1301.43(d). Thereafter, no provision in the Agency's hearing regulations affords a respondent the right to file a written statement of position and to submit evidence. Given that the Agency's regulations do not provide any right to file a written statement after the initial 30-day period for responding to the Order to Show Cause, Respondent cannot claim that it has been denied ''fair notice'' that it had to submit its hearing request within the 30-day period.

Thus, while the Controlled Substances Act requires the Agency to provide a hearing conducted pursuant to the APA's procedures for adjudications, *see* 21 U.S.C. 824(c), the Agency provided Respondent with that opportunity and was prepared to provide it with that hearing. At that hearing, Respondent could have challenged the Government's evidence through, *inter alia,* the cross-examination of its witnesses. Respondent could also have presented evidence in its defense had it complied with the ALJ's pre-hearing orders. In short, the Agency is not required to provide Respondent with more procedural rights than Congress mandated in the CSA. *Cf. Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519 (1978). And while the Agency has provided a limited right to submit a written statement, the Agency is not required to create a new procedural right to provide Respondent, which waived its right to a hearing only after months of largely unsuccessful pre-hearing litigation, with an alternative way of presenting evidence.

Respondent further argues that applying 21 CFR 1301.43 (the regulation requiring the filing of a written statement within 30 days of receipt of the Show Cause Order) to its circumstances, ''produces a result contrary to the Agency's interest in administrative efficiency.'' Resp's. Ltr., at 3. It argues that under the ALJ's interpretation, ''respondents who have made a timely request for hearing but later realize that they have no need or desire to participate in a hearing would be left with two choices: Continue to require the Agency to hold a hearing or abandon all opportunity to be heard in any manner whatsoever.'' *Id.* Respondent further argues that faced with this choice, ''such respondents would be strongly discouraged from waiving an unnecessary hearing and preventing a waste of Agency time and resources.'' *Id.* at 3–4.

This choice is, however, no different than that frequently confronted in litigation when a party recognizes that his opponent has a strong case and is likely to prevail at trial. Moreover, Respondent's proposed new procedural right would actually create the opposite incentive: Instead of submitting its written statement at the outset, it induces a respondent to litigate, knowing that if things go badly, it can then take a different tack by submitting its written statement. Moreover, in Respondent's view, it is also entitled to submit testimonial evidence in the form of affidavits and thus preclude the Government from cross-examining its witnesses.

Upon receipt of a Show Cause Order, a party is entitled to fair notice of the factual and legal basis for the actions proposed by the Government. 21 U.S.C. 824(c). And where a respondent chooses to litigate, the Government is obligated to provide a respondent with fair notice of the evidence it is likely to confront at the hearing. However, creating a new procedural right that allows a party, which has litigated for months on end, to then waive its right to a hearing on the eve of that hearing but nonetheless present its evidence in written form, does not in any sense promote administrative efficiency. To the contrary, it incentivizes litigation by providing two bites of the apple.[7]

Respondent also takes issue with the CALJ's application of the ''good cause'' standard in evaluating whether it Statement was timely submitted. Resp's. Ltr., at 4. And it further argues that even if the ''good cause'' standard applies, it has satisfied the standard. *Id.* I disagree.

As explained above, the two Agency rules that granted Respondent the right to file a written statement required it do so within the 30-day period for requesting a hearing. Putting that aside, DEA has applied the ''good cause'' standard in a variety of contexts in assessing whether an untimely filing should be excused, including to the untimely submission of a statement of position. *See Ronald A. Green,* 80 FR 50031 (2015) (deeming physician's pleading captioned as ''Response to First Amended Complaint and Motion to Dismiss,'' which was filed with the Agency more than three months after service of Show Cause Order as his statement of position, and applying ''good cause'' standard in assessing whether it was timely filed); *see also Rene Casanova,* 77 FR 58150, 58150 (2012) (upholding ALJ's application of good cause standard in denying untimely filed request for an extension to file exceptions); *Daniel B. Brubaker,* 77 FR 19322, 19323 (2012) (upholding ALJ's application of good cause standard in denying untimely motion to file supplemental prehearing statement out of time); *Kamir Garces-Mejias,* 72 FR 54931, 54932–33 (2007) (applying good cause standard in upholding ALJ's termination of hearing where respondent failed to comply with ALJ's order to file pre-hearing statement). *See also* 21 CFR 1301.43(d) (applying good cause standard in assessing whether an untimely hearing request should be excused); *id.* 1316.57 (''All documentary evidence and affidavits not submitted and all witnesses not identified at the prehearing conference shall be submitted or identified to the presiding officer as soon as possible, with a showing that the offering party had good cause for failing to so submit or identify at the prehearing conference.'').

Respondent further argues that even if the good cause standard applies to the submission of its written statement, it has satisfied the standard because the Agency has interpreted the standard ''with reference to case law'' applying the excusable neglect standard, and under that standard, it has demonstrated good cause. Resp's. Ltr., at 4. Respondent is correct that the Agency has interpreted the good cause standard in a manner that aligns it with the good cause standard of various federal rules of procedure. *See Keith Ky Ly,* 80 FR 29025, 29027–28 & n.2 (2015). Thus, Respondent's untimely filing of its Statement may be excused upon a showing of excusable neglect. Respondent, however, has failed to show excusable neglect.

As the basis of its argument, Respondent's counsel argues that he did not become counsel for Respondent until February 2015 when original counsel withdrew, at which time he ''discovered that the DEA had refused to return Respondent's records in violation of Agency policy and the clear directions of the Magistrate Judge who issued the administrative inspection warrant.'' Resp's. Ltr., at 4. He further maintains that he ''also discovered that the scanned images of those documents which had been provided to Respondent contained annotations that were not on the records when the DEA removed them from the pharmacy [and] also found the images to be illegible in part.'' *Id.* Continuing, he argues that ''[i]t was impossible for Respondent to know within 30 days of receiving the Order to Show Cause that the Government would rely on portions of the documents that the DEA refused to return to Respondent, since the Government first

[7] Unexplained by Respondent is whether, in its view, there is any limit to when it could waive its right to a hearing and submit a written statement. For example, could it require the Government to put on its case in chief, determine how strong the case was, and then waive its right to a hearing and submit a written statement?

revealed this on December 2, 2014 when [Government counsel] filed the Government's prehearing statement.'' *Id.* According to Respondent's counsel, he ''determined that a hearing under these circumstances would be futile'' and Respondent decided to waive its right to a hearing.[8] *Id.*

These arguments do not establish excusable neglect (or any other form of good cause), and certainly not with respect to Respondent's delay in filing its statement until approximately five months after it was served with the Show Cause Order. As for the contention that the Agency violated ''the clear directions of the Magistrate Judge'' because it refused to return the records to Respondent, Respondent does not identify any language in the Administrative Inspection Warrant which set a date by which the Government was required to return its records. Nor does it identify any court order issued by the Magistrate Judge requiring the return of the records with which the Government failed to comply.[9] As for Respondent's claims that some of the documents contained notations that were not on them when they were seized and that some of the documents were ''illegible in part,'' Respondent has not even identified which documents have these characteristics, let alone explain why these documents were relevant to the specific allegations raised by the Government. Moreover, to the extent the Government intended to rely on any document that was purportedly illegible, Respondent offers no explanation for why its previous counsel did not seek legible copies.

Also unpersuasive is Respondent's assertion that ''[i]t was impossible for [it] to know within 30 days of receiving the [Show Cause] Order that the Government would rely on portions of the documents that the DEA refused to return to'' it and that it did not know what documents it would rely on until December 2, 2014, when the Government filed its prehearing statement. The CALJ, however, granted Respondent an extension of time to allow it to file its prehearing statement on January 2, 2015, which it did. Moreover, even if Respondent did not know what documents the Government intended to rely on until December 2, 2014, this does not explain why Respondent then waited another three and a half months to file its written statement.

I further reject the contention that these circumstances rendered the hearing futile. Indeed, in cases brought against two related pharmacies which Respondent's current counsel also participated in and made similar arguments regarding the Government's purported unlawful retention of its records, I rejected the Government's dispensing allegations as unsupported by substantial evidence. *See Superior Pharmacy I and Superior Pharmacy II,* 81 FR 31310, 31334–337 (2016). I also rejected various recordkeeping allegations as not being supported by either the CSA or DEA regulations. *Id.* at 31338. And while I accepted the Government's audit allegations in *Superior,* I noted that the respondents had approximately 80 days from the date on which they were served with the show cause orders (at which time they also were provided with copies of their records) to file their prehearing statements and had ample time to conduct their own investigation of the allegations. *Id.* at 31337 n.62.

Notably, in the *Superior* matters, the respondents made similar arguments with respect to the audits and yet they provided charts which purported to show the results of their own audits when they filed their untimely exceptions to the ALJ's Recommended Decision. In declining to consider this evidence, I noted that there was no foundation for its consideration and that it was not newly discovered evidence; I also observed that Respondent ''did not identify any records that were necessary to complete their audits which were not provided to them when their records were returned.'' *Id.* So too here. Notably, as part of Respondent's Statement of Position, it submitted the affidavit of Victor Obi, the brother of Respondent's owner (and the owner of the two Superior Pharmacies), who avers that he is Respondent's independent pharmacy consultant. Resp.'s Position Statement, Attachment 3, at 1.

In the affidavit, Mr. Obi avers that he reviewed the purchasing, return and dispensing records for the pharmacy for the same audit period as used by the Government; Obi further avers that he conducted an audit of the various drugs and dosage strengths audited by the Government and disputes the results of the Government's audit for the various drugs. *Id.* at 3–6. Notably, Obi executed the affidavit on March 20, 2015. *Id.* at 6. Unexplained by Respondent is why Mr. Obi was unable to complete his audit before the date by which it was required to file its prehearing statement, or a supplemental prehearing statement which it could have filed without leave of the CALJ if it did so before 2 p.m. on February 20, 2015. *See* Preliminary Order Regarding Scope of Proceedings, Prehearing Ruling, & Protective Order, at 7 (Jan. 13, 2015).

Of further note, in its Pre-hearing Statement, Respondent represented that it intended to call a witness who was a former DEA Diversion Program Manager who ''will testify regarding errors in the audits performed by the agents/investigators involved in the investigation of Edge Pharmacy.'' Resp. Prehearing Statement, at 5. Presumably, Respondent's prior counsel would not have made this representation without the proposed witness having conducted an investigation of the audit allegations and found that there were errors. Yet when the Government field its Motion *in Limine* to preclude this witness's testimony on the ground that Respondent had ''fai[ed] to identify a single error'' in the audits, Motion *in Limine,* at 6; Respondent's new counsel did not oppose the motion, thus suggesting that this proposed witness had not, in fact, performed an audit.

Notably, Respondent's conclusion that a hearing would have been ''futile'' came only after months of pre-hearing litigation, and to the extent the hearing would have been futile, this was largely the result of the strategic choices made by its counsel. Although the record does not establish when Mr. Obi finally performed his audit, Respondent clearly had ample time to investigate the allegations and disclose its proposed evidence prior to the hearing if it believed the allegations were untrue. And while Respondent's prior counsel may well have been neglectful in failing to thoroughly investigate the allegations, that neglect is not excusable. *See Pioneer Inv. Servs. Co.* v. *Brunswick Assoc. Limited Partnership,* 507 U.S. 380, 397 (1993) (one who ''voluntarily chose [its] attorney as [its] representative in the action . . . cannot . . . avoid the consequences of the acts or omissions of this freely selected agent. Any other notion would be wholly inconsistent with our system of representative litigation, in which each party is deemed bound by the acts of [its] lawyer-agent and is considered to have notice of all facts, notice of which can be charged upon the attorney'') (int. quotation and citation omitted). *See also*

[8] Respondent's counsel also devotes considerable discussion to the give and take between himself and Government counsel over the timing and filing of his written statement after he appeared in the proceeding. The discussion, however, adds nothing either way in determining whether Respondent has met the good cause standard as Respondent had been served with the Show Cause Order four months before it hired new counsel, and Respondent's prior counsel filed numerous pleadings on its behalf up until he withdrew.

[9] The warrant required only that a prompt return of the warrant itself be made. It appears that copies of the records were provided to Respondent's original counsel on October 16, 2014, the date on which Respondent was served with the Show Cause Order.

U.S. v. *$29,410.00 in U.S. Currency,* 600 Fed. Appx. 621, 623–24 (10th Cir. 2015) (excusable neglect not established where counsel failed to respond to an answer or interrogatories for over three months and offered no reasonable explanation); *Brodie* v. *Gloucester Township,* 531 Fed. Appx. 234, 237 (3d Cir. 2013) (excusable neglect not established to support extension of time to file notice of appeal when client's counsel ''could have filed a notice of appeal, but chose not to do so''); *A.W. Anderson* v. *Chevron Corp.,* 190 FRD. 5, 10 (D.D.C. 1999) (failure to oppose motion for attorneys' fees not excusable neglect when ''[t]he decision . . . was by any measure a calculated decision by [p]rior [c]ounsel''); *see also id.* at 11 (client ''bound by the strategic choices of her counsel that later turn out to be improvident'') (citing *Douglas* v. *Kemp,* 721 F.Supp. 358 (D.D.C. 1989)).

Nor has Respondent otherwise demonstrated good cause for filing its written statement more than four months after the fact.[10] Notably, in accepting Respondent's written statement, the CALJ noted that ''because of the procedural choices made by Respondent in the course of the litigation,'' specifically, its decision not to oppose the Government's Motion *in Limine* and its failure to file its written statement within the time allowed by the regulations, Respondent would be foreclosed from putting forward its defense. CALJ Ltr., at 4. Invoking 21 CFR 1316.47(b), the CALJ, notwithstanding his previous discussion of Respondent's procedural choices, then asserted that the interests of justice ''will be better served by applying principles of reasonableness'' and found, *sua sponte,* that there was good cause to extend Respondent's ability to respond to the Order to Show Cause and accepted its statement on the Agency's behalf. *Id.* (citing 21 CFR 1316.47(b)).

Under this regulation, ''[t]he Administrative Law Judge, *upon request and showing of good cause,* may grant a reasonable extension of the time allowed for response to an Order to Show Cause.'' 21 CFR 1316.47(b) (emphasis added). However, as explained above, in his August 7, 2015 filing, Respondent asserted that this provision does not apply to the filing of its written statement even though the statement is now its ''response to'' the Show Cause Order, and in any event, Respondent never requested an extension of time to file its written statement. In short, the plain language of this provision does not contemplate *sua sponte* rulings by the ALJ. Rather, it explicitly requires that the respondent in a proceeding seek an extension and imposes on a respondent the affirmative obligation to show ''good cause,'' neither of which were done here.

I am also unpersuaded by Respondent's after-the-fact assertion that there was good cause (in response to my Order) to excuse its belated filing because it could not prepare its Statement of Position until December 2, 2014, when the Government filed its Pre-Hearing Statement and notified it of what documents were to be used as evidence. Resp.'s Ltr., at 6. As set forth above, the regulation authorizes the granting of only ''a reasonable extension of time.'' 21 CFR 1316.47(b). While the reasonableness of an extension is dependent on the circumstances, here, Respondent's showing does not establish that it needed three and a half months after this date to file its written statement, and the extension clearly exceeds the bounds of reasonableness.

To be sure, in *Leonard Browder, d/b/a Lominick's Pharmacy, Family Pharmacy, Inc., Aiken Drug Co., Woodruff Drug Co.,* 57 FR 31214 (1992), the Agency's Decision noted that it had considered a respondent's statement of position, notwithstanding that it was not submitted until a year and a half after the respondent initially requested a hearing and after negotiations to settle the matter were unsuccessful. The decision is, however, bereft of any discussion as to the basis for accepting the respondent's statement of position and the then-applicable regulations, and thus, the decision is of limited precedential value.[11] No subsequent decision of the Agency has cited *Browder,* and as explained above, the Agency has long since made clear that the ''good cause'' standard is to be applied in determining whether to accept an untimely filing.

In accepting Respondent's statement, the CALJ also explained that he was ''applying principles of reasonableness.'' However, as explained above, courts generally do not allow parties to escape the consequences of deliberate strategic decisions made by their lawyers in litigation. *See Pioneer,* 507 U.S. at 397; *$29,410.00 in U.S. Currency,* 600 Fed. Appx. at 623–24; *Brodie,* 531 Fed. Appx. at 237; *A.W. Anderson* v. *Chevron Corp.,* 190 FRD. at 10. Here, Respondent had ample opportunity to investigate the allegations and prepare a defense. Moreover, even after it failed to oppose the Government's Motion *in Limine,* it nonetheless could have gone to hearing, where it could have cross-examined the Government's witnesses and attempted to show that the Government's evidence was not reliable.

In short, the Agency's procedural rules are clear and provided Respondent with ample means to protect its interests.[12] It could have filed its written statement within 30 days of receipt of the Show Cause Order. If Respondent had shown ''good cause,'' it could have filed its written statement even beyond the 30-day period for requesting a hearing if it did so within a reasonable period of time but not months later. And it could have gone to a hearing. Respondent does not, however, have the right to re-write the Agency procedural rules to fit its litigation strategy.[13]

In my Order addressing the Government's Motion for Clarification, I held that because Respondent had waived its right to a hearing, it had waived its right to submit any evidence in refutation of the Government's case.[14] I further deemed it unnecessary to decide whether, under the Agency's regulations (21 CFR 1301.43), Respondent's waiver of its right to a hearing also precludes it from challenging the sufficiency of the Government's evidence, as well as the Government's position on matters of law and the appropriate sanction. Instead, I exercised my discretion to allow

[10] Respondent could also have sought an extension of time to respond to the Show Cause Order, and upon a showing of good cause, the ALJ could have granted a reasonable extension of time to do so. 21 CFR 1316.47(b). However, Respondent did not avail itself of this provision.

[11] For example, in *Browder,* the Government may have consented to the filing, thus rendering it unnecessary for the respondent to establish good cause.

[12] In its August 7, 2015 response to my Order, Respondent argued that the untimely filing of its Statement of Position does not prejudice the Government. Yet, as explained later in this Decision, in its Objection to the Government's Motion for Clarification, Respondent claims that the record is now closed (Objection, at 7), because the Government failed to object to the cancellation of the hearing. It further argues that because the Government did not submit a statement of position to the CALJ, his ''report includes no evidence or argument in favor of the Government's case'' and thus, ''[t]he Government failed to carry the burden of proof assigned to it.'' *Id.* at 9. As Respondent Objection's make clear, its purpose in submitting its untimely Statement of Position is to prejudice the Government.

[13] In his letter to the former Administrator, the CALJ set forth in detail the procedural events which occurred from the date Respondent's former counsel withdrew and Respondent's new counsel entered an appearance, the various representations made by Respondent's new counsel, and as the CALJ explained, ''the failure on the part of Respondent's (new) counsel to honor the commitments made to the tribunal.'' CALJ Letter, at 2.

[14] In my Order, I directed the Government to provide Respondent with a copy of its Request for Final Agency Action as well as the record submitted in support of its Request. Order, at 4.

Respondent to file a brief limited to these issues.

While I adhere to that ruling in this matter, for future proceedings, I conclude that the waiver of the right to a hearing encompasses not only the waiver of the right to present evidence but the right to present legal arguments challenging the proceedings, including arguments challenging the sufficiency of the allegations, the sufficiency of the evidence, the Government's position on matters of law, and the appropriate sanction. In short, a party waiving its right to a hearing waives the right to be heard with respect to any issue under consideration.

Other Issues

As noted above, after Respondent waived its right to a hearing, the Government filed its Motion for Clarification. Therein, the Government sought clarification as to its obligations to provide copies of any documents submitted to me as well as whether Respondent had the right to continue to respond to its submissions. Mot. for Clarification, at 1–2.

Respondent objected to the Government's motion. In its Objection, it raised several contentions beyond those discussed above. Specifically, Respondent argued that once it waived its right to a hearing and the ALJ transmitted the record, the Government was not allowed to continue to litigate the proceeding. Resp.'s Objection, at 8–9. Respondent further argues that ''the Government had the opportunity to submit facts and arguments or present evidence at a hearing but chose not to do so'' even though it had the ''right to participate in a hearing.'' *Id.* at 6. Continuing, it argues that ''the Government made a strategic decision to allow Respondent to file its written position and sit in silence when the ALJ announced he would cancel the hearing'' and that ''[t]he Government could have objected [sic] the cancellation of the hearing'' or ''presented its evidence in writing'' but ''chose to remains mute while plotting to attempt to present its case directly to the Administrator in *ex parte* communications.'' *Id.* at 7. Thus, it argues that I must decide this matter based on the record transmitted to me by the ALJ. Finally, it argues that the Government has no basis for submitting its motion to me and that I have ''no authority under DEA regulations or the APA to respond to the Government's Motion.'' *Id.* at 9.

I reject Respondent's arguments. While it is true that Agency's procedural rules do not explicitly authorize the filing of a motion for clarification, the rules also do not explicitly authorize the filing of a variety of motions, including motions to enlarge the time to file a prehearing statement (which Respondent filed and the ALJ granted), motions to compel (which Respondent also filed but which the ALJ did not grant because Respondent did not make a sufficient showing to establish its entitlement to relief), and motions *in limine.*

Moreover, Respondent's position that while it was waiving its right to a hearing, it was entitled to continue to participate in the proceeding raised an issue of first impression. The Government was entitled to seek clarification of its obligations given the uncertainty created by Respondent's hearing waiver. As for Respondent's contention that I do not have authority to respond to the Government's motion, the APA specifically grants the Agency discretionary authority to ''issue a declaratory order to . . . remove uncertainty.'' 5 U.S.C. 554(e).

I also reject Respondent's contention that the Government is now foreclosed from presenting to me its evidence in support of the proposed revocation. In Respondent's view, the Government is simply a ''person'' under the Agency's regulation (21 CFR 1316.42(e)) entitled to a hearing or to participate in a hearing, or to submit a written statement of position. Respondent argues that ''a hearing may only be cancelled if all persons entitled to a hearing *or to participate in a hearing* waive their opportunity to participate in a hearing.'' Resp.'s Objection, at 6. It then argues that because ''the Government has the burden of proof . . . it must participate if a hearing is held'' and that ''a hearing can occur even if some, but not all parties choose not to participate.'' *Id.* And Respondent faults the Government for not objecting to the cancellation of the hearing or presenting its evidence in writing to the ALJ. *Id.* at 7.

Notwithstanding that 21 CFR 1316.42(e) defines the ''[t]he term *person* [to] include[] an individual, corporation, government or governmental subdivision or agency,'' when the Government initiates an Order to Show Cause proceeding, it is not a ''person entitled to a hearing and desiring a hearing'' within the meaning of 21 CFR 1316.47 (or 21 CFR 1301.43). Indeed, this language is fairly read as encompassing only the recipient of the Show Cause Order. *See* 21 CFR 1316.47 (''Any person entitled to a hearing and desiring a hearing shall, within the period permitted for filing, file a request for a hearing . . . .''); 21 CFR 1301.43(a) (''Any person entitled to a hearing pursuant to § 1301.32 or §§ 1301.34–1301.36 and desiring a heating shall, within 30 days *after the date of receipt of the order to show cause* . . . file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter.'') (emphasis added).

For the same reason, *i.e.,* because it initiated the proceeding, when the Government initiates an Order to Show Cause proceeding, it is not a ''person entitled to participate in a hearing pursuant to § 1301.34 or § 1301.35(b).'' 21 CFR 1301.43(b). With respect to § 1301.34, this provision applies to a narrow category of cases which are not initiated by the Government—specifically where an applicant seeks a registration to import a schedule I or II controlled substance. Under this provision, the Agency is required to give notice to registered manufacturers as well as other applicants for registration to manufacturer the same basic substance, and upon request of such manufacturer or applicant, the Agency ''shall hold a hearing on the application.'' 21 CFR 1301.34(a). While the Government does not initiate the proceeding, it may intervene in the proceeding as a ''person entitled to participate in a hearing.'' 21 CFR 1301.43(b). *See also e.g., Chattem Chemicals, Inc.,* 71 FR 9834, 9834 (2006), *pet. for rev. denied sub nom. Penick Corp, Inc.,* v. *DEA,* 491 F.3d 483, 493 (D.C. Cir. 2007); *Penick Corp., Inc.,* 68 FR 6947, 6947 (2003), *pet. for rev. denied sub nom. Noramco, Inc.,* v. *DEA,* 375 F.3d 1148, 1159 (D.C. Cir. 2004). Indeed, this is the only circumstance in which the Government can be fairly described as a ''person entitled to participate in a hearing.'' [15]

As for its argument that the Government could have presented ''its evidence at a hearing before the ALJ or filed . . . its written position on the matters of fact and law'' with the ALJ, and thus, it should be barred from submitting its evidence to me, the Agency's longstanding and consistent practice is that where a party waives its right to a hearing, the Government is entitled to present its evidence directly to the Administrator, who is the ultimate factfinder. *Cf. Reckitt & Colman, Ltd.* v. *Administrator,* 788 F.2d

[15] 21 CFR 1301.43(b) also refers to the provisions of 1301.35(b), which allows for registered bulk manufacturers of a basic substance in schedule I or II (as well as applicants for registration to manufacture the basic substance) to ''participate in a hearing'' where the Government has issued a Show Cause Order proposing the denial of an application for registration ''to manufacture in bulk'' the same basic class and the applicant has requested a hearing. Here too, the Government is not a ''person entitled to participate in a hearing.'' Rather, it is the initiator of the proceeding.

22, 26 (quoting 5 U.S.C. 557(b) (''On appeal from or review of the initial decision, the agency has all the powers which it would have in making the initial decision. . . .'')).

This is so, even where the respondent has initially requested a hearing but subsequently either waives its right to a hearing or is deemed to have waived its right to a hearing by failing to comply with an ALJ's orders. *See Wheatland Pharmacy,* 78 FR 69441 (2013) (explicit waiver); *Al-Alousi, Inc.,* 70 FR 3561 (2005) (waiver deemed because of failure to file pre-hearing statement); *J & P Distributor,* 68 FR 43754 (2003) (withdrawal of hearing request); *DuVall's Drug Store, Inc.,* 54 FR 15031 (1989) (''As a result of Respondent's withdrawal of the earlier request for a hearing, the Administrator concludes that Respondent has waived any opportunity for a hearing on the issues raised in the Order to Show Cause, and issues this final order based upon the information contained in the DEA investigative file.''); *Faunce Drug Store,* 47 FR 30122, 30122–23 (1982) (waiver of hearing based on failure to file prehearing statement; ''[t]he law does not require this agency to go through the useless and wasteful exercise of convening a hearing for the presentation of both sides of the controversy when one side has failed to show that it has a case to be heard . . . . This Administration cannot permit the parties that appear before it to choose which orders to obey and which orders to disregard'').

Given Respondent's waiver of its right to a hearing, the Government was not required to put on its case before the CALJ or submit a written statement at that juncture. Rather, consistent with the Agency's longstanding practice, the Government was entitled to submit its Request for Final Agency Action and its supporting evidence directly to my Office.[16]

While acknowledging that the CALJ's letter to the former Administrator ''does not conform to the typical format of a recommended decision,'' Respondent further argues that it is a recommended decision as ''it provides a statement of reasoning and is clearly intended to constitute a transfer of the record to the Administrator.'' Resp.'s Objection, at n.17. However, the CALJ's letter is not a recommended decision and does not purport to be a transmittal of the record.

The CALJ's letter is not titled as a recommended decision and most importantly, it does not contain any of the required elements of a recommended decision, which include ''recommended findings of fact and conclusions of law, with reasons therefore; and [h]is recommended decision.'' 21 CFR 1316.65(a)(2). Indeed, the CALJ made no recommendation with respect to how the Agency should decide this matter. CALJ Letter, at 4 (''I . . . accept its Statement of Position on the Agency's behalf, and herein forward it to you for whatever consideration or action (if any) you deem appropriate in this matter.'').

So too, the CALJ's letter contains no statement to the effect that it is the certification and transmittal of the record. Nor was the CALJ's letter accompanied by the pleadings of the parties (with the exception of the Respondent's statement), the CALJ's orders, or other materials such as a listing of the procedural exhibits and a docket sheet. And of course, it does not include any evidence other than the affidavits attached to Respondent's statement.

That the CALJ's letter does not certify the record is for good reason, as his duty to certify the record exists only when a proceeding goes to a hearing or is resolved through summary disposition. 21 CFR 1316.52. Upon Respondent's waiver of its right to a hearing, the CALJ's jurisdiction over the matter ceased. Indeed, in his letter to the prior Administrator, the CALJ specifically noted that ''the authority of the administrative law judge commences and ends with the existence of a valid hearing request by one entitled to a hearing.'' CALJ Letter, at 4. I therefore also reject Respondent's contention that I am foreclosed from considering the Government's Request for Final Agency Action and the evidence submitted in support thereof.

The Unexecuted Declaration

On review of the Government's submission, my Office noted that one of the declarations submitted by the Government had not been executed. On August 15, 2016, I issued an Order directing the Government to notify my Office as to whether an executed copy of the declaration existed. Order (Aug. 15, 2016). I further ordered the Government, if an executed copy exists, to provide the executed declaration as well as an explanation as to why the executed copy was not submitted with its Request for Final Agency Action. *Id.* I also ordered the Government to serve a copy of its response to my Order on Respondent and allowed Respondent to file a response to the Government's filing no later than five (5) business days from the date of receipt of the Government's filing. *Id.*

On August 18, 2016, the Government filed its response to my Order and a motion to supplement/correct the record. Therein, the Government represented that while the declaration had been executed ''on August 28, 2015, and provided to Government counsel *via* email that same day[,] . . . the executed page was inadvertently omitted from the version of the declaration that was submitted to the Acting Administrator.' '' Government's Response to Order and Motion to Supplement/Correct the Record, at 1–2. The Government further moved to enter the executed declaration into the record arguing that there was ''no prejudice'' to Respondent. *Id.* at 2. In addition to providing a copy of the executed declaration, the Government attached a copy of an email from the Diversion Investigator, who was the affiant, which was sent to Government counsel on August 28, 2015 and has the subject line of ''Last page of Affidavit.'' *Id.* at 10. The email further states: ''Attached is the last page of the affidavit with my signature per our conversation.'' *Id.*

Respondent objects to the Government's motion. It argues that ''[t]here is no precedent for the Administrator to allow the Government to establish the evidentiary foundation for documents in the Investigative File after the File has been transferred to the Administrator for final agency action.'' Respondent's Response to the Government's Response to Order and Motion to Supplement the Record, at 2 (hereinafter, Response to Mot. to Supp.). It further argues that the Government is attempting to submit ''additional evidence into the record'' and that the Government has not made ''the requisite showing . . . to reopen the record'' or established ''good cause.'' *Id.* at 2–4 (citing 21 CFR 1319.57, a regulation which does not exist). And Respondent also contends that it would be prejudiced if I ''allowed the Government to enter the [s]ignature [p]age into the record of these proceedings.'' *Id.* at 5.

According to Respondent, ''[o]nce the Investigative File is transferred to [me] for final agency action, the Investigative File (and any pleadings or written statements) constitutes the record on which the'' final decision must be based. *Id.* at 3. Respondent then argues that the Government is seeking to reopen the record and therefore, the Government must show that the evidence ''was previously unavailable''

[16] A different result might obtain had Respondent sought summary disposition in its favor. Under that circumstance, the Government would have clearly been on notice that it needed to oppose the motion and demonstrate through affidavits the existence of disputed material facts, and thus failure to provide such affidavits/declaration at that juncture could well have been fatal to the Government's case. Respondent did not, however, move for summary disposition.

and that it ''would be material and relevant to the matter in dispute.'' *Id.* And Respondent contends that the Government's representation that it had received the signature page on August 28, 2015 but inadvertently failed to include the page when it submitted the Investigative File establishes that the evidence was available to the Government when it submitted the declaration. *Id.*

Contrary to Respondent's understanding, unlike in a proceeding conducted by an Administrative Law Judge, no rule of the Agency specifies the point at which the record is closed and can only be supplemented by filing a motion to re-open and demonstrating that the evidence was previously unavailable. *Cf.* 21 CFR 1316.65(c) (''Not less than twenty-five days after the date on which he caused copies of his report to be served upon the parties, the presiding officer shall certify to the Administrator the record. . . .''). Indeed, where a party has waived its right to a hearing and the Government has submitted a Request for Final Agency Action, the Government has, on occasion, filed a supplement to its Request for Final Agency Action and included additional information regarding criminal and state board proceedings. *See Keith Ky Ly,* 80 FR 29025, 29032 (2015); *Algirdas J. Krisciunas,* 76 FR 4940, 4941 n.3 (2011). As long as due process is not offended, such filings and the accompanying evidence have been accepted into the record without requiring any showing that the evidence was previously unavailable.[17]

In any event, the declaration is not additional evidence. Rather, but for an executed signature page, the same exact declaration was submitted by the Government with its Request for Final Agency Action and the Government was directed to serve a copy of its filing on Respondent.[18] Notably, Respondent did not move to strike the declaration as originally filed by the Government. Nor in its Reply to the Government's Request for Final Agency Action did Respondent raise any issue as to the validity of the declaration. *Cf. Noblett* v. *General Electric Credit Corp.,* 400 F.2d 442, 445 (10th Cir. 1968) (holding that ''[a]n affidavit that does not measure up to the standards of [old rule] 56(e) is subject to a motion to strike; and formal defects are waived in the absence of a motion or other objection'').

Respondent further argues that I should not accept the signed declaration because the Government has not established good cause [19] but only that it ''inadvertently omitted'' the signature page when it submitted the Request for Final Agency Action.[20] Response to Mot. to Supp., at 4. While Respondent argues that ''agency precedent does not recognized simple inadvertence as good cause,'' *id.* at 5; it is mistaken. For example, in *Tony Bui,* 75 FR 49979, 49980 (2010), the respondent's counsel used an incomplete address when he mailed the hearing request resulting in the hearing request being returned to respondent's counsel, and when the latter re-submitted the request, it was received out of time. While not specifically using the word ''inadvertence'' to describe the act of Respondent's counsel, the Agency nonetheless upheld the ALJ's ruling that good cause had been shown to excuse the untimely filing.[21]

To be sure, in determining whether to excuse an untimely filing, these cases have also looked at such factors as whether the offending party promptly corrected its omission and whether the opposing party was prejudiced. As for the first of these factors, upon being notified of the issue the Government has promptly corrected the omission. *Cf.* Fed. R. Civ. P. r.11 (a) (''The court must strike an unsigned paper unless the omission is promptly corrected after being called to the attorney's or party's attention.'').[22]

Respondent further argues that it will be prejudiced if the new declaration is admitted. Response to Mot. to Supp., at 5. Yet it makes no assertion that actually establishes prejudice. While the Government, in its Request for Final Agency Action, argued that Respondent failed to maintain accurate records and failed to electronically link CSOS records and specifically relied on the declaration, Respondent, in its Response to the Request for Final Agency Action, did not address the various recordkeeping allegations at all. *Compare* Request for Final Agency Action, at 28–30, *with* Respondent's Response to Request for Final Agency Action, at 2–27. Notably, Respondent offered no explanation as to why it did not address the allegations for which the declaration was offered, let alone argue that it deemed it unnecessary to do so because the declaration was legally insufficient.

Moreover, even now in response to the Government's Motion to admit the signed declaration, Respondent does not maintain that it will be prejudiced because when it prepared its response to the Request for Final Agency Action, it determined that the unsigned declaration was not legally sufficient to provide evidentiary support for those allegations and therefore did not address them. *See* Resp. to Gov. Response to Order and Motion to Supplement the Record, at 5–6. In short, because Respondent offers only conclusory assertions of prejudice, I accept the signed declaration into the record.[23]

[17] Respondent cites several Agency cases in support of its contention that a party must demonstrate that the evidence was previously unavailable when seeking to re-open the record. Respondent's Response to Government's Response to Order and Motion to Supplement the Record, at 3 (citing *Wesley G. Harline,* 64 FR 72678 (1999); *Robert M. Golden,* 61 FR 24808 (1996); *Bienvenido Tan,* 76 FR 17673 (2011)). However, in each of these proceedings, a hearing had been conducted by an ALJ and the record had been certified by the ALJ and transmitted to the Office of the Administrator/Deputy Administrator. *See Harline,* 64 FR at 72684–85; *Golden,* 61 FR at 24808. Moreover, in *Tan,* the ALJ had conducted the hearing and issued her recommended decision when the respondent sought to admit an affidavit addressing the ALJ's findings that he had failed to address several critical deficiencies identified by the ALJ in her decision. 76 FR at 17675. Thus, at that stage of the proceeding, the only remaining step for the ALJ (other than to address the respondent's request to re-open) was to certify and transmit the record.

[18] No claim is raised by Respondent that the Government failed to provide it with the declaration when it was served with the Request for Final Agency Action.

[19] Respondent cited to 21 CFR 1316.57 as support for its contention that the Government was required to establish ''good cause'' to accept its untimely filing. Respondent's Resp. to Motion to Supplement, at 4–5. This regulation applies, however, only where a hearing is being conducted by an ALJ. Nonetheless, for the purpose of this decision, I assume, without deciding that the ''good cause'' standard applies to the Government's motion.

[20] Actually, the Government did submit the signature page with its Request for Final Agency Action. The problem was that the page that was submitted did not include the DI's signature and date.

[21] Nor is this the only instance in which the Agency has excused negligent or inadvertence on the part of a respondent's attorney. In *Mark S. Cukierman, Denial of Government's Interlocutory Appeal,* 8–11 (No. 12–67) (unpublished), the Agency held that a respondent had established good cause to excuse the untimely filing of a hearing request when the attorney's assistant was directed to, but failed to file a hearing request before going on vacation, and on the due date, the attorney was unable to verify that the request was filed because he was undergoing dental surgery. Slip. Op., at 10. The Agency held that there was good cause notwithstanding that it found that ''Respondent's counsel should have been more diligent in supervising his subordinate to ensure that she had filed the request.'' *Id.*

[22] Even if this provision does not apply to affidavits or declarations, it nonetheless supports the notion of allowing a party to correct an oversight with respect to its filing as long as it acts promptly. Of further note is Fed. R. Civ. P. r. 56(e)(1). It provides that ''[i]f a party fails to properly support an assertion of fact or fails to properly address another party's assertion of fact as required by Rule 56(c), the court may . . . give an opportunity to properly support or address the fact[.]''

[23] Respondent further argues that it ''believes that the Signature Page itself and the accompanying email [submitted by the Government] raise issues''

Continued

Respondent's Surrender of Its Registration and Withdrawal Request

On August 30, 2016, Counsel for Respondent notified my Office that it would surrender its DEA Certificate of Registration effective at 11:59 p.m. that day. Letter from D. Linden Barber, Esq., to the Acting Administrator, at 1 (Aug. 30, 2011). Respondent's Counsel also advised that it had returned its unused order forms to the DEA Tampa Office and that it had delivered its controlled substances to a reverse distributor. *Id.*

While Respondent's surrender of its registration rendered moot the issue of whether its registration should be revoked, during the course of the proceeding Respondent filed a renewal application. No regulation of the Agency provides that the surrender of a registration also acts as the withdrawal of a pending application. To the contrary, under an Agency regulation, when an applicant has been served with a show cause order, the applicant must either show that ''good cause'' exists to allow it to withdraw its application or that ''withdrawal is in the public interest.'' 21 CFR 1301.16(a). Accordingly, my Office notified Respondent by email (which was copied to the Government) that for the matter to be dismissed, Respondent needed to request permission to withdraw its application. *See* 21 CFR 1301.16(a). My Office thus directed Respondent to address whether it was willing to withdraw its application.

Thereafter, Respondent's Counsel filed a letter requesting withdrawal. Letter from D. Linden Barber, Esq., to the Acting Administrator, at 1 (Aug. 31, 2011). Therein, Respondent's Counsel argued that withdrawal of its application ''is in the public interest as it accomplishes DEA's purpose in issuing the Order to Show Cause, namely, removing [Respondent's] authority to handle controlled substances.'' *Id.* Having considered Respondent's showing, I conclude that granting its withdrawal request is not ''in the public interest.'' 21 CFR 1301.16(a).

The Agency has set forth several factors it considers in determining whether the granting of a request to withdraw is in the public interest. *See Vincent G. Colisimo,* 79 FR 20911 20913 (2014); *Liddy's Pharmacy, L.L.C.,* 76 FR 48887, 48888 (2011). These factors include the potential prejudice to the Government were the request granted, the nature of the misconduct, the extent to which the Agency's resources have been expended in the litigation and review of the matter, whether the respondent has remained in business or professional practice, and whether the respondent has agreed to not reapply for registration. *See Colisimo,* 79 FR at 20913; *Liddy's,* 76 FR at 48888.

To be sure, Respondent's surrender of its registration serves the public interest to some degree by ending its authority to handle controlled substances. The Controlled Substances Act does not, however, prohibit a former registrant from reapplying for a registration for any particular period of time, and in fact, a former registrant can reapply immediately following its surrender of a registration. Notably, Respondent's counsel has represented only that his client ''ha[s] no intention of applying for a DEA Registration in the near future.'' Letter from D. Linden Barber, Esq., to the Acting Administrator, at 1 (Aug. 30, 2016). Thus, it is clear that Respondent intends to remain in business and reapply for a DEA registration.

Moreover, my Office has expended substantial resources in the review of this matter and the preparation of this Decision and Order. *See id.* As discussed below, that review has determined that Respondent's pharmacists committed egregious violations of the Controlled Substances Act.[24] However, were I to grant its request to withdraw, Respondent would escape the consequences of the findings of fact and legal conclusions that are warranted by the record in this proceeding. Under these circumstances, the potential prejudice to the Government is substantial and the harm to the public interest is manifest. *See Bobby D. Reynolds, et al.,* 80 FR 28643, 28643 n.2 (2015). I therefore conclude that granting Respondent's request to withdraw its application is not in public interest. 21 CFR 1301.16(a). I also conclude that Respondent has not demonstrated ''good cause'' to allow it to withdraw.

Having considered the record submitted by the Government, and the parties' legal arguments as to the sufficiency of the evidence, I make the following findings of fact.

Findings of Fact

Respondent is licensed by the Florida Board of Pharmacy as a Community Pharmacy. For much of this proceeding, Respondent was also the holder of DEA Certificate of Registration FE1512501, pursuant to which it was authorized to dispense controlled substances in schedules II through V as a retail pharmacy, at the registered address of 2039 E. Edgewood Drive, Lakeland, Florida. According to the registration records of the Agency, while Respondent's registration was due to expire on August 31, 2015, on July 8, 2015, it submitted a timely renewal application. This action kept its registration in effect until August 30, 2016, *see* 21 CFR 1301.36(i), when Respondent surrendered its registration. Letter from D. Linden Barber, Esq., to the Acting Administrator, at 1 (Aug. 20, 2016); *see also* 21 CFR 1301.36(i).

However, while Respondent no longer holds a registration, for reasons explained previously, Respondent's application remains pending in this proceeding. This precludes a finding of mootness. *See Liddy's Pharmacy, L.L.C.,* 76 FR at 48888.

Respondent is owned by Harrieth Aladiume. Gov. Declaration (hereinafter, GA) 3, at 1. Ms. Aladiume's brother is Victor Obi-Anadiume. *Id.* Mr. Obi-Anadiume is the owner of several pharmacies in the Tampa Bay area, including two pharmacies whose registrations I recently revoked.[25] *See Superior Pharmacy I and Superior Pharmacy II,* 81 FR 31309, 31341 (2016). Mr. Obi-Anadiume is also the owner of a third Tampa pharmacy (Jet Pharmacy); on March 31, 2015, Mr. Obi surrendered Jet's registration for cause.[26] GA 3, at 2.

In addition, Mr. Obi-Anadiume owns or owned two pain clinics: (1) 24th

and that it ''cannot identify any point of relation between the Signature Page and the email to indicate that the two documents have any connections to each other whatsoever.'' Response to Gov. Motion to Supplement the Record, at 4. Respondent further suggests that testimony or additional documentary evidence may be necessary to link the two documents. *Id.*

The Government, however, has submitted to me the entire declaration, which is signed and dated below the statement: ''I hereby declare under penalty of perjury that the forgoing is true and correct pursuant to 28 U.S.C. 1746.'' GA 2, at 6 (corrected). As the declaration has been signed and dated under the penalty of perjury, I deem it unnecessary to inquire into the ''connections'' between the email and the signature page.

[24] Various agency proceedings clearly establish that the Superior Pharmacies and Edge were owned by brother (Mr. Victor Obi) and sister (Ms. Harrieth Aladiume). *See Superior Pharmacy I and Superior Pharmacy II,* 81 FR 31310 (2016). So too, agency proceedings establish that Hills Pharmacy was owned by Ms. Hope Aladiume, another sister of Mr. Obi and Ms. Harrieth Aladiume. *Hills Pharmacy, L.L.C.,* 81 FR 49816 (2016).

While Victor Obi was a consultant to both Hills Pharmacy and Edge Pharmacy and participated in both proceedings by attending the hearing in *Hills* and providing an affidavit in *Edge,* the record in *Edge* does not establish that he was actively involved in the operation and management of the latter pharmacy. Thus, notwithstanding the familial links, the findings rendered in my decisions regarding the misconduct committed by Superior Pharmacies I and II and Hills would likely not be entitled to preclusive effect were Edge Pharmacy to apply for a new registration and could cause substantial prejudice to the Government.

[25] The Superior pharmacies were located at 3007 W. Cypress Street, Suite I, Tampa, Fl. 33609 and 5416 Town 'N' Country Blvd., Tampa, Fl. 33615.

[26] Jet Pharmacy was located at 2310 West Waters Ave., Suite J, Tampa, Fl.

Century Medical Clinic, located at 7747 W. Hillsborough Ave., Tampa, Fl., and (2) MD Plus Clinic, located at 2039 Edgewood Drive, Suite 110B, Lakeland, Fl. *Id.* The MD Plus Clinic was located in a suite adjacent to that occupied by Respondent. *Id.; see also* Gov. Declaration 1, Attachment B, at 1. On or about October 15, 2012, the State of Florida, Agency for Health Care Administration, served the MD Plus Clinic with an administrative complaint which sought to revoke its health care clinic license and impose administrative fines. GA 1, Attachment B, at 12–13. On March 26, 2013, Mr. Obi-Anadiume entered into a settlement agreement with the State on MD Plus's behalf, pursuant to which he surrendered its license.[27] *Id.* at 14, 18.

The Dispensing Allegations

On February 4, 2013, DEA Investigators executed an Administrative Inspection Warrant (AIW) at Respondent, pursuant to which they seized the schedule II prescriptions and other documents pertaining to Respondent's purchases and distributions of controlled substance. GA 3, at 1–2. The Investigators also created a mirror image of Respondent's computer data. *Id.* at 2. A review of the data showed that from January 1, 2011 through February 4, 2013, more than 93 percent of the schedule II dosage units dispensed by Respondent (463,392 out of 497,104 du) were dispensed pursuant to prescriptions written by six doctors employed by Mr. Obi-Anadiume, and nearly 85 percent of the dosage units were filled pursuant to prescriptions written by a single doctor, Victor Thiagaraj Selvaraj.[28] GE 10, at 1. The data also showed that 27 doctors (other than those employed by Mr. Obi) prescribed the remaining dosage units (33,742 du) dispensed by Respondent). *Id.*

According to one of the Investigators, following the seizure of the prescriptions, the prescriptions and their labels were scanned electronically and provided to Robert Parrado, R.Ph., who reviewed them and provided his opinion. GA 2. Mr. Parrado holds a Bachelor of Science in Pharmacy from the University of Florida and has been licensed as pharmacist in Florida since 1971. GA 1, at 1. Mr. Parrado has practiced as a pharmacist in both the hospital and community pharmacy setting and owned two pharmacies for approximately 19 years. *Id.*

Mr. Parrado was a member of the Florida Board of Pharmacy from December 2000 through February 2009 and served as both its Vice-Chairman (in 2003) and Chairman (in 2004). *Id.* While on the Board, he ''presided over numerous disciplinary matters,'' including some which involved the diversion of controlled substances. *Id.* Mr. Parrado testified that he is familiar with both federal and state laws and regulations applicable to the prescribing and dispensing of controlled substances including 21 CFR 1306.04(a); Florida Stat. Ann. §§ 465.016(1)(i), 465.023(1)(h), and 893.04(2)(a), and Fla. Admin. Code r.64B16–27.831. *Id.* at 1–2.

Mr. Parrado then opined as to the various steps a Florida pharmacist must take to ensure that any prescription ''is written pursuant to an appropriate physician-patient relationship, as well as being clinically appropriate and safe to dispense.'' *Id.* at 2. These included reviewing ''the patient's age, gender, address, current or previous medical conditions, drug allergies and condition being treated, [the] physician's address and specialty or area of practice,'' the ''appropriateness of therapy'' and whether there is ''any therapeutic duplication.'' *Id.* In addition, Mr. Parrado testified that the prescription must be reviewed to determine if it contains all required information including the patient's name and address, the prescriber's name and address, the prescriber's DEA number, the drug name, dosage form, strength, quantity, and instructions for use. *Id.*

Mr. Parrado further opined that when a controlled substance prescription is presented, a pharmacist must take additional steps to verify the legitimacy of the prescription and prevent potential abuse and diversion. *Id.* These include ''reviewing the quantity of the medication prescribed; appropriate dosage; the location of the patient's home from the physician and/or the pharmacy; trends in the physician's prescribing habits; and the number of pharmacies the patient has used for similar medications.'' *Id.* at 2–3. Mr. Parrado then opined that ''a reasonably prudent'' Florida pharmacist ''must be familiar with'' various indicia that create a suspicion that a controlled substance prescription may be abused or diverted. *Id.* Mr. Parrado termed these indicia ''red flags'' and explained that ''a 'red flag' is anything about a prescription that would cause the pharmacist to be concerned that the prescription was not issued for a legitimate medical purpose in the usual course of professional practice.'' These include:

1. There is a significant distance between the addresses of the patient and the prescriber and/or the pharmacy;
2. The prescription is for the highest strength and/or large quantities;
3. Multiple patients arrive at the pharmacy in close temporal proximity and present similar prescriptions which were issued by the same physician or clinic;
4. Patients are willing to pay large amounts using cash or cash equivalents (check or credit card) for narcotics when the same drugs are available at other pharmacies for lower prices;
5. The prescriber writes similar prescriptions for each patient for ''narcotics in identical or nearly identical quantities . . . regardless of the patient's individualized medical conditions'';
6. The prescriber issues cocktail prescriptions for such drugs as oxycodone, benzodiazepines, and carisoprodol;
7. The prescriber issues prescriptions for ''two or more'' drugs which are ''known to treat the same condition in the same manner,'' such as two immediate release opioids.

Id. at 3–4.

Mr. Parrado testified that ''[w]hen confronted with a red flag or red flags concerning a prescription for controlled substances, a pharmacist must try to resolve the red flags to determine whether . . . the prescriptions is legitimate'' and must do so ''prior to filling the prescription.'' *Id.* at 4. He testified that the steps taken depend on the type of red flag and may include questioning the patient and/or contacting the physician. *Id.* He also testified that ''[w]hen a pharmacist contacts a physician to address red flags presented by the prescription, the standard practice in Florida is for the pharmacist to note it on the

[27] The record does not include the complaint, and in any event, Mr. Obi was not required to admit to any of the allegations. GA 1, Attachment B, at 15.

[28] According to the online records of the Florida Department of Health (DOH), of which I take official notice, Dr. Selvaraj was Board Certified in Family Medicine but not pain medicine or anesthesiology. *See* 5 U.S.C. 557(c). Of further note, on November 5, 2013, the DOH ordered the emergency restriction of Dr. Selvaraj's license to practice medicine based on findings which included that he ''prescrib[ed] large quantities and types of Schedule II–IV controlled substances to Patients without adequate supporting documentation and without any legitimate medical purpose.'' *In re: The Emergency Restriction of the License of Victor Thiagaraj Selvaraj, M.D.,* at 65 (Fla. DOH, Nov. 5, 2013) (No. 2012–04201). The Board further concluded that ''Dr. Selvaraj violated Section 458.331(1)(q), Florida Statutes,'' which prohibits ''[p]rescribing, dispensing, [or] administering . . . any controlled substance, other than in the course of the physician's professional practice.'' *Id.* at 73.

Of further note, on March 21, 2016, Dr. Selvaraj voluntarily relinquished his medical license ''to avoid further administrative actions'' and ''agree[d] to never reapply for licensure as a Medical Doctor in the State of Florida.'' *See* Voluntary Relinquishment of License, at 1, *In re: The License of Victor Thiagaraj Selvaraj, M.D.* (Mar. 22, 2016). On August 16, 2016, the Florida Board of Medicine accepted Dr. Selvaraj's offer to voluntarily relinquish his medical license. *See id.* at Final Order, at 1–2.

prescription'' and ''[i]f there is no documentation on the prescription addressing the red flag and resolving the red flag, you can assume that the red flag was not resolved.'' *Id.*

Mr. Parrado further testified that ''[w]hile some red flags can be resolved, there are other red flags (or combination and patterns of red flags) that a pharmacist cannot resolve by contacting the physician, running a State prescription monitoring search, or obtaining more information from the patient.'' *Id.* As an example, Mr. Parrado set forth a scenario in which a pharmacist is:

> presented with (1) a group of patients who all travelled a significant distance to the pharmacy and/or to the physician to obtain controlled substance prescriptions; (2) patients arriving at the pharmacy on the same day with prescriptions from the same doctor for the same controlled substances; (3) . . . the controlled substance is a highly addictive and highly diverted drug.

Id. Mr. Parrado then explained that a phone call ''to the physician to verify the prescription would not resolve the red flag'' because while the ''call may establish that there is a relationship between the patient and the'' physician, there ''may not be a legitimate patient-physician relationship, and the prescription may not be for a legitimate medical purpose.'' *Id.* at 4–5.

Mr. Parrado then discussed various groups of prescriptions and whether the red flags presented by the prescriptions presented resolvable or unresolvable red flags. *Id.* at 5. The first of these were nine prescriptions for oxycodone 30 mg written on January 10, 2011 by Dr. Selvaraj of Mr. Obi-Anadiume's MD Plus Clinic which was located in the adjacent space. *Id.;* GE 3, at 1–9. Respondent filled each of the prescriptions the same day. GE 3, at 1–9.

The prescriptions were issued in the following quantities to the following patients (with the approximate distances they travelled to MD Plus and Respondent): 224 du to J.R. of Port Orange (113 miles); 224 du to C.R. of Middleburg (173 miles); 224 du to R.M. of Wesley Chapel (41 miles); 168 du to L.J. of Cocoa (96 miles); 168 du to D.J. of Melbourne (102 miles); 196 du to W.K. of Satsuma (141 miles); 224 du to J.H. of Ocala (98 miles); 196 du to C.S. of Jacksonville (197 miles); and 196 du to C.W. of Milton (450 miles). GE 3, at 1–9; GE 17, at 1–21. Each of the patients paid with cash or a cash equivalent with the prices ranging from $560 to $686 depending on the quantity. GE 3, at 1–9.

Regarding these nine prescriptions, Mr. Parrado testified:

> In my professional opinion, nine different individuals who (1) travel, on average, more than 156 miles to Respondent's pharmacy; (2) obtain prescriptions for large, and in some cases, identical amounts of 30 milligram oxycodone tablets from the same physician on the same day; and (3) pay between $560 and $686 for their prescriptions creates a situation that is too suspicious and indicates the prescriptions were not issued for a legitimate medical purpose. Therefore, the combination of events creates an unresolvable red flag which, applying the standard of practice of pharmacy in Florida, precludes a reasonably prudent pharmacist from dispensing these prescriptions.

GA 1, at 5.

Mr. Parrado then discussed nine oxycodone 30 prescriptions which were issued by Dr. L.C. of the MD Plus Clinic and dispensed by Respondent on January 6, 2011. *Id.* The prescriptions were issued in the following amounts to the following patients: 224 du to J.D., 196 du to D.W., and 168 du to T.T., all of Jacksonville (197 miles); 196 du to S.H. of Palatka (148 miles); 168 du to E.R. and 196 du to J.B., both of Interlachen (139 miles); 196 du to D.N. of Winter Haven; 196 du to J.B. of Port Orange (113 miles), and 224 du to M.H. of Maitland (66 miles). GE 3, at 10–18; GE 17, at 18, 22–31. Each of the patients paid with either cash or cash equivalents and the prescriptions ranged in priced from $516 for 168 du to $672 for 224 du. GE 3, at 10–18.

Regarding these prescriptions, Mr. Parrado testified:

> In my professional opinion, nine different individuals who (1) travel, on average, more than 134 miles to Respondent's pharmacy; (2) obtain prescriptions for large, and in some cases, identical amounts of 30 milligram oxycodone tablets from the same physician on the same day; and (3) pay between $516 and $672 for the prescriptions creates a situation that is too suspicious and indicates the prescriptions were not issued for a legitimate medical purpose. Therefore, the combination of events creates an unresolvable red flag which, applying the standard of practice of pharmacy in Florida, precludes a reasonable prudent pharmacist from dispensing the prescriptions.

GA 1, at 5.

Next, Mr. Parrado discussed seven oxycodone 30 prescriptions issued by Dr. L.C. of the MD Plus Clinic and dispensed by Respondent on January 7, 2011. *Id.* at 5–6. The prescriptions were issued in the following amounts to the following patients: 224 du to J.T.,[29] 196 du to K.W., and 196 du to R.D., all of Jacksonville (197 miles); 224 du to I.P. of St. Augustine (161 miles); 196 du to E.M. of Zephyrhills (30 miles); 168 du to T.M. of MacClenny (183 miles); and 196 du to L.L. of Ocala (98 miles). GE 3, at 19–25. With the exception of the prescription issued to E.M., each of the prescriptions was paid for with cash or cash equivalents, with the prices ranging from $504 to $672 depending on the quantity. *See id.;* GE 17, at 31–35.

Regarding these prescriptions, Mr. Parrado testified:

> In my professional opinion, seven different individuals who (1) travelled, on average, more than 150 miles to Respondent's pharmacy; (2) obtained prescriptions for large, and in some cases, identical amounts of 30 milligram oxycodone tablets; (3) obtained these prescriptions from the same physician on the same day; and (4) six of them paid between $504 and $672 for the prescriptions creates a situation that is too suspicious and indicates the prescriptions were not issued for a legitimate medical purpose. Therefore, the combination of events creates an unresolvable red flag which, applying the standard of practice of pharmacy in Florida, precludes a reasonable prudent pharmacist from dispensing the prescriptions.

GA 1, at 6.

Government Exhibit 3 contains additional prescriptions for oxycodone 30 that were issued by Dr. Selvaraj during the month of January 2013. Mr. Parrado testified that the prescriptions were ''all for large quantities of highly addictive opioids.'' GA 1, at 6. Among the prescriptions were those dispensed to the following patients, each of whom paid in cash or cash equivalents and who resided in the following towns (with the approximate distance to Respondent):

L.J. of Cocoa (102 miles) for 168 du at a cost of $1344;

E.V. of New Smyrna (113 miles) for 112 du at a cost of $896;

A.B. of Lake City (172 miles) for 168 du at a cost of $1260 [30];

S.C. of Jacksonville (197 miles) for 150 du at a cost of $1200;

T.W. of Milton (450 miles) for 168 du at a cost of $1344;

L.M. of Lakeland (same town) for 168 du at cost of $1344;

M.E. of Cantonment (474 miles) for 150 du at a cost of $1200;

R.B. of Palatka (148 miles) for 168 du at a cost of $1344;

R.R. of Lakeland for 140 du at a cost of $1120;

C.C. of Cocoa for 140 du at a cost of $1120;

[29] Mr. Parrado also reviewed a medical record for J.T. which was provided by Respondent. I discuss Mr. Parrado's testimony regarding the medical record later in this decision.

[30] Later in his declaration, Mr. Parrado provided additional information regarding the legitimacy of A.B.'s prescription based on a partial patient file which was provided by Respondent and submitted by the Government with its Request for Final Agency Action. I discuss his testimony later in this decision.

L.S. of MacClenny (183 miles) for 100 du at a cost of $800.

GE 3, at 45–46, 49–50, 55–56, 59–60, 69–80; GE 17, at 49, 54, 57.

Mr. Parrado opined that these and the other prescriptions [31] presented unresolvable red flags based on: (1) The distances the patients were travelling, (2) the large quantities and in some instances identical amounts, (3) their issuance by a single doctor; and (4) the prices the patients were paying. GA 1, at 7. He then opined that ''based on the standard of practice of pharmacy in Florida,'' Respondent's pharmacists should not have filled the prescriptions. *Id.*

Mr. Parrado also addressed the 17 prescriptions contained in GE 12. Each of these prescriptions were issued by Dr. Selvaraj of the MD Plus Clinic between October 24 and October 29, 2012 and include prescriptions for oxycodone 30, Dilaudid (hydromorphone 4 and 8 mg), MS Contin (morphine sulfate continuous release 60 and 100 mg), and methadone. *See* GE 12. Earlier in his declaration, Mr. Parrado testified that ''the normal daily dose of hydromorphone is 24 milligrams.'' GA 1, at 6.

The Exhibit includes prescriptions for 180 oxycodone 30 and 120 Dilaudid 8 issued by Dr. Selvaraj on October 29, 2012 (and filled by Respondent the same day) to K.P. of Yulee, Florida, a distance of 222 miles from Respondent. GE 12, at 1–4; GE 17, at 75. K.P. paid $1350 in cash or cash equivalents for the oxycodone and another $360 for the Dilaudid, for a total of $1710. GE 12, at 2, 4. Were K.P. a legitimate chronic pain patient, her yearly costs for these two drugs would have totaled more than $20,000.[32]

Also on October 29, Dr. Selvaraj issued prescriptions for 70 oxycodone 30 and 112 Dilaudid 4, which Respondent filled, to L.G. of Micanopy, a distance of 120 miles from Respondent. *Id.* at 5–8; GE 17, at 77. L.G. paid $525 for the oxycodone and $168 for the Dilaudid in cash or cash equivalents. *Id.* at 6, 8. The Exhibit also includes prescriptions issued on October 24, 2012 by Dr. Selvaraj to T.W. of Milton, a distance of 450 miles, which Respondent filled the same day. *Id.* at 31–34. T.W. paid in cash or cash equivalents $1260 for 168 oxycodone 30 and $420 for 140 Dilaudid 8 mg, for a total of $1680. *Id.* at 32, 34.

Exhibit 11 contains several additional prescriptions which were written by Dr. Selvaraj on October 29 and filled by Respondent the same day. These include prescriptions for 160 oxycodone 30 and 56 Dilaudid 4 issued to S.K. of St. Augustine, the latter being 161 miles from Respondent. GE 11, at 55–58. S.K. paid $1200 for the oxycodone and $84 for the Dilaudid in cash or cash equivalents. *Id.* at 56, 58.

Also on October 29, Dr. Selvaraj issued prescriptions for 84 Dilaudid 8 and 56 MS Contin 100 to D.K. of Interlachen (139 miles), which Respondent filled the same day.[33] *Id.* at 49–53. The same day, Dr. Selvaraj issued a prescription for 140 Dilaudid 8 to S.C. of Hawthorne (127 miles). *Id.* at 53; GE 17, at 51. S.C. filled the prescription the same day, paying $420 in cash or cash equivalents. *Id.* And on October 29, Dr. Selvaraj issued a prescription to S.H., also of Hawthorne, for 56 MS Contin 60, which Respondent filled the same day. GE 12, at 9. Thus, here again, six out-of-town patients, all of whom travelled at least 126 miles to obtain the drugs, presented a total of 10 prescriptions for schedule II controlled substances on a single day.

On October 26, Dr. Selvaraj issued a prescription for 168 Dilaudid 8 to S.C. of Pensacola, Florida, a distance of 470 miles from Respondent. *Id.* at 11; GE 17, at 80. Respondent filled the prescription the same day, for which S.C. paid $504 in cash or cash equivalents. *Id.* at 12. (Of further note, the dosing instruction called for one tablet every four hours, *id.* at 11, or 48 mg per day, more than double the normal daily dose).

The Exhibit contains still more prescriptions for Dilaudid 8 with quantities ranging from 112 to 168 du and dosing instructions that exceeded the 24 mg normal daily dose and which were issued to C.W–O. and C.M. of Interlachen (139 miles), *id.* at 13–14, 21–22; J.S. of Gainesville (132 miles), *id.* at 15–16; and L.L. and B.K. of Ocala (98 miles). *Id.* at 19–20, 29–30. With respect to these prescriptions, each of the patients paid in cash or cash equivalents, with the prescriptions costing between $336 and $420. *Id.*

With respect to the prescriptions in GE 12, Mr. Parrado testified:

> In my professional opinion, (1) the distances travelled by these customers; (2) the type and quantities of the controlled substances prescribed; (3) the fact that the prescriptions were all issued by the same physician; and (4) the high prices paid for oxycodone all created a situation that is too suspicious and indicates the prescriptions were not issued for a legitimate medical purpose. Therefore, the combination of events creates an unresolvable red flag which, applying the standard of practice of pharmacy in Florida, precludes the pharmacist from dispensing the controlled substances.

GA 1, at 7.

With respect to the prescriptions found at pages 15–26 of GE 12, which were the Dilaudid prescriptions issued to C.W–O., C.M., J.S., L.L., as well the prescriptions for Dilaudid and methadone issued to T.P. of Satsuma (141 miles from Respondent) and dispensed on October 25, 2012, Mr. Parrado offered additional testimony as to why these prescriptions presented unresolvable red flags. *Id.* He testified that:

> based on my experience, no pharmacy would be confronted with six legitimate prescriptions issued to five different customers, all of whom resided at least 84 miles away from the pharmacy and acquired their prescriptions on the same day from the same physician. In reviewing the prescription number (''RX numbers'') printed on the labels . . . I can conclude that, out of ten consecutively filled schedule II prescriptions dispensed by this pharmacy on the same day, six of them were for out of town customers. This combination of events creates an unresolvable red flag which, applying the standard of practice of pharmacy in Florida, precludes a reasonably prudent pharmacist from dispensing the prescriptions.

Id. at 7–8. This reasoning applies equally to the prescriptions Respondent dispensed on October 29, 2012, when six patients, all of whom resided at least 126 miles from Respondent, presented 10 prescriptions for schedule II narcotics.[34]

Government Exhibit 13 contains 10 prescriptions for schedule II controlled substances that were issued by Dr. Selvaraj on October 22, 2012 and dispensed by Respondent the same day. GE 13, at 11–30. Notably, four of the patients received prescriptions for both oxycodone 30 and Dilaudid 8.

Specifically, Respondent dispensed 112 du of oxycodone 30 and 168 du of Dilaudid 8 to H.W. of Satsuma (141 miles). *Id.* at 13–16. H.W. paid $840 for the oxycodone and $504 for the Dilaudid. *Id.* at 14, 16.

Respondent dispensed 100 du of oxycodone 30 and 84 du of Dilaudid 8 to C.T. of Jacksonville (197 miles). *Id.* at

[31] The exhibit also includes multiple prescriptions for smaller quantities of oxycodone 30 which ranged from 56 du to 84 du. *See generally* GE 3. Here again, however, the patients were generally travelling long distances and paying in cash for the prescriptions.

[32] Were K.P. a terminally ill patient, it does not seem likely that she would travel 222 miles each way to obtain her medication.

[33] D.K. paid $252 for the Dilaudid and $84 for the MS Contin. GE 11, at 50, 52.

[34] The Rx numbers for the October 29 prescriptions begin at 2010345 and end at 2010356, with two single number gaps. GE 12, at 10; GE 11, at 50; *see also* GE 11, at 52, 54, 56, 58; GE 12, at 2, 4, 6, 8.

17–20. C.T. paid $750 for the oxycodone and $252 for the Dilaudid. *Id.* at 18, 20.

Respondent dispensed 112 oxycodone 30 and 56 Dilaudid 8 to SW., also of Jacksonville. *Id.* at 21–24. SW. paid $840 for the oxycodone and $168 for the Dilaudid. *Id.* at 22, 24.

And Respondent dispensed 120 oxycodone 30 and 168 Dilaudid 8 to J.T. of San Mateo (136 miles), which is south of Jacksonville. *Id.* at 27–30. J.T. paid $900 for the oxycodone and $504 for the Dilaudid.[35] *Id.* at 28, 30.

Regarding these prescriptions (as well as those in this Exhibit dispensed on next day), Mr. Parrado noted that ''the combination of events surrounded [sic] these prescriptions created an unresolvable red flag.'' GA 1, at 8. Mr. Parrado specifically noted ''the distances travelled by these customers,'' ''the type and quantities of the controlled substances,'' ''that the prescriptions were all issued by the same physician,'' and ''the high prices paid for [the] oxycodone.'' *Id.* Mr. Parrado then added that:

> the ten prescriptions dispensed by Respondent[ ] . . . on October 22, 2012, create a situation that is too suspicious and indicates the prescriptions were not issued for a legitimate medical purpose. Based on my experience, no pharmacy would be confronted with ten legitimate prescriptions issued to six different customers, all of whom resided at least 104 miles away from the pharmacy and acquired their prescriptions on the same day from the same physician. Additionally, based on my review of the RX numbers printed on the labels,[36] I can conclude that, out of ten consecutively filled schedule II prescriptions filled by this pharmacy on the same day, all ten were issued to out of town customers. Therefore, the combination of events surrounded [sic] these prescriptions creates an unresolvable red flag which, applying the standard practice of pharmacy in Florida, precludes a reasonably prudent pharmacists [sic] from dispensing the prescriptions.

Id. (citing GE 13, at 11–30).

Still other examples of this are found in GE 14, which contains eight prescriptions for various schedule II drugs which were written on December 5, 2012 by Dr. Selvaraj and dispensed by Respondent on the same day for patients who lived in Ocala (98 miles), Interlachen (139 miles), Middleburg (173 miles), Citrus Springs (88 miles), Jacksonville (197 miles), and Holt (432 miles). GE 14, at 35–50. All but one of the patients paid with cash or cash equivalents. *See id.* The prescriptions include oxycodone 30 for 168 du dispensed to J.D. of Middleburg for $1260 and 150 du dispensed to D.E. of Jacksonville for $1125. *Id.* at 39–40, 43–44. Other prescriptions include Dilaudid 8 for 180 du to D.J. of Holt for $540 and 168 du to T.W. of Interlachen for $504, both of which provided for a dosing approximately double the normal daily dose of 24 mg. *Id.* at 45–46, 49–50.

Other prescriptions in GE 14 include those issued on December 10, 2012 by Dr. Selvaraj to C.R. of Citrus Springs for 112 Dilaudid 8 and 168 oxycodone 30, which Respondent filled the same day. GE 14, at 1–4. C.R. paid $1260 for the oxycodone and $336 for the Dilaudid in cash or cash equivalents. *Id.* at 2, 4. Also on December 10, 2012, Dr. Selvaraj issued to M.E. of Cantonment (474 miles) a prescription for 150 du of oxycodone 30, which Respondent filled the same day. *Id.* at 9–10. M.E. paid $1125 in cash or cash equivalent for the oxycodone. *Id.* at 10.

On December 6, 2012, Dr. Selvaraj issued a prescription to C.C. of Cocoa (96 miles) for 140 oxycodone 30, which Respondent filled the same day. *Id.* at 25–26. C.C. paid $1050 in cash or cash equivalents for the drugs. *Id.* at 26.

Also on December 6, 2012, Respondent filled prescriptions issued the same day by Dr. Selvaraj to M.K. of Jacksonville for 112 Dilaudid 4, 168 oxycodone 30, and 56 MS Contin 60. *Id.* at 27–32. M.K. paid $1260 for the oxycodone, $168 for the Dilaudid, and $70 for the MS Contin, in cash or cash equivalents. *Id.* at 28, 30, 32.

On December 6, Respondent filled a prescription issued the same day by Dr. Selvaraj for 168 oxycodone 30 to L.B., who also provided a Jacksonville address. *Id.* at 33–34. L.B. paid $1260 in cash or cash equivalents for the drugs. *Id.* at 34. Of further noted, Respondent's dispensing software assigned the prescription number 2010572 to L.B.'s prescription and the numbers 2010573 through 2010575 to M.K.'s prescriptions, which suggests that the prescriptions were presented in close temporal proximity. *Id.* at 28, 30, 32.

On December 4, 2012, Respondent filled prescriptions issued the same day by Dr. Selvaraj for 112 oxycodone 30 and 84 Dilaudid 8 to J.M., of Satsuma. GE 14, at 55–58. J.M. paid $840 for the oxycodone and $252 for the Dilaudid in cash or cash equivalents.[37] *Id.* at 56, 58.

Regarding the prescriptions in this Exhibit, Mr. Parrado testified that they presented the red flags of ''the distances travelled by [the] customers,'' ''the types and quantities of the controlled substances''; ''that the prescriptions were all issued by the same physician,'' and ''the high prices paid for [the] oxycodone.'' GA 1, at 8. While Parrado explained that these ''must be resolved prior to dispensing,'' thus suggesting that the red flags were resolvable, he concluded otherwise with respect to the eight prescriptions Respondent dispensed on December 5, 2012. GA 1, at 8–9. Specifically, he testified that:

> the eight prescriptions dispensed by Respondent[] on December 5, 2012 create a situation that is too suspicious and indicates the prescriptions were not issued for a legitimate medical purpose. In my experience, no pharmacy would be confronted with eight legitimate prescriptions issued to seven different customers, all of whom resided at least 93 miles away from the pharmacy and acquired their prescriptions on the same day from the same physician. Also, after reviewing the RX numbers printed on the labels, I can also conclude that, out of ten consecutive schedule II prescriptions filled by Respondent on the same day . . . at least eight were issued to out of town customers. This combination of events creates an unresolvable red flag which, applying the standard of practice of pharmacy in Florida, precludes a reasonably prudent pharmacist from dispensing the prescriptions.

Id. at 8–9 (citing GE 14, at 35–50).

Mr. Parrado offered similar testimony with respect to the prescriptions dispensed by Respondent on November 26 and 29, 2012, which are found in GE 15. Each of the eleven prescriptions dispensed by Respondent on November 26 was issued by Dr. Selvaraj on the same day, with the patients travelling from Gibsonton (38 miles), Hawthorne (2 patients; 127 miles), St. Augustine (161 miles), New Smyrna (113 miles), Yulee (222 miles), Lake City (172 miles), Davenport (28 miles) and Micanopy (120 miles).[38] GE 15, at 35–56. Here again, Mr. Parrado explained that:

> [t]hese prescriptions contained red flags that are too suspicious and indicate the prescriptions were not issued for a legitimate

[35] Other prescriptions dispensed by Respondent on this day include 56 Dilaudid 8 to C.H. of Palm Bay, Florida (approximately 101 miles from Respondent) and 120 Dilaudid 8 to D.M. of Milton (450 miles), both of whom paid cash or with cash equivalents. GE 13, at 11–12, 29–30.

[36] The RX numbers were consecutively numbered from 2010300 through 2010309. *See* GE 13, at 14, 16, 18, 20, 22, 24, 26, 28, and 30.

[37] GE 14 contains a total of 31 prescriptions which were written by Dr. Selvaraj for schedule II drugs and were filled by Respondent during the month of December 2012. The closest any of the patients lived from the MD Plus Clinic and Respondent was 69 miles. *See* GE 14, at 51–52 (S.C., who provided a Bradenton address).

[38] The prescriptions included 180 oxycodone 30 and 120 Dilaudid 8 issued to K.P. of Yulee, who paid $1350 for the oxycodone and $360 for the Dilaudid, GE 15, at 43–46; as well 168 oxycodone 30 and 112 Dilaudid 4 issued to L.G. of Micanopy, who paid $1266 for the oxycodone and $168 for the Dilaudid; both patients paid with cash or cash equivalents. *Id.* at 44, 46; 53–56. The prescriptions also included 168 oxycodone 30 issued to A.B. of Lake City, who paid $1260 in cash or cash equivalents. *Id.* at 47–48.

medical purpose. In my experience, no pharmacy would be confronted with eleven legitimate prescriptions issued to nine different customers, seven of whom resided at least 113 miles away from the pharmacy and acquired their prescriptions on the same day from the same physician. In reviewing the RX numbers printed on the labels, I can conclude that, out of fifteen consecutive schedule II prescriptions filled by the pharmacy at that time, eleven were for customers who resided at least 28 miles away from the Respondent's pharmacy. Therefore, the combination of events surrounding the prescriptions dispensed on November 26, 2012 . . . creates an unresolvable red flag which, applying the standard of practice of pharmacy in Florida, precludes a reasonably prudent pharmacist from dispensing the prescriptions.

GA 1, at 9–10. *See also id.* at 9 (discussing prescriptions dispensed by Respondent on Nov. 29, 2012 to: S.M. of Lake City (172 miles) for methadone and MS Contin; B.J. of Navarre (463 miles) for MS Contin; S.D. of Valrico (28 miles) for Dilaudid; W.B. of Interlachen for Dilaudid (139 miles); and T.A. of Ocala (98 miles) for Dilaudid) (''The combination of events surrounded [sic] these prescriptions creates an unresolvable red flag which, applying the standard of practice of pharmacy in Florida, precludes a reasonably prudent pharmacists [sic] from dispensing the prescriptions.'').

As noted above, Mr. Parrado also reviewed the medical records of several patients (whose prescriptions are discussed above) that Respondent provided to the Government as proposed exhibits prior to deciding to waive its right to a hearing.[39] These included those of A.B., who travelled from Lake City (172 miles) and filled a prescription for 168 oxycodone 30 on January 21, 2013. According to A.B.'s record, she first saw Dr. Selvaraj on September 20, 2011; according to the progress note, at this visit he prescribed 168 oxycodone 30, 56 Xanax 1 mg (a benzodiazepine) and 56 Soma (carisoprodol) 350 mg to her. RE 9, at 344–46.[40]

As Mr. Parrado noted, on the day of her initial visit to the MD Plus Clinic and Dr. V.S., A.B. was subjected to a drug screen and tested negative for opiates/morphine and benzodiazepines. *Id.* at 314. As Mr. Parrado then explained, her negative test was:

an indication she may have been opiate naïve at the time she obtained her prescriptions. However, the medical records indicate [that] she was prescribed a large dose of oxycodone (168-thirty milligram tablets) and a large dose of alprazolam, a benzodiazepine (Xanax, 56-one milligram tablets). These are also red flags for diversion.

GA 1, at 12.

Mr. Parrado further noted that at A.B.'s first visit, she was also prescribed carisoprodol, a drug that was placed in schedule IV of the CSA effective on January 12, 2012.[41] *Id.; see also* DEA, *Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV,* 76 FR 77330 (2011). As Mr. Parrado testified, ''[t]he combination of these three drugs (oxycodone, alprazolam, and carisoprodol) constitutes one of the most commonly abused drug cocktails in the State of Florida and is an additional red flag for diversion.'' GA 1, at 12.

Mr. Parrado further noted that the visit notes contained ''various diagnoses [which] appear inconsistent and suspicious.'' *Id.* Specifically, the note for A.B.'s Dec. 13, 2011 visit lists a diagnosis of DDD or Degenerative Disc Disease yet the note for her next visit on January 10, 2012 contains no such notation and instead suggests she had a rotator cuff/shoulder issue. *Compare* RE 9, at 339 with *id.* at 336. Yet the former diagnosis then reappears in the notes for a February 2012 visit ''without explanation.'' GA 1, at 12 (citing RE 9, at 334).

Also, the notes for A.B.'s October and November 2011 visits indicate that the diagnosis was spondylosis, as that is the justification provided by the physician for prescribing more than a ''72 hour dose of [a] controlled substance . . . for chronic non/malignant pain.'' RE 9, at 341 (Nov. 15, 2011 visit) and *id.* at 343 (Oct. 18, 2011 visit). Yet this diagnosis does not appear in the note for her December 2011 or any subsequent visit. *See id.* at 308 (3/19/13), 310 (2/18/13), 311 (1/21/13), 317 (12/21/12), 319 (11/26/12), 321 (9/21/12), 323 (8/7/12), 325 (7/9/12), 327 (6/8/12), 329 (5/11/12), 332 (3/6/12), 334 (2/7/12), 336 (1/10/12), 339 (12/13/11).

Mr. Parrado also found that some visit notes intermittently listed a diagnosis of a disc bulge. Specifically, he noted that this diagnosis was listed in the December 13, 2011 note, but not in the January 10 and February 7, 2012 visit notes, only to re-appear in the March and May 2012, before disappearing until the December 21, 2012 note. GA 1, at 12; *see also* RE 9, at 339, 336, 334, 332, 329, 327, 325, 323, 321, 319, 317.

Mr. Parrado also reviewed the medical files provided by Respondent for J.T., one of the three patients from Jacksonville who, on January 7, 2011, obtained a prescription for a large dose of oxycodone 30 (224 du) from Dr. Selvaraj and filled it at Respondent. Included as an attachment to Mr. Parrado's declaration were two more oxycodone prescriptions that J.T. obtained from Dr. Selvaraj and filled at Respondent. GA 1, at Attachment A, at 3–6. These prescriptions, which were issued and filled on July 15, 2011, provided J.T. with 224 oxycodone 30 and 84 Percocet 10/325 (oxycodone/acetaminophen). *Id.*

As Mr. Parrado explained, J.T.'s medical record for his July 15, 2011 visit states: ''Looks like he has taken too much of medication [S]oma or Xanax.'' RE 9, at 1646; *see also* GA 1, at 12. The visit note further states ''Slurred Speech'' and that ''Pt is reluctant to go to ER'' but that he ''went to [the] ER eventually.'' RE9, at 1646; *see also* GA 1, at 12. Yet the visit note also has check marks indicating that J.T. was ''alert'' and ''oriented.'' RE9, at 1646; *see also* GA 1, at 12. Dr. Selvaraj nonetheless noted that he was keeping J.T. on the ''[s]ame meds as before.'' RE 9, at 1647.[42]

Respondent's Challenges to the Government's Evidence on the Dispensing Allegations

Respondent raises a variety of challenges to the Government's evidence on the dispensing allegations. Foremost are its challenges to Mr. Parrado's testimony and his credibility. These include: (1) That he has provided testimony that is inconsistent with testimony he gave in another proceeding; (2) that his opinions are invalid because they were based on incomplete information in that he was not provided with the pharmacy's due diligence records on the patients, and (3) that he expressed opinions outside of his expertise when he commented on the medical records. Respondent's Reply to Govt. Request for Final Agency Action, at 2–13. Respondent also argues that the Government has not met its burden of proof because it has not shown: (1) That the prescriptions were invalid, and (2) that its pharmacists did not resolve the red flags prior to

[39] According Mr. Parrado's declaration, Respondent's owner had stated in a sworn affidavit that it ''obtain[s] copies of certain medical records from the prescribing physician for [Respondent's] files.'' GA 1, at 11.

[40] While labeled at RE 9, the patient files were actually submitted by the Government as attachments to Mr. Parrado's declaration. However, the files were not assigned a GE number.

[41] However, at the time of A.B.'s first visit on September 20, 2011, carisoprodol was controlled under Florida law. *See* Fla. Sta. Ann. § 893.03(4)(jjj) (2011).

[42] Mr. Parrado further noted that J.T.'s chart ''never explained why [he] would travel from Jacksonville to Edge[] in order to obtain narcotics, a trip of approximately 197 miles.'' GA 1, at 12–13.

dispensing the controlled substances.[43] *Id.* at 13–21.

The Challenges to Mr. Parrado's Credibility

Respondent challenges Mr. Parrado's credibility arguing that the opinions in his declaration ''are in critical respects a direct contradiction to the sworn testimony that [he] gave in the Hills Pharmacy matter on March 10, 2015.'' Resp.'s Reply, at 4. Of greatest potential consequence here[44] is Respondent's contention that Mr. ''Parrado's previous testimony directly contradicts his offered opinion that the prescriptions submitted by the Government in [this matter] contain red flags that are unresolvable.'' *Id.* at 6.

According to Respondent, in the *Hills Pharmacy* matter (*see* 81 FR 49816 (2016)), Mr. Parrado ''testified that all of the red flags, even in combination, are resolvable.'' Resp.'s Reply, 6. As support for this contention, Respondent cites to three excerpts from Mr. Parrado's testimony in that matter.

Contrary to Respondent's understanding, Mr. Parrado's testimony in the *Hills Pharmacy* matter is not part of the record in this proceeding. Rather, as 5 U.S.C. 556(e) makes clear, ''[t]he transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, constitutes the *exclusive record for decision* in accordance with section 557 of this title'' (emphasis added).

While Respondent attached various snippets of Mr. Parrado's testimony to its Reply to the Government's Request for Final Agency Action, I previously made clear that because Respondent waived its right to a hearing, it is barred from submitting *any evidence* in refutation of the Government's case. Order at 5 (July 29, 2016). This includes evidence of prior and purportedly inconsistent statements. Notably, Respondent's counsel also represented the respondent in *Hills Pharmacy,* whose hearing was held on March 10–11, 2015 and prior to Respondent's decision to waive its right to a hearing in this matter, and the Government's prehearing statements informed Respondent that Mr. Parrado would also testify that numerous prescriptions presented unresolvable red flags (Gov. Supplemental Prehearing Statement, at 3). Thus, if Respondent's counsel believed that Mr. Parrado would then give materially inconsistent testimony in this proceeding, he should have pursued impeachment of the testimony through the hearing process.

However, lest there be any concern on the part of the Court of Appeals that I have credited testimony which is inconsistent with his prior testimony, I have reviewed Mr. Parrado's testimony in the *Hills* matter and find that Respondent both ignores relevant portions of his testimony and otherwise mischaracterizes those portions cited in its Reply. For example, in its direct examination, the Government asked Mr. Parrado: ''are some red flags unresolvable?'' Tr. 60, *Hill Pharmacy, L.L.C.,* 81 FR 49815 (2016). After answering ''yes,'' Mr. Parrado was asked: ''[c]an you cite any examples?'' *Id.* Mr. Parrado answered: ''[r]ight off the top of my head, a group of multiple people traveling a long distance, all getting the exact same or very similar prescriptions from one physician and all coming in with very, very large quantities of cash, that would be unresolvable to me.'' *Id.* at 60–61. Then asked by the Government: ''And those would be prescriptions that you as a pharmacist would refuse to fill?'' Mr. Parrado answered: ''[a]bsolutely.'' *Id.* at 61. Mr. Parrado offered similar testimony that a prescription for oxycodone 30 which was presented by a patient who had travelled from St. Augustine and paid $784 in cash raised an unresolvable red flag when these red flags were occurring ''over and over every day.'' *Id.* at 70–71. *See also id.* at 84 (''[C]ould something like this happen once occasionally a person travels a long way and pays cash? Of course. Does it happen consistently day after day after day? No. That's what would be a nonresolvable red flag.'').

It is true that when asked on cross-examination if ''every red flag you've talked about today could potentially be resolved?'' Mr. Parrado's answered ''[t]hat's correct.'' Tr. 127. However, the question did not ask if the combination of the red flags (*i.e.,* that multiple patients, who travelled long distances and obtained prescriptions for large doses of oxycodone 30, a known drug of abuse, from the same doctor, presented those prescriptions to Respondent on the same day and at times in sequence, and were willing pay large sums of cash for the drugs) was resolvable.[45] Accordingly, I reject Respondent's contention that Mr. Parrado has given prior inconsistent testimony on the issue of whether certain prescriptions presented unresolvable red flags.

Respondent also argues that Mr. Parrado's opinions were based on inadequate information because he ''did not review any of Respondent's Due Diligence Checklists . . . when formulating his opinion'' and relied solely on the prescriptions and the printouts showing the distances between where the patients resided and Respondent. Resp. Reply, at 7. Once again, Respondent relies on Mr. Parrado's testimony from the *Hills* matter[46] notwithstanding that it is not evidence in the proceeding.

However, here too, the Government had disclosed to Respondent the substance of Mr. Parrado's testimony in this proceeding prior to Respondent's decision to waive the hearing and Respondent's counsel was familiar with Parrado's testimony in the *Hills* matter.

[43] Respondent also argues that I should reject the Government's request that I draw the adverse inference that Respondent's pharmacists did not resolve the red flags because Respondent did not produce any documentary evidence to support the assertions in the affidavits of its pharmacists that they resolved red flags. Respondent's Reply, at 21–24. I discuss my resolution of this issue later in this decision.

[44] Respondent also takes issue with Mr. Parrado's testimony that if a pharmacist does not document the resolution of red flags on the prescription itself, '''you can assume that the red flag was not resolved,''' arguing that there is no authority for this assertion and that ''pharmacists are also permitted to and commonly do maintain documentation in a separate file or in a computer system.'' Resp. Reply, at 4–5 (GA 1, at ¶ 13). Respondent further notes Mr. Parrado's testimony in *Hills Pharmacy* acknowledging that under Florida law governing a pharmacist's obligation to verify a patient's identity, a pharmacist can make a Xerox copy of the patient's identity and need not also document his resolution of this issue on the prescription. *Id.*

The *Hills Pharmacy* transcript is not part of the record of this proceeding, and in any event, because I find credible Mr. Parrado's testimony to the effect that the combination of red flags attendant with many of the prescriptions which were presented to the pharmacy on the same day or days rendered the red flags unresolvable, the issue of whether the pharmacists documented their attempted resolution of red flags is irrelevant.

[45] Respondent's counsel points to a further colloquy in the *Hills* matter, in which on cross-examination, he asked: ''Well, in fact . . . you said everything could be a red flag, right?'' and Mr. Parrado answered: ''And everything could be resolvable.'' Tr. 145 (quoted in Resp. Reply, at 6). However, Respondent's counsel then stated: ''No. Am I not asking'' to which Mr. Parrado replied: ''I'm sorry if I misunderstood your question.'' Tr. 145. In response, Respondent's counsel again asked: ''You have said everything could be a red flag, right?'' prompting the Government to object that Mr. Parrado ''did not say that'' and the ALJ sustained the objection. *Id.* The colloquy thus does not support Respondent's assertion that Mr. Parrado ''testified that all of the red flags, even in combination, are resolvable.'' Resp. Reply., at 6.

[46] That testimony involved a series of questions in which Mr. Parrado acknowledged that in determining ''whether a pharmacist followed the standard practice of pharmacy in filling a prescription, it would be helpful . . . to know what the pharmacist knew about the patient,'' the patient's condition, ''the patient's history with opioids'' and what the pharmacist knew about the prescriber. Tr. 177–78, *Hills Pharmacy,* 81 FR 49816. Even considering Mr. Parrado's testimony in *Hills,* as Mr. Parrado explained in this proceeding, ''given the nature and pattern of the red flags associated with these prescriptions, it appears the clinic and/or physicians may be complicit in the diversion of controlled substances. Thus, even if the pharmacist contacted the physicians to verify the prescriptions, that act would not resolve all the red flags presented by the prescriptions.'' GA 1, at 10.

Thus, if Respondent believed that Mr. Parrado's testimony in *Hills* was inconsistent with his testimony in this proceeding that numerous prescriptions presented unresolvable red flags, he should have pursued this by going to hearing where he could have cross-examined Mr. Parrado.

Moreover, as Mr. Parrado explained:

> While some red flags can be resolved, there are other red flags (or combination and patterns of red flags) that a pharmacist cannot resolve by contacting the physician, running a State prescription monitoring search, or obtaining more information from the patient. . . . For example, if you are presented with (1) a group of patients who all travelled a significant distance to the pharmacy and/or to the physician to obtain controlled substance prescriptions; (2) patients arriving at the pharmacy on the same day with prescriptions from the same doctor for the same controlled substances; (3) and the controlled substance is a highly addictive and highly diverted drug, such a combination of facts indicated that the physician may be complicit in the diversion. As a result, a call to the physician to verify the prescription would not resolve the red flag. The phone call may establish that there is a relationship between the patient and the practitioner, but there still may not be a legitimate patient-physician relationship, and the prescription may not be for a legitimate medical purpose.

GA 1, at 4–5. Indeed, as found above, Mr. Parrado identified multiple instances in which prescriptions were filled by Respondent, notwithstanding that the combination of red flags rendered the red flags unresolvable. Unexplained by Respondent is why, given the compelling level of suspicion created by the combinations of red flags, knowing the patient's history with opioids or purported condition would alter the conclusion that Dr. Selvaraj issued the prescriptions without a legitimate medical purpose.

Finally, Respondent argues that Mr. Parrado provided opinions outside of the scope of his expertise as a pharmacist when he offered various opinions on the contents of the medical records. Resp. Reply, at 11–13. However, with respect to Pt. A.B., it was entirely within Mr. Parrado's expertise as a pharmacist to note that she was prescribed a large dose of oxycodone, notwithstanding that on the day of her initial visit to Dr. Selvaraj she was subjected to a drug test and tested negative for opiates thus suggesting that she was opiate naïve, as well as that she was prescribed a large dose of alprazolam, while also testing negative for benzodiazepines. It was also clearly within Mr. Parrado's expertise as a pharmacist to note that the medical records show she was prescribed oxycodone, alprazolam and carisoprodol, and this combination of drugs ''constitutes one of the most commonly abused drug cocktails in the State of Florida and is an additional red flag for diversion.'' GA 1, at 12. Indeed, under the rules of the Florida Board of Pharmacy, a pharmacist is required to conduct prospective drug use review on each prescription and identify such issues as ''[o]ver-utilization,'' ''[d]rug-drug interactions,'' ''[i]ncorrect drug dosage,'' and ''[c]linical abuse/misuse.'' Fla. Admin. Code R.64B16–27.810 (1).

As for Mr. Parrado's discussion of Dr. V.S's frequently changing diagnoses of A.B., with the diagnoses disappearing only to reappear months later, even a lay person can recognize the inherently suspicious nature of this. While Respondent now argues that it did not obtain the records ''so that [its] pharmacists could review them and evaluate the physician's medical judgment, but . . . to ensure that a valid patient-prescriber relationship exist,'' Resp. Reply, at 12; Respondent fails to address why any pharmacist who reviewed these records [47] would believe that a valid patient-prescriber relationship existed given: (1) That A.B. tested negative for opiates at the first visit and yet Dr. Selvaraj prescribed a large dose of oxycodone to her, (2) that Dr. Selvaraj also prescribed other controlled substances to A.B., including alprazolam and carisoprodol which were known to be highly abused as a drug cocktail and did so at her first visit, and (3) the changing nature of the diagnoses.

Likewise, with respect to J.T., given that a pharmacist is required under the Board's rule to conduct prospective drug utilization review on every prescription and identify such issues as ''[c]linical misuse and abuse,'' Fla. Admin. Code R. 64B16–27.810, it is clearly within Mr. Parrado's expertise to opine on the appropriateness of dispensing the prescriptions (for 224 oxycodone 30 and 84 Percocet 10) given that J.T.'s medical record documents that his speech was slurred and that it ''looks like he has taken too much medication [S]oma or Xanax.'' Accordingly, I reject Respondent's contention with respect to Mr. Parrado's discussion of the medical records of these two patients.

[47] Mr. Parrado acknowledged that ''it is not within the standard of practice of pharmacy to regularly review medical records.'' GA 1, at 14. However, as he also explained, ''if Respondent's pharmacist had reviewed these records, they would have had additional reasons *not* to fill the prescriptions for controlled substances issued to A.B. [and] J.T.'' *Id.* Of further note, I adopt Mr. Parrado's discussion of the medical records only with respect to A.B. and J.T.

The Recordkeeping Allegations

In support of its recordkeeping allegations, the Government submitted the declaration of a Diversion Investigator (DI) who participated in the execution of the AIW at Respondent. GA 2, at 2. According to the DI:

> During the execution of the AIW, DEA personnel conducted various activities on the premises, including copying/seizing pharmacy records, receipts, and prescriptions. . . . Also seized was a copy of Respondent's controlled substance inventory. *See* GE 6. Based on this inventory, prescriptions, and the records of receipt which were provided by the pharmacy, DEA conducted an audit of Respondent's controlled substances. The results of the audit showed significant overages of seven different controlled substances[:] oxycodone 30 mg; methadone 10 mg; hydromorphone 4 mg and 8 mg; and morphine 30 mg, 60 mg, and 100 mg. *See* GE 4. For instance, the audit showed that Respondent had dispensed and/or disposed of twice as many 30-milligram oxycodone tablets as it had acquired.

Id.

The Government's other evidence regarding the audit includes a computation chart created by the DI showing the audit results for these drugs and dosage forms for the period of June 10, 2011 through February 4, 2013 which purports to show various overages. GE 4. Also submitted for the record is a drug inventory taken on June 10, 2011 which is signed by Respondent's pharmacy manager, GE 5, and a document which appears to be a spreadsheet of the schedule II orders placed by Respondent during 2011 (which includes the name of the distributor, the transaction date, order form number, quantity and package size, and the drug and its dosage). GE 6, at 1–5. While this Exhibit also includes the supplier's copy of several schedule II order forms [48] (as well as an invoice and a notice from an unidentified distributor stating that it was not filling the entire order), the Exhibit does not include a closing inventory. Moreover, at no point in her declaration did the DI state that a closing inventory was done on February 4, 2013 as listed on the computation chart. *See* GA 2, at 2. Nor did she otherwise explain how she performed the audit. *See id.* Accordingly, the Government has not

[48] DEA Schedule II order forms have three copies: A purchaser is required to submit the first two copies to the supplier and retain the third copy for its records. 21 CFR 1305.13)(a); *see also id.* at 1305.17(a). The supplier retains copy one and submits copy two to the Special Agent in Charge ''in the area in which the supplier is located.'' *Id.* § 1305.13(d). If, however, the supplier does not accept the order, ''the supplier must return'' copies one and two ''to the purchaser with a statement as to the reason.'' *Id.* § 1305.15(b).

established a sufficient foundation for giving weight to the audit results.

The DI, however, provided credible testimony that Respondent was missing various schedule II records. According to the DI, ''during the execution of the AIW, Respondent was unable to locate any records of receipt for 2011,'' and when Respondent's attorney was asked if the records ''could be located, [he] replied that he 'could not make records appear if they weren't here.' '' *Id.* The DI further testified that the attorney ''then called Respondent's [PIC] who confirmed that the receipt records for 2011 could not be located.'' *Id.*

According to the DI, she subsequently obtained information from the Agency Automation of Reports and Consolidated Orders System (ARCOS). *Id.* (discussing GE 3, at 1–5). Under DEA regulations, registered manufacturers and distributors are required to report to the Agency both acquisition and distribution transactions for various controlled substances included all schedule II drugs. 21 CFR 1304.33(c). The information was compiled in the document found at GE 6, at 1–5, which lists each filled schedule II order by distributor, transaction date, order form number, drug name, package size and quantity for the year 2011. Reviewing the list, the DI determined that Respondent was missing its Copy 3 for 103 different orders, these being the orders placed on or after February 4, 2011.[49] GA 2, at 3.

The DI also testified ''that Respondent failed to properly complete various'' Schedule II order forms ''by failing to state the number of packages shipped and/or the date shipped.'' *Id.* As an example, the DI cited an order form (GE 6, at 6) Respondent submitted on February 8, 2011 to Lifeline Pharmaceutical on which it listed two separate orders for 24 packages of 100 dosage units of oxycodone 30 mg tablets. GA 2, at 3. Apparently referring to the second line item which contains no entries for the national drug code, packages shipped, and date shipped, the DI testified that the order form ''shows an order for 24 packages of oxycodone 30 mg tablets but fails to show . . . how many, if any, of those packages were shipped.'' *Id.* The DI made the same assertion with respect to line items on several other order forms, noting that the order forms did not show the ''quantity received or dates received.'' *Id.*

According to the DI, these were violations of 21 CFR 1305.13(e). *Id.* The Government did not, however, produce any evidence showing that any portion of these particular line items was actually shipped.

The DI also testified that she found an order form which listed Respondent as the supplier of 6 packages of 100 du of Dilaudid 8 to Bellco Drug Corp. of North Amityville, New York, but that Respondent did not list the number of packages shipped and the date shipped. GA 2, at 3 (citing GE 9). The DI alleged that this was a violation of 21 CFR 1305.15(b). *Id.* at 4. The DI also testified that she found that Respondent ''failed to forward Copy 2 of the form to the Special Agent in Charge . . . of the DEA in the area where Respondent is located,'' which she alleged was a violation of 21 CFR 1305.13(d). *Id.* However, while the Government submitted a copy of a Return Authorization Form issued by Bellco which authorized Respondent to return the drugs to it, GE 8, at 2; it provided no further evidence that Respondent actually returned the drugs.

Finally, the DI testified that she examined records of Respondent's orders that were placed using the Controlled Substances Ordering System, which is an electronic system for ordering controlled substances. GA 2, at 4. According to the DI, ''Respondent presented only paper printouts and did not have any complying electronic data'' for 42 orders that it placed using the system. *Id.* at 4–5. The DI alleged that this was a violation of 21 CFR 1305.27(a).

Discussion

Under the CSA, ''[t]he Attorney General may deny an application for [a practitioner's] registration . . . 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 the case of a retail pharmacy, which is deemed to be a practitioner, *see* id. § 802(21), Congress directed the Attorney General to consider the following factors in making the public interest determination:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing or conducting research with respect to 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.

''[T]hese factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). It is well settled that I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[ ] appropriate in determining whether'' to deny an application. *Id.; see also MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482.[50]

Under the Agency's regulation, ''[a]t any hearing for the denial of a registration, the Administration shall have the burden of proving that the requirements for such registration pursuant to . . . 21 U.S.C. [§]823 . . . are not satisfied.'' 21 CFR 1301.44(d). In this matter, while I have considered all of the factors, the Government's evidence in support of its *prima facie* case is confined to factors two and four.[51] I find that the record provides

[49] While the ARCOS data includes orders placed in January 2011 and on February 1, 2011, *see generally* GE 6, at 1; the DI did not include any orders before February 4, 2011, GA 2, at 3; as federal law only requires that an order form be ''preserve[d] . . . for a period of two years.'' 21 U.S.C. 828(c)(2).

[50] In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's or applicant's misconduct. *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821. Likewise, findings under a single factor can support the denial of an application.

[51] As to factor one, there is no evidence that the Florida Department of Health has either made a recommendation to the Agency with respect to Respondent, or taken any disciplinary action against Respondent. *See* 21 U.S.C. 823(f)(1). However, even assuming that Respondent currently possesses authority to dispense controlled substances under Florida law and thus meets a prerequisite for obtaining a new registration, this finding is not dispositive of the public interest inquiry. *See Mortimer Levin,* 57 FR 8680, 8681 (1992) (''[T]he Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest.''). Accordingly, this factor is not dispositive either for, or against, the granting of Respondent's application. *Paul Weir Battershell,* 76 FR 44359, 44366 (2011) (citing *Edmund Chein,* 72 FR 6580, 6590 (2007), *pet. for rev. denied, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008)).

As to factor three, I acknowledge that there is no evidence that Respondent, its owner, its manager, or any of its pharmacists, has been convicted of an offense under either federal or Florida law ''relating

substantial evidence that Respondent's pharmacists violated their corresponding responsibility when they dispensed many of the prescriptions at issue. I also find that the Government has established by substantial evidence that Respondent has failed to maintain accurate records, as well as other violations. Accordingly, I conclude that the Government has made a *prima facie* showing that granting Respondent's pending application ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f). Because Respondent's written statement of position and its accompanying affidavits were not timely submitted and Respondent has not otherwise shown good cause for its untimely submission, I hold that Respondent has not rebutted the Government's *prima facie* showing. Because I find that Respondent's misconduct is egregious, I will order that Respondent's pending application be denied.

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

The Dispensing Allegations

''Except as authorized by'' the CSA, it is ''unlawful for any person [to] knowingly or intentionally . . . manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance.'' 21 U.S.C. 841(a)(1). Under the Act, a pharmacy's registration authorizes it ''to dispense,'' *id.* § 823(f), which ''means to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner.'' *Id.* § 802(10).

The CSA's implementing regulations set forth the standard for a lawful controlled substance prescription. 21 CFR 1306.04(a). Under the regulation, ''[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' *Id.* Continuing, the regulation provides that:

> [t]he 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.* 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 section 309 of the Act (21 U.S.C. 829) and the person *knowingly filling* such a purported prescription . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.[52]

Id. (emphasis added).

As the Agency has made clear, to prove a violation of the corresponding responsibility, the Government must show that the pharmacist acted with the requisite degree of scienter. *See JM Pharmacy Group, Inc., d/b/a Farmacia Nueva and Best Pharma Corp.,* 80 FR 28667, 28669 (2015). Thus, the Government can prove a violation by showing either that: (1) The pharmacist filled a prescription notwithstanding his/her actual knowledge that the prescription lacked a legitimate medical purpose; or (2) the pharmacist was willfully blind (or deliberately ignorant) to the fact that the prescription lacked a legitimate medical purpose. *See id.* at 28671–72. As to establishing that a pharmacist acted with ''willful blindness, proof is required that: '(1) the defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact.' '' *Id.* at 28672 (quoting *Global-Tech Appliances, Inc.,* v. *SEB S.A.,* 563 U.S. 754, 769 (2011)).

As found above, Mr. Parrado gave extensive testimony that numerous prescriptions that were written by Dr. Selvaraj (as well as other MD Plus doctors) presented ''red flags'' which created a strong suspicion as to whether the prescriptions were issued for a legitimate medical purpose. While Mr. Parrado testified that some of the red flags were potentially resolvable, he also identified numerous prescriptions that presented multiple red flags such that the combination of red flags created a level of suspicion of such compelling force that the issue of the legitimacy of the prescriptions was unresolvable. Specifically, Mr. Parrado identified as such those instances when on the same day, multiple patients, who had travelled long distances, presented prescriptions for large quantities of oxycodone 30 (and Dilaudid) which had been written by Dr. Selvaraj of the pain clinic, which was located next door and was owned by the brother of Respondent's owner, and were willing to pay large sums in cash (or cash equivalents) for the prescriptions.[53]

Respondent nonetheless argues that the Government's proof was inadequate to prove that its pharmacists knowingly dispensed (or were willfully blind to the fact) that the prescriptions lacked a legitimate medical purpose. Resp. Reply, at 15–18. It suggests that the Government must put forward ''direct evidence'' to show that prescriptions were issued unlawfully. *Id.* at 15.

Contrary to Respondent's understanding, the invalidity of a prescription can be proved by circumstantial evidence. *See, e.g., United States* v. *Leal,* 75 F.3d 219, 223 (6th Cir. 1996); *United States* v. *Veal,* 23 F.3d 985, 988 (6th Cir. 1994) (per curiam); *United States* v. *Hayes,* 595 F.2d 258, 261 (5th Cir. 1979). Indeed, Respondent undercuts its argument when it notes that in *Holiday CVS,* ''[t]he Agency has also found . . . that certain prescriptions were invalid due to a particular combination of 'red flags' apparent during a dispensing event: Multiple patients with addresses outside the state coming to the pharmacy to pay cash for the same 'high alert' medications in the same or similar quantities written by the same physician, who practices hundreds of miles away from the pharmacy.'' Resp. Reply, at 15–16 (citing 77 FR at 62318, 62345 n.105). Thus, circumstantial evidence can support a finding that a controlled substance prescription was issued without a legitimate medical purpose and that a pharmacist dispensed the prescription either having actual knowledge of that fact or acted with willful blindness to that fact.

Respondent attempts to distinguish *Holiday CVS,* arguing that the combination of red flags at issue there differs significantly from those at issue here. *Id.* at 16. Specifically, Respondent argues that in *Holiday CVS,* the patients travelled long distances from the doctors to the pharmacies, whereas here, the patients filled their prescriptions next door to their doctor and thus did what most people do—fill their prescription at a pharmacy near the doctor's office. *Id.* at 16–17. It also

to the manufacture, distribution or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied, MacKay* v. *DEA,* 664 F.3d 808 (10th Cir. 2011). The Agency has therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

[52] As the Supreme Court has 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, the provision 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)).

[53] Because I agree with Mr. Parrado's analysis that numerous prescriptions presented combinations of red flags that were unresolvable even if the pharmacist called Dr. Selvaraj (and the other MD Plus doctors) or questioned the patient, the Government's failure to produce the patient profiles or the so-called ''due diligence checklists'' is irrelevant.

argues that because the MD Plus Clinic (whose doctors issued the overwhelming majority of the prescriptions) was a pain management clinic, ''it is not reasonable to expect Respondent's pharmacists to be suspicious when a higher than average number of customers from the clinic next door fill a prescription for an opioid, even if the quantity is high.'' *Id.* at 17. And finally, Respondent argues that in *Holiday CVS,* the prescriptions were presented by persons from out-of-state and that ''[n]one of the prescriptions in this case were filled for customers from out-of-state'' and that ''the customers who travelled from *out-of-town* did so to visit his or her physician in a particular specialty practice, not Respondent's pharmacy.'' *Id.* at 17–18. Respondent then argues that the ''customers also travelled a significantly shorter distance, by hundreds of miles, to visit the prescribing physician than the customers traveled in *Holiday CVS.*'' *Id.* at 18.

Respondent's proffered distinctions are not persuasive. As for the distinction that the customers were not from out-of-state and did not travel as far as the customers did in *Holiday CVS,* many of them nonetheless travelled substantial distances from their residences to the MD Plus Clinic to obtain the prescriptions when undoubtedly, there were legitimate pain management clinics located far closer to where they lived. As for the argument that the customers did not travel long distances to fill their prescriptions but simply did so next door, putting aside that it is not normal that patients would travel long distances to see a doctor for a legitimate medical condition unless that doctor was a specialist of some renown, the fairer inference, given that the clinic was owned by the brother of Respondent's owner, is that the patients filled the prescriptions at Respondent because they knew they could do so with no questions asked.

Nor am I persuaded by Respondent's contention that because the MD Plus Clinic was a pain clinic, it was not reasonable for Respondent's pharmacists to be suspicious of the prescriptions, even though they were frequently for a high quantity. As found above, doctors employed by Victor Obi, the brother of Respondent's owner, accounted for more than 93 percent of the schedule II dosage units dispensed by Respondent and Dr. Selvaraj's prescriptions alone accounted for nearly 85 percent of the schedule II dosage units dispensed. Significantly, Dr. Selvaraj had no specialty training in pain management and yet repeatedly prescribed large quantities of highly abused schedule II narcotics, to include oxycodone 30 and Dilaudid. And finally, the evidence shows that the patients were willing to pay large sums in cash or cash equivalents (frequently more than $1,000) for the prescriptions, which, if they were legitimate chronic pain patients, they would need on a monthly basis.

In short, the combination of red flags attendant with many of the prescriptions provided compelling circumstantial evidence that the prescriptions issued by Dr. Selvaraj lacked a legitimate medical purpose. Because I agree with Mr. Parrado that in various situations, the combination of red flags rendered the issue of the prescriptions' legitimacy unresolvable, I conclude that Respondent's pharmacists had actual knowledge that the prescriptions lacked a legitimate medical purpose. 21 CFR 1306.04(a). And because many of the prescriptions were clearly illegitimate, it does not matter that the Government, in support of its theory that some of the prescriptions presented resolvable red flags which were not resolved, produced only the prescriptions (which lacked documentation that the red flags were resolved) and no other evidence showing that the red flags were unresolved. As the Fifth Circuit has explained:

> Verification by the issuing practitioner on request of the pharmacist is evidence that the pharmacist lacks knowledge that the prescription was issued outside the scope of professional practice. But it is not an insurance policy against a factfinder's concluding that the pharmacist has the requisite knowledge despite a purported but false verification. . . . What is required by [a pharmacist] is the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute because he knows that the issuing practitioner issued it outside the scope of medical practice.

United States v. *Hayes,* 595 F.2d 258, 260 (5th Cir. 1979). I therefore also reject Respondent's contention that the Government has not proved that its pharmacists violated 21 CFR 1306.04(a) because the Government did not present sufficient evidence to show that the red flags were not resolved prior to dispensing the prescriptions.[54] Reply to Request for Final Agency Action, at 18–19.

I therefore find that the record supports the conclusion that Respondent's pharmacists dispensed numerous prescriptions for schedule II narcotics, including oxycodone 30 and Dilaudid, knowing that the prescriptions were not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. 21 CFR 1306.04(a). This finding is relevant in assessing both Respondent's experience in dispensing controlled substances (Factor Two) and its compliance with applicable laws related to controlled substances (Factor Four). Most significantly, Respondent's dispensing violations are egregious and provide reason alone to conclude that its registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).

The Recordkeeping Allegations

The Government further argues that Respondent failed to keep accurate records. Request for Final Agency Action, at 28–30. As support for the allegations, the Government argues that after the DIs conducted the audit, Respondent ''was unable to account for significant overages [or] shortages of oxycodone, hydromorphone, and morphine.'' *Id.* at 28. It further argues that Respondent: (1) Failed to properly maintain its DEA Schedule II Order Forms to show the date on which it received controlled substances and the quantity received; (2) failed to retain Copy 3 of the Order Forms ''to the supplier''; (3) ''failed to accurately

[54] Because I conclude that many of the prescriptions presented unresolvable red flags and that the Respondent's pharmacists knew the prescriptions lacked a legitimate medical purpose, I need not address Respondent's contention that imposing liability based on its pharmacists' failure to document the resolution of red flags on the prescriptions ''defies the fundamental notion of fair notice.'' Reply to Request, at 19. In short, Respondent and its pharmacists had fair notice of what was required of them from the text of the Agency's corresponding responsibility rule, which provides that ''[a]n 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 section 309 of the Act (21 U.S.C. [§]829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'' 21 CFR 1306.04(a).

Based on Respondent's failure to produce evidence showing that it had resolved the red flags, the Government seeks an adverse inference that Respondent did not resolve the red flags. Req. for Final Agency Action, at 35–36. However, because I find persuasive Mr. Parrado's testimony that the circumstances surrounding the presentation of many of the prescriptions rendered the suspicion created by the attendant red flags unresolvable, I need not address Respondent's contention that the Government was inappropriately seeking to shift the burden of proof to it. *See* Reply to Req., at 21.

As for the Government's contention that Respondent dispensed prescriptions ''in an improper manner,'' because the prescriptions as issued lacked the patient's address, *see* Req. for Final Agency Action, at 28; for reasons explained elsewhere, I reject its contention. *See Superior Pharmacy I and Superior Pharmacy II,* 81 FR at 31336 n.58.

complete executed'' Schedule II Order Forms; (4) ''failed to accurately complete'' a Schedule II Order form ''when it acted as a supplier of controlled substances'' and ''failed to forward this form to the local DEA Special Agent in Charge''; and (5) failed to electronically link its receipts to the original orders it placed through the Controlled Substance Order System. *Id.* at 29–30.

As for the audit allegations, as found above, the Government's evidence does not provide a sufficient foundation to consider the audit results. I thus reject the audit allegations.

Nonetheless, the Government did put forward substantial evidence to support several of its recordkeeping allegations. As found above, during the execution of the AIW, Respondent could not produce its records of receipts for calendar year 2011 and upon review of the orders that were reported to the Agency's ARCOS database by Respondent's suppliers, the DI ultimately determined that Respondent was missing its copy of the Schedule II Order Forms (Copy 3) for 103 orders which were placed after February 4, 2011. Respondent was required to maintain these documents for two years. *See* 21 U.S.C. 828(c)(2) (''Every person who gives an order required under subsection (a) of this section shall, at or before the time of giving such order, make or cause to be made a duplicate thereof on a form to be issued by the Attorney General . . . and shall, if such order is accepted, preserve such duplicate for a period of two years and make it available for inspection and copying . . . .''). Respondent thus violated federal law by failing to maintain these order forms.[55]

The DI further found that upon reviewing Respondent's records of the orders it placed using the Controlled Substance Order System, there were 42 orders for which Respondent documented the receipt of controlled substances and the date received on a paper copy of the order form. Respondent did not, however, electronically link these records ''to the original order'' and archive the record. Respondent thus violated DEA's regulation. *See* 21 CFR 1305.22(g) (''When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived.'').

The evidence with respect to Factor Four thus establishes that Respondent has failed to comply with several of the CSA's recordkeeping requirements. Of these violations, Respondent's failure to retain 103 schedule II order forms is especially egregious and provides further support for the conclusion that its registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).

Sanction

Where, as here, the Government has established grounds to deny an application, a respondent must then ''present[ ] sufficient mitigating evidence'' to show why it can be entrusted with a new registration. *Samuel S. Jackson,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller,* 53 FR 21931, 21932 (1988)). '' 'Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), [DEA] has repeatedly held that where [an applicant] has committed acts inconsistent with the public interest, the [applicant] must accept responsibility for [its] actions and demonstrate that [it] will not engage in future misconduct.'' *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009) (citing *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Jackson,* 72 FR at 23853; *John H. Kennedy,* 71 FR 35705, 35709 (2006); *Cuong Tron Tran,* 63 FR 64280, 64283 (1998); *Prince George Daniels,* 60 FR 62884, 62887 (1995).

While an applicant must accept responsibility for its misconduct and demonstrate that it will not engage in future misconduct in order to establish that its registration is consistent with the public interest, DEA has repeatedly held that these are not the only factors that are relevant in determining the appropriate disposition of the matter. *See, e.g., Joseph Gaudio,* 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of an applicant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer,* 76 FR 19386, 19387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation''); *Paul H. Volkman,* 73 FR 30630, 30644 (2008); *see also Paul Weir Battershell,* 76 FR 44359, 44369 (2011) (imposing six-month suspension, noting that the evidence was not limited to security and recordkeeping violations found at first inspection and ''manifested a disturbing pattern of indifference on the part of [r]espondent to his obligations as a registrant''); *Gregory D. Owens,* 74 FR 36751, 36757 n.22 (2009).

So too, the Agency can consider the need to deter similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Gaudio,* 74 FR at 10095 (quoting *Southwood,* 71 FR at 36503). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoption of ''deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions'').

As found above, the record establishes that Respondent's pharmacists engaged in egregious misconduct by knowingly dispensing numerous controlled substance prescriptions for such highly abused narcotics as oxycodone 30 and hydromorphone that were issued outside of the usual course of professional practice and lacked a legitimate medical purpose. 21 CFR 1306.04(a). This misconduct strikes at the core of the CSA's purpose of preventing drug abuse and diversion. *See Gonzales* v. *Oregon,* 546 U.S. at 274. Respondent's failure to maintain numerous schedule II order forms is also egregious misconduct. The Agency has a manifest interest in deterring registrants from engaging in similar misconduct with respect to both the dispensing of controlled substances and the maintenance of required records.

Thus, the record fully supports the conclusion that Respondent's registration ''would be inconsistent with the public interest'' and that its application should be denied. 21 U.S.C. 823(f). And because Respondent failed to timely submit its Position Statement and the attached affidavits and has not demonstrated good cause to excuse its untimely filing, I do not consider whether the affidavits provide sufficient evidence to refute the Government's

[55] As for the allegations that various Order Forms contained entries which showed that drugs were ordered but that Respondent never completed the form to show how much of the order was received and the date it was received, the Government put forward no evidence to show that Respondent received any portion of the particular line items for which no quantity or date of receipt was noted. To the extent the Government believes that Respondent was obligated to note on the Order Form that no part of a particular line item was received, as I have previously explained, the regulation requires only that a purchaser record ''the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.'' 21 CFR 1305.13(e). As I have previously explained, if no portion of a line item is received, then there is no date on which it is received. *See Superior Pharmacy,* 81 FR at 31338 & n.64. Thus, I reject the allegation.

The Government also alleged that Respondent had failed to provide a copy of an Order Form for the return of Dilaudid to a supplier to the Special Agent in Charge, as well as that it had failed to note on the Form the number of packages shipped and the date shipped. Req. for Final Agency Action, at 29–30. As the Government produced no evidence that Respondent actually returned the drugs, I reject the allegation.

prima facie case. Accordingly, I will deny Respondent's application.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Edge Pharmacy, L.L.C., for a DEA Certificate of Registration as a retail pharmacy, be, and it hereby is, denied. This Order is effectively immediately.

Dated: October 11, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–25226 Filed 10–18–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (OJP) Docket No. 1728]

Meeting of the Global Justice Information Sharing Initiative Federal Advisory Committee

AGENCY: Office of Justice Programs, Justice.

ACTION: Notice of meeting.

SUMMARY: This is an announcement of a meeting of the Global Justice Information Sharing Initiative (Global) Federal Advisory Committee (GAC) to discuss the Global Initiative, as described at *www.it.ojp.gov/global.*

DATES: The meeting will take place on Tuesday, November 29, 2016, from 9:00 a.m. to 4:00 p.m. ET, and Wednesday, November 30, 2016, from 9:00 a.m. to 11:30 a.m. ET.

ADDRESSES: The meeting will take place at the Office of Justice Programs (in the Main Conference Room), 810 7th Street, Washington, DC 20531; Phone: (202) 514–2000 (**Note:** This is not a toll-free number).

FOR FURTHER INFORMATION CONTACT: J. Patrick McCreary, Global Designated Federal Employee (DFE), Bureau of Justice Assistance, Office of Justice Programs, 810 7th Street, Washington, DC 20531; Phone: (202) 616–0532 (**Note:** This is not a toll-free number); Email: *James.P.McCreary@usdoj.gov.*

SUPPLEMENTARY INFORMATION: This meeting is open to the public. Due to security measures, however, members of the public who wish to attend this meeting must register with Mr. J. Patrick McCreary at the above address at least seven (7) days in advance of the meeting. Registrations will be accepted on a space available basis. Access to the meeting will not be allowed without registration. All attendees will be required to sign in at the meeting registration desk. Please bring photo identification and allow extra time prior to the meeting.

Anyone requiring special accommodations should notify Mr. McCreary at least seven (7) days in advance of the meeting.

Purpose

The GAC will act as the focal point for justice information systems integration activities in order to facilitate the coordination of technical, funding, and legislative strategies in support of the Administrations justice priorities.

The GAC will guide and monitor the development of the global information sharing concept. It will advise the Assistant Attorney General, OJP; the Attorney General; the President (through the Attorney General); and local, state, tribal, and federal policymakers in the executive, legislative, and judicial branches. The GAC will also advocate for strategies for accomplishing a global information sharing capability.

Interested persons whose registrations have been accepted may be permitted to participate in the discussions at the discretion of the meeting chairman and with approval of the DFE.

J. Patrick McCreary,

Global DFE, Bureau of Justice Assistance, Office of Justice Programs.

[FR Doc. 2016–25217 Filed 10–18–16; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Exemptions From Certain Prohibited Transaction Restrictions

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Grant of Individual Exemptions.

SUMMARY: This document contains exemptions issued by the Department of Labor (the Department) from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and/or the Internal Revenue Code of 1986 (the Code). This notice includes the following: 2016–03, The Michael T. Sewell, M.D., P.S.C. Profit Sharing Plan, D–11813; 2016–04, Plumbers' Pension Fund, Local 130, U.A., D–11822; 2016–05, Sears Holdings 401(k) Savings Plan and the Sears Holdings Puerto Rico Savings Plan, D–11846 and D–11847; 2016–06, Sears Holdings 401(k) Savings Plan and the Sears Holdings Puerto Rico Savings Plan, D–11851 and D–11852; 2016–07, Liberty Media 401(k) Savings Plan, D–11858; 2016–08, Baxter International Inc., D–11866; and 2016–09, Sears Holdings 401(k) Savings Plan and the Sears Holdings Puerto Rico Savings Plan, D–11871 and D–11872.

SUPPLEMENTARY INFORMATION: A notice was published in the **Federal Register** of the pendency before the Department of a proposal to grant such exemption. The notice set forth a summary of facts and representations contained in the application for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, DC. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition the notice stated that any interested person might submit a written request that a public hearing be held (where appropriate). The applicant has represented that it has complied with the requirements of the notification to interested persons. No requests for a hearing were received by the Department. Public comments were received by the Department as described in the granted exemption.

The notice of proposed exemption was issued and the exemption is being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App. 1 (1996), transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

Statutory Findings

In accordance with section 408(a) of the Act and/or section 4975(c)(2) of the Code and the procedures set forth in 29 CFR part 2570, subpart B (76 FR 66637, 66644, October 27, 2011) [1] and based upon the entire record, the Department makes the following findings:

(a) The exemption is administratively feasible;

(b) The exemption is in the interests of the plan and its participants and beneficiaries; and

(c) The exemption is protective of the rights of the participants and beneficiaries of the plan.

[1] The Department has considered exemption applications received prior to December 27, 2011 under the exemption procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, 32847, August 10, 1990).