repeatedly engaged in the self–abuse of a Schedule II controlled substance, and done so notwithstanding the attempts by the Arizona Board to assist Registrant to rehabilitate himself. I therefore hold that Registrant has engaged in ''such other conduct which may threaten public health or safety,'' 21 U.S.C. 823(f)(5), and that he has committed acts which render his registration ''inconsistent with the public interest.'' *Id.* § 824(a)(4). This conclusion provides a further reason to revoke Registrant's registration and to deny any pending applications.

**Order**

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration BG6908757, issued to Aaron Gloskowski, D.O., be, and it hereby is, revoked. I further order that any pending application of Aaron Gloskowski, D.O., to renew or modify his registration, be, and it hereby is, denied. This Order is effective immediately.

Dated: October 7, 2011.

**Michele M. Leonhart,**

*Administrator.*

[FR Doc. 2011–28011 Filed 10–27–11; 8:45 am]

**BILLING CODE 4410–09–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. 10–55]**

### Linda Sue Cheek, M.D., Decision and Order

On December 30, 2010, Administrative Law Judge (ALJ) Timothy D. Wing issued the attached recommended decision. Thereafter, Respondent filed exceptions to the decision.

Having reviewed the entire record including Respondent's exceptions, I have decided to adopt the ALJ's rulings, findings of fact, conclusions of law, and recommended order, except as discussed below. Accordingly, I will order that Respondent's application be denied.

Before proceeding to discuss Respondent's exceptions, a discussion of the ALJ's consideration of ''community impact'' evidence is warranted. *See* ALJ at 33–35.[1] Therein, the ALJ acknowledged the recent decision in *Gregory Owens, D.D.S.,* 74 FR 36751 (2009). In *Owens,* I explicitly declined to extend the holding of *Pettigrew Rexall Drugs,* 64 FR 8855, 8859–60 (1999), which cited evidence that a pharmacy was ''one of two pharmacies in a relatively poor, medically underserved community'' as ground for staying a revocation order, to the case of a prescribing practitioner. 74 FR at 36757. As *Owens* explained, ''consideration of the socioeconomic status of a practitioner's patient population is not mandated by the text of either 21 U.S.C. 823(f) or 824(a)(4).'' *Id. Owens* further explained that such a rule is ''unworkable'' and ''would inject a new level of complexity into already complex proceedings and take the Agency far afield of the purpose of the CSA's registration provisions, which is to prevent diversion.'' *Id.*

The ALJ further noted, however, that in *Imran I. Chaudry, M.D.,* 69 FR 62081, 62083–84 (2004), the Agency had ''considered and given weight to community impact evidence, without specifically citing *Pettigrew.''* ALJ at 34. Notwithstanding the lengthy explanation *Owens* provided as to why community impact evidence is irrelevant in a proceeding involving a prescribing practitioner, the ALJ reasoned that in ''[i]n light of [*Chaudry*], I find that community impact evidence as a threshold matter is not entirely irrelevant.'' *Id.*

While in *Chaudry,* the Agency noted that evidence that the respondent, who was a cardiologist, practiced in a medically underserved community ''provide[d] some support for maintaining [his] registration,'' the Agency further held that this evidence ''also has a negative implication for continued registration'' because Respondent placed the community at risk by abusing methamphetamine and distributing it to another physician. 69 FR at 62084. Thus, in *Chaudry,* while the registrant was the only cardiologist in ''a town of approximately 4,000 people,'' the Agency actually relied on this evidence to revoke the practitioner's registration.

The decision in *Chaudry* did not, however, explain to what factor this evidence—whether cited in mitigation by the registrant or cited in aggravation by the final decision—was relevant. While it is possible to view such evidence as relevant (at least when offered as evidence of an aggravating circumstance) in determining whether a registrant has engaged in ''such other conduct as may threaten public health and safety,'' 21 U.S.C. 823(f)(5), a practitioner's self-abuse of a controlled substance ''threaten[s] public health and safety'' without regard to the socioeconomic characteristics of the community in which he or she practices.[2]

Moreover, my review of *Chaudry* reinforces the correctness of my conclusion in *Owens.* As I explained in *Owens,* ''[t]he public interest standard of 21 U.S.C. § 823(f) is not a freewheeling inquiry but is guided by the five specific factors which Congress directed the Attorney General to consider; consideration of the socioeconomic status of a practitioner's patient population is not mandated by the text of either 21 U.S.C. §§ 823(f) or 824(a)(4), which focus primarily on the acts committed by a practitioner.'' 74 FR at 36757.

As I further explained in *Owens* (as well as in numerous other cases), ''where the Government has made out a *prima facie* case that a practitioner has committed acts which render [her] registration inconsistent with the public interest, the relevant inquiry is * * * whether the practitioner has put forward 'sufficient mitigating evidence to assure the Administrator that he can be entrusted with the responsibility carried by such a registration.' '' *Id.* (quoting *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008)). Moreover, in numerous decisions, I have made clear that ''this inquiry looks to whether the registrant has accepted responsibility for [her] misconduct and undertaken corrective measures to prevent the re-occurrence of similar acts.'' *Id.* As explained in *Owens,* ''[w]hether a practitioner treats patients who come from a medically underserved community or who have limited incomes has no bearing on whether [she] has accepted responsibility and undertaken adequate corrective measures.[3]'' *Id.*

In *Owens,* I also noted that the diversion of prescription controlled substances ''has become an increasingly serious societal problem, which is particularly significant in poorer communities whether they are located in rural or urban areas.'' *Id.* (citing *George C. Aycock,* 74 FR 17529, 17544 n.33 (2009); *Laurence T. McKinney,* 73 FR 43260 (2008); *Paul H. Volkman,* 73

[1] All citations to the ALJ's decision are to the slip opinion as issued by him.

[2] While the decision noted that the registrant had also distributed methamphetamine to another physician, this conduct would clearly fall within factor four, ''[c]ompliance with applicable State, Federal, or local laws relating to controlled substances.'' 21 U.S.C. 823(f)(4).

[3] Of course, in determining the appropriate sanction, DEA also considers the extent and egregiousness of a registrant's misconduct, the degree of the registrant's candor, as well as the Agency's interest in deterring others from engaging in similar acts. *See Owens,* 74 FR at 36757; *Paul Weir Battershell,* 76 FR 44359 (2010); *Joseph Gaudio,* 74 FR 10083, 10095 (2009); *Janet Thornton,* 73 FR 50354 (2008).

FR 30630 (2008); *Medicine Shoppe-Jonesborough,* 73 FR 364)). *See also id.* (citing U.S. General Accounting Office, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem* 31–32 (Dec. 2003) (noting that ''the Appalachian region, which encompasses parts of Kentucky, Tennessee, Virginia, and West Virginia, has been severely affected by prescription drug abuse, particularly pain relievers * * * for many years'')). As I further explained, ''the residents of this Nation's poorer areas are as deserving of protection from diverters as are the citizens of its wealthier communities, and there is no legitimate reason why practitioners should be treated any differently because of where they practice or the socioeconomic status of their patients.'' [4] *Id.*

It is acknowledged that there is no evidence in this record that Respondent was engaged in diverting controlled substances.[5] Rather, the principal allegations involve Respondent's having been mandatorily excluded from participation in Federal health care programs by the Secretary of the Department of Health and Human Services pursuant to 42 U.S.C. 1320a–7(a) following her conviction for having committed Health Care Fraud in violation of 18 U.S.C. 1347, as well as her having issued controlled substance prescriptions without a registration. ALJ Ex. 1, at 1–2 (citing 21 U.S.C. 823(f) & 824(a)(5)).

Under 21 U.S.C. 824(a)(5), the Attorney General is authorized to suspend or revoke a registration ''upon a finding that the registrant * * * has been excluded (or directed to be excluded) from participation in a program pursuant to'' 42 U.S.C. 1320a–7(a). As I recently explained, *see Terese, Inc.,* 76 FR 46843, 46846 (2011), this provision subjects to revocation the registration of a practitioner who has been mandatorily excluded ''from participation in any Federal health care program'' based on her conviction for an offense falling within one of four categories of offenses including a ''[f]elony conviction relating to health care fraud.'' 42 U.S.C. 1320a–7(a)(3). The consequence of the exclusion is to prohibit Respondent from participating ''in any capacity in the Medicare, Medicaid, and all Federal health care programs as defined in section 1128B(f) of the Social Security Act.'' GX 6 (letter from Reviewing Official, Health Care Program Exclusions, Office of Counsel to the Inspector General, Department of Health and Human Services, to Respondent (Sep. 30, 2008)).

In enacting 42 U.S.C. 1320a–7, Congress was obviously aware that many of the beneficiaries of Medicaid, Medicare, and other health care programs (such as SCHIP) are residents of medically underserved communities. Yet Congress made the exclusion of a provider from participation in these programs mandatory upon conviction of one of the four categories of offenses enumerated in 42 U.S.C. 1320a–7(a), including a conviction for Health Care Fraud. Given this, it makes no sense for the Agency to consider community impact evidence in exercising its authority under 21 U.S.C. 824(a)(5).

I therefore re-affirm my holding in *Owens* that community impact evidence is not relevant in determining whether to grant a prescribing practitioner's application under 21 U.S.C. 823(f) or to revoke an existing registration under the various authorities provided in 21 U.S.C. 824(a). I further hold that to the extent *Chaudry* (or any other case involving a prescribing practitioner) suggests otherwise, it is overruled.

The ALJ also found that on February 12, 2009, the Virginia Medical Board reinstated Respondent's medical license. ALJ 26. The ALJ further concluded that this action ''weigh[s] in favor of a finding that Respondent's registration would not be inconsistent with the public interest, at least as of February 12, 2009.'' *Id.*

However, following the closing of the record, on July 8, 2011, the Virginia Board of Medicine issued an Order following a hearing it conducted on June 24, 2011; I take official notice of the Board's Order.[6] *See In re: Linda Sue Cheek, M.D.* (Va. Bd. Med., Jul 8, 2011). The Board made numerous findings, the most significant being that Respondent committed unprofessional conduct in violation of Va. Code Ann. § 54.1–2915.A(16) & (17). *Id.* at 8. The Board also indefinitely suspended Respondent's medical license ''for a period of no less than twelve (12) months from entry of [its] Order.'' *Id.*

Under the Controlled Substances Act, a practitioner must possess authority to dispense controlled substances under the laws of the State in which she practices in order to hold a DEA registration. *See* 21 U.S.C. 823(f) (''The Attorney General shall register practitioners * * * to dispense * * * controlled substances * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices.''); *id.* § 802(21) (''The term 'practitioner' means a physician * * * licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices * * * to * * * dispense * * * a controlled substance in the course of professional practice. * * *''); *see also* 21 U.S.C. 824(a)(3) (authorizing the revocation of a registration where registrant ''has had his State license * * * suspended * * * by competent State authority and is no longer authorized by State law to engage in the * * * dispensing of controlled substances''). Accordingly, this development provides a further basis to deny Respondent's application. *See Robert Wayne Mosier, D.O.,* 75 FR 49950 (2010) (citing cases) (''DEA has consistently held that holding authority under state law is a prerequisite for obtaining a registration under the CSA.''). Moreover, even if Respondent had prevailed on the other allegations (or rebutted the Government's *prima facie* case), the loss of her state authority would still require the denial of her application.

**Respondent's Exceptions**

Respondent filed extensive exceptions to the ALJ's decision. Most of these exceptions (which do not comply with DEA's regulations because they do not cite to the transcript or exhibits, *see* 21 CFR 1316.66(a)), involve challenges to

[4] In *Owens,* the ALJ relied on the fact that roughly ten percent of the practitioner's patients were from an underserved community and that a majority of his patients had limited finances. 74 FR at 36757 n.22. I rejected this evidence noting that ''the ALJ's reasoning begs the question of how many patients from underserved areas would a practitioner have to treat to claim the benefit of the rule.'' *Id.* I also rejected the ALJ's reliance on the fact that a majority of the registrant's patients had limited incomes, because determining what constitutes a patient with a limited income or finances and how many patients (or what percentage of patients) a practitioner must have to claim entitlement to this rule was unworkable. *Id.*

While the evidence adduced here (which the ALJ rejected as insufficient) was primarily limited to Respondent's assertion that she ''was the only pain management doctor reasonably available in southwestern Virginia,'' ALJ at 34; here again, there are no workable standards for determining whether other doctors are reasonably available. Moreover, the CSA's primary purpose is to prevent the diversion of controlled substances and nothing in the respective statutes (21 U.S.C. 823(f) & 824(a)) directs the Agency to consider community impact evidence in determining whether to grant an application for registration or to continue an existing registration.

[5] To make clear, there was no evidence of diversion in *Owens* either.

[6] Under the Administrative Procedure Act (APA), an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is ''entitled on timely request, to an opportunity to show to the contrary.'' 5 U.S.C. 556(e); *see also* 21 CFR 1316.59(e). Respondent can dispute the facts of which I take official notice by filing a properly supported motion for reconsideration within twenty days of service of this Order, which shall begin on the date it is mailed.

the ALJ's credibility determinations and what Respondent maintains was the ALJ's ''predetermined prejudice against'' her, Resp. Exc. at 4, including the ALJ's finding that Respondent lacked candor and gave inconsistent explanations. *Id.* at 11. The ALJ personally observed the demeanor of the various witnesses and evaluated each witness's testimony for its consistency and inherent probability. *See Dewey C. MacKay,* 75 FR 49956, 49963 (2010) (citing *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474 (1951)). Moreover, having reviewed the entire record, I find no reason to reject the ALJ's various factual findings.

Furthermore, I find no basis to conclude that the ALJ was biased against Respondent. As the Supreme Court has explained, ''judicial rulings alone almost never constitute a valid basis for a bias or partiality motion.'' *Likety* v. *United States,* 510 U.S. 540, 555 (1994). That an ALJ, upon considering the evidence, finds much of a party's evidence either not credible or unreliable, does not establish bias. Accordingly, I reject Respondent's exceptions to the ALJ's factual findings.

Respondent further takes exception to the ALJ's findings that she does not accept responsibility for the various acts of misconduct which were proven on this record. With respect to her Health Care Fraud conviction, Respondent argues that by pleading guilty and complying with the various requirements of her sentence, she has accepted responsibility. Resp. Exc. at 6. With respect to the allegation that she wrote controlled substance prescriptions without a registration, Respondent argues that she admitted to writing two prescriptions by mistake shortly after her medical license was restored by the State and that she ''is only aware of [two] prescriptions'' which she wrote and ''admitted to.'' *Id.* at 8. Respondent also takes exception to the ALJ's finding that she unlawfully used another physician's DEA registration to issue controlled substance prescriptions, arguing that she acted as a nurse practitioner, who was supervised by another physician, who reviewed the patient files and authorized the prescriptions. *Id.* at 9–10. According to Respondent, there is nothing in either Federal law or the Virginia Board of Medicine's rules that prohibit one physician from supervising another. *Id.* at 9. Moreover, Respondent argues that if DEA had timely issued her a new registration, ''the complaint here would not have any substance'' and that DEA's failure to grant her application demonstrates an ''abject plan to create the scenario in which to charge [her] with committing a crime.'' *Id.* at 10.

As for the ALJ's finding that Respondent did not accept responsibility for her Health Care Fraud conviction, it is true that pleading guilty and complying with her sentence is probative evidence of whether she has accepted responsibility. However, Respondent did not stop there. Instead, as the ALJ found (and the testimony shows), Respondent maintained that her conviction was ''unjust[],'' Tr. 386, as it was based on ''six billing incidents * * * when I was out of the country,'' that ''the most I got paid over or extra was $ 11.00 per visit,'' and that the U.S. Attorney's Office had brought her down ''for $ 66.00.'' *Id.* at 384–85. Moreover, Respondent testified that it was her belief that the prosecution was ''purely * * * a result of the fact that I treat pain, and I prescribe opiates, and that the agenda of the United States Government is to stop the treatment of pain in this country.'' *Id.* at 383. Respondent did not explain, however, why, if she had only defrauded the Government of $66, the District Court ordered her to pay more than $24,000 in restitution, including more than $17,000 to the Virginia Medicaid Program and more than $7,000 to Medicare. GX 4, at 2. Moreover, as the ALJ noted, she further testified that ''[i]f this is fraud, maybe we need more of it.'' Tr. 382. Thus, the ALJ properly held that Respondent did not accept responsibility for her Health Care Fraud conviction.

As for the ALJ's finding that Respondent did not accept responsibility for her prescribing without holding a registration, it is acknowledged that she admitted to having written a prescription for Ambien (zolpidem), a schedule IV controlled substance, 21 CFR 1308.14(c)(51), on February 23, 2009, and a prescription for Lyrica (pregabalin), a schedule V controlled substance, *id.* 1308.15(e), on March 20, 2009. However, when confronted with evidence that she had written other prescriptions such as one for Lortab (hydrocodone), a schedule III controlled substance, *id.* 1308.13(e)(1), on April 6, 2009, Respondent testified that ''I cannot say this is my signature.'' Tr. 492. She then suggested that the Government had fabricated the prescription. *Id.*[7] Respondent also testified that she could not ''verify'' two other controlled substance prescriptions which bore a signature in her name. Tr. 493–94 (discussing GXs 11 & 12).[8] The ALJ properly found this testimony ''palpably incredible.'' ALJ at 28.

So too, Respondent asserted that she had an agreement with another physician (Dr. Shultz) under which she acted as a nurse practitioner and evaluated the patients and was supervised by Dr. Schultz; Respondent further claimed that Dr. Schultz would then review her evaluation and authorize a controlled substance prescription for the patients, which was then called in to the patient's pharmacy by Respondent or her staff. *See* RX 41. However, during an interview with a Diversion Investigator, Dr. Schultz stated that she only went to Respondent's clinic on Thursdays. Tr. 117–18. Dr. Schultz further told the Investigator that she did not give Respondent permission to call in prescriptions under her registration. *Id.* at 115.[9]

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[7] When asked whether she had written this prescription, Respondent testified: ''I cannot say that that is my signature.'' Tr. 492. When asked why she could not, Respondent answered:

I cannot say that that is my signature. I am not opposed to the idea that the government can do a lot of things. And I do not, without having had this information, and be[ing] able to do some research on my own, I will not admit to this being my signature or my prescription.

*Id.* When then asked whether she was ''asserting that the government may have falsified this document?,'' Respondent answered: ''Very possible.'' *Id.*

Respondent's failure to accept responsibility is further manifested by her contentions that if DEA had timely issued her a new registration, ''the complaint here would not have any substance'' and that DEA's failure to grant her application demonstrates an ''abject plan to create the scenario in which to charge [her] with committing a crime.'' Resp. Exc. at 10. However, no one forced Respondent to issue prescriptions without a registration and DEA's regulation clearly states that ''[n]o person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person.'' 21 CFR 1301.13(a). Also, given Respondent's exclusion under 42 U.S.C. 1320–7(a), DEA had no obligation to grant her application.

[8] Respondent maintained that she did not break any law by writing prescriptions which were not filled. Tr. 491, 493. However, under Federal law, the issuance of a prescription constitutes the constructive transfer of a controlled substance even if a pharmacist subsequently refuses to fill the prescription. *United States* v. *Roya,* 574 F.2d 386 (7th Cir. 1978); *United States* v. *Tighe,* 551 F.2d 18 (3d Cir. 1977).

[9] Against this evidence is a document signed on June 25, 2009, which purports to be a memorialization of a verbal contract entered into on February 23, 2009 between Respondent and Dr. Schultz. RX 41. Among this document's terms are that Dr. Schultz ''will approve medications as recommended by Dr. Cheek and allow Dr. Cheek or her staff to call them into the pharmacy in her name.'' *Id.* Continuing, the document states: ''Basically, Dr. Cheek is acting as a nurse practitioner would, under Dr. Schultz's supervision. Dr. Schultz reviews and signs the records of all patients receiving scheduled drugs on a regular basis.'' *Id.*

On June 25, 2009, the same day that the above document was signed, Respondent discussed with

DEA Investigators found numerous controlled substance prescriptions which were called into local pharmacies under Dr. Schultz's DEA registration by either Respondent or her employee, A.Y. *Id.* at 119; GXs 15–17. Upon reviewing the prescriptions, an Investigator determined that most of them were called in on days other than Thursdays. Tr. 118. Moreover, both the ALJ and Virginia Board (which conducted its own formal hearing) found Respondent's testimony that she was working under the supervision of Dr. Schultz to not be credible and that the arrangement was a sham. ALJ at 28–30; *see also In re Linda Sue Cheek,* at 4 (''The Board determined that [Respondent's] testimony concerning the arrangement that she had with Individual A [10] to provide patients with controlled substances, whereby Individual A was to establish a practitioner-patient relationship and issue prescriptions for controlled substances, was not credible. The Board finds that [Respondent] intended to circumvent her inability to prescribe Schedule II–V controlled substances as a result of not having a valid DEA registration.''). Thus, I reject Respondent's exception and agree with the ALJ that ''[t]he evidence as a whole demonstrates that Respondent's claim that she was working at the direction of Dr. Schultz is not supported by credible evidence.'' ALJ at 30.

Under Federal law, it is ''unlawful for any person knowingly or intentionally * * * to use in the course of the * * * dispensing of a controlled substance * * * a registration number which is * * * issued to another person.'' 21 U.S.C. 843(a)(2). It is also unlawful to dispense a controlled substance without first obtaining a registration to do so. 21 U.S.C. 822(a)(2). The evidence shows that Respondent committed multiple violations of both provisions.[11]

Accordingly, the record establishes three independent grounds for denying Respondent's application: (1) Her loss of state authority, *see* 21 U.S.C. 823(f); (2) her having violated Federal law by issuing controlled substance prescriptions when she did not possess a registration, *see id.* § 824(a)(4); and (3) her having been mandatorily excluded from participation in Federal Health Care programs based on her conviction for Health Care Fraud. *See id.* § 824(a)(5). In addition, the record establishes that Respondent has not accepted responsibility for her misconduct. Therefore, I will order that Respondent's application be denied.

## 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 Linda Sue Cheek, M.D., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This order is effective November 28, 2011.

Dated: October 17, 2011.

**Michele M. Leonhart,**

*Administrator.*

*Robert W. Walker, Esq.,* for the Government

*Linda Sue Cheek, M.D., Pro se,* for the Respondent

## Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge

### Introduction

Timothy D. Wing, Administrative Law Judge. This proceeding is an adjudication pursuant to the Administrative Procedure Act, 5 U.S.C. 551 *et seq.,* to determine whether the Drug Enforcement Administration (''DEA'' or ''Government'') should deny Respondent's pending application for a DEA Certificate of Registration (''COR''). Without this registration, Respondent, Linda Sue Cheek, M.D. (''Respondent''), of Dublin, Virginia, would be unable to lawfully possess, prescribe, dispense, or otherwise handle controlled substances in the course of her practice.

On March 13, 2010, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause (''OSC'') seeking the denial of Respondent's pending application as a practitioner for registration in Schedules II through V, alleging that issuing a registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f) and that Respondent has been excluded from participation in a federal health care program as defined in 21 U.S.C. 824(a)(5). (ALJ Ex. 1 at 1.) The OSC alleged in substance: (a) Respondent had been excluded from participation in all federal health care programs for a period of five years following her guilty plea to one count of health care fraud in federal district court on February 21, 2008; and (b) Respondent surrendered her DEA COR number BC4510865 on November 17, 2008, but thereafter continued to issue numerous prescriptions for controlled substances using the surrendered COR, as well as the COR of another practitioner without authorization.

Respondent, acting *pro se,* timely requested a hearing (ALJ Ex. 2), which was held in Roanoke, Virginia, between October 5–6, 2010. After acknowledging that she understood her right to representation, as codified at 21 CFR 1316.50, Respondent elected to represent herself during the hearing. (*See* ALJ Exs. 3 & 4.) Both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties filed proposed findings of fact, conclusions of law and argument. All of the evidence and post-hearing submissions have been considered, and to the extent the parties' proposed findings of fact have been adopted, they are substantively incorporated into those set forth below.

### Issue

Whether the record evidence establishes by substantial evidence that Respondent's pending application for a DEA COR as a practitioner in Schedules II through V should be denied because such registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f) and because Respondent has been excluded or directed to be excluded from participation in a health care program pursuant to 21 U.S.C. 824(a)(5).

### Evidence and Incorporated Findings of Fact

I find, by a preponderance of the evidence, the following facts:

*I. Background*

Respondent's State Medical License

On June 4, 2008, the Virginia Department of Health Professions ordered Respondent's medical license

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Dr. Schultz her conversation with the DEA Investigator. Respondent testified:

And when she told me she had said, ''No, I haven't told anybody they can use my DEA number,'' I said, ''Kathy, you allow us to call in prescriptions for our patients. That is using your DEA number.'' ''Oh, I didn't realize that,'' was her reply.

Tr. 422.

[10] The Board identified Individual A as ''a practitioner of osteopathic medicine who held [a DEA] registration, under which Individual A authorized prescriptions for controlled substances for Respondent's patients.'' *In re Linda Sue Cheek,* at 2. The Board's findings make clear that Individual A is Dr. Schultz.

[11] As noted above, Respondent analogized her relationship with Dr. Schultz to that of a nurse practitioner who is supervised by a physician. Apparently, the Virginia Board did not find the analogy persuasive as it found Respondent guilty of unprofessional conduct. *See In re Linda Sue Cheek,* at 2–4, 8. It is also noted that while the Virginia Board's rules allow a nurse practitioner to prescribe controlled substances, ''a practice agreement between the nurse practitioner and the supervising physician'' must be submitted and approved by both the Board of Medicine and the Board of Nursing. 18 VAC90–40–30; *id.* 90–40–40(3). In addition, the State's rules require that ''[t]he nurse practitioner shall include on each prescription written or dispensed his signature and prescriptive authority number as issued by the board and the Drug Enforcement Administration (DEA) number, when applicable.'' *Id.* 90–40–110.

suspended due to Respondent's felony conviction for health care fraud before the United States District Court for the Western District of Virginia. (Gov't Ex. 5.)

On October 29, 2008, after a formal administrative hearing, the Virginia Board of Medicine (''Board'') issued an Order denying reinstatement of Respondent's medical license, which remained on indefinite suspension. The Order precluded Respondent from petitioning the Board for reinstatement until Respondent presented satisfactory written evidence that she had successfully completed a Board-approved comprehensive physician competency evaluation. (Gov't Ex. 7.)

On January 8, 2009, Respondent petitioned the Board for reinstatement, after completing the required comprehensive physician competency evaluation. (Resp't Ex. 17.) On February 12, 2009, the Virginia Department of Health Professions notified Respondent of the decision to reinstate Respondent's medical license to full and unrestricted status with all attendant rights and privileges. (Resp't Ex. 18.)

Respondent Linda Sue Cheek, M.D.

Respondent graduated from the University of Texas Health and Science Center at San Antonio, earning a Doctor of Medicine degree on May 23, 1992. (Resp't Ex. 1.) Respondent completed her first year of family practice training at the University of Texas Health Science Center at San Antonio and successfully completed her last two years of training at Roanoke Memorial Hospital in Roanoke, Virginia in June 1995. The Virginia Department of Health Professions, Board of Medicine, issued Respondent a license to practice medicine and surgery on July 1, 1993. Respondent has since maintained a family practice to include a specialty in pain management and alternative medicine. Since 1998, Respondent has completed a number of medical training activities to include: Traditional Chinese Medicine, acupuncture, herbal medicine, Qi Gong, Clinical Issues in Primary Care, evidence-based wellness, clinical hypnosis, The Psychology of Health, Immunity and Disease, numerous pain management courses, addiction and drug diversion courses and homeopathic courses, among others. (Resp't Exs. 7–16.)

Respondent held DEA COR BC4510865 as of July 18, 1995, as a practitioner in controlled substances in Schedules II through V, at the registered address 28 Town Center Drive, Dublin, Virginia, which was last renewed on August 24, 2007. This COR had an expiration date of August 31, 2010. In a letter dated November 14, 2008, Respondent voluntarily surrendered her COR after a formal administrative hearing and denial of reinstatement of Respondent's medical license by the Virginia Board of Medicine on October 29, 2008. (*See* Gov't Ex. 8; Tr. 73–76.) On February 16, 2009, Respondent applied for a new registration with DEA as a practitioner in Schedules II through V, 28 Town Center Drive, Dublin, Virginia 24084. (Gov't Ex. 1.)

*II. Investigation of Respondent*

In support of the allegations contained in the OSC, the Government presented at hearing the testimony of three witnesses: Special Agent Jeffrey Overbeck, U.S. Department of Health and Human Services, Office of Inspector General (''SA Overbeck''), Diversion Investigator Steven Tomaziefski, U.S. Drug Enforcement Administration (''DI Tomaziefski''), and Special Agent Robert Slease, U.S. Department of Health and Human Services, Office of Inspector General (''SA Slease'').

SA Overbeck testified in substance that he has been a special agent for approximately nine years and has approximately twenty-one years of law enforcement experience. In his current position, SA Overbeck specializes in investigating Medicare and Medicaid fraud. SA Overbeck testified that his office began an investigation of Respondent on September 20, 2005, based on information provided by law enforcement agencies regarding concerns with Respondent's prescribing of narcotics and the use of ''cleansing sessions'' at Respondent's practice. (Tr. 31–32.) SA Overbeck further testified that the investigation revealed the cleansing sessions consisted of a group of patients that were required to either watch a movie or listen to a family nurse practitioner talk, before the patients could obtain prescriptions. If patients required additional medication they would have to repeat the cleansing sessions, which cost patients ''up to an additional hundred dollars a month, because they were required to buy supplements, and herbal supplements * * *'' before they could obtain prescription medications. (Tr. 42.) Respondent then billed the cleansing sessions as individual office visits, even though Respondent knew from a prior audit that Medicaid, Medicare and Anthem [12] would not pay for cleansing sessions.

SA Overbeck also testified that investigative findings revealed that Respondent's practice, New River Medical Associates, Inc., in Dublin, Virginia focused on pain management and alternative medicine. Respondent also employed two family nurse practitioners. Respondent and the two nurse practitioners each had Medicare, Medicaid and Anthem provider numbers, which could be billed for the services that each provided. On a number of occasions, Respondent submitted a bill for services under Respondent's provider number when Respondent was not actually present, contrary to the rules and regulations for ''incident to'' billing. (Tr. at 33–39.) SA Overbeck's testimony was fully credible. His testimony was internally consistent and the witness was able to recall factual events with a reasonable level of certainty.

Documentary evidence included Respondent's December 9, 2007, signed agreement to plead guilty to a one-count information charging health care fraud in violation of 18 U.S.C. 1347. (Gov't Ex. 3.) On May 27, 2008, the United States District Court for the Western District of Virginia entered a judgment pursuant to a plea of guilty by Respondent to one count of health care fraud, 18 U.S.C. 1347, for offense conduct ending in March 2006. Respondent was sentenced to ''probation for a term of: Four (4) years,'' with conditions of supervision, a $100.00 assessment, $1,000.00 fine and restitution in the amount of $24,210.37. (Gov't Ex. 4.)

A September 30, 2008 letter from the U.S. Department of Health and Human Services, Office of Inspector General, notified Respondent she was ''excluded from participation in any capacity in the Medicare, Medicaid, and *all* Federal health care programs as defined in section 1128B(f) of the Social Security Act (Act) for the minimum statutory period of 5 years.'' The exclusion action was effective twenty days from the date of the letter. (Gov't Ex. 6.)

DI Tomaziefski testified in substance that he has been a diversion investigator with DEA for approximately five years, and following initial training was assigned to Roanoke, Virginia. DI Tomaziefski's experience includes participation as a lead investigator in approximately thirty regulatory investigations, and his duties also include reviewing pending applications for DEA registration. DI Tomaziefski testified to becoming aware of Respondent in August of 2008, and learning that Respondent had previously pled guilty and had her medical license suspended. (Tr. 68–70.) In September 2008 he contacted Respondent regarding her DEA registration but decided not to take any action regarding surrender of her DEA

[12] Anthem is a health insurance provider. (*See* Tr. 474.)

registration because of a pending petition by Respondent for reinstatement of her medical license. DI Tomaziefski further testified to contacting Respondent in November 2008 following the indefinite suspension of Respondent's medical license by the Commonwealth of Virginia, and discussing the surrender of her controlled substances privileges. In a letter to DI Tomaziefski dated November 14, 2008, Respondent relinquished her DEA COR. (Gov't Ex. 8; *see* Tr. 75.)

DI Tomaziefski further testified that in April 2009 he received information from the Virginia Department of Health Professions pertaining to two prescriptions that were written and signed by Respondent using her surrendered DEA number. (Tr. 79–80.) One prescription, for ''Lyrica 75 mg capsule #60 (sixty)'' with two refills, dated March 20, 2009, was not filled by a pharmacy. (Tr. 81; Gov't Ex. 9.) The second prescription, for ''Ambien 10 mg tablet #30 (thirty)'' with five refills, dated February 23, 2009, was filled by a pharmacy in Wytheville, Virginia. (Tr. 82–83; Gov't Ex. 13.) DI Tomaziefski further testified that he next began looking at different pharmacies for prescriptions that Respondent may have written. On May 19, 2009, DI Tomaziefski received by facsimile a three-page letter from Respondent (*see* Gov't Ex. 18) stating that she was aware that DEA ''is scouring the area for infractions of scripts for controlled drugs written by me * * *'' (Gov't Ex. 18 at 1.) She admitted that on the first day she got her medical license back, she conducted ''business as I always have, and signed all the scripts for the patients * * *'' but realized halfway through the morning that she did not have a DEA COR. (*Id.*) Respondent also stated ''I am willing to go to jail for providing the people of Southwest Virginia with relief from their suffering.'' (*Id.* at 2.) Respondent also advised in the letter that she had hired a Dr. Schultz *locum tenens* to see patients that needed her, explaining that

> Dr. Schultz saw the patients on her own from September, 2008 to February, 2009. When I got my license in February 2009, I asked her to continue assisting me with the scheduled medications, since I did not have my DEA certificate. She had experience with working with nurse practitioners, so she had no problem supervising me in the same manner. She also established her own practice in my building, so that those patients with Medicare, Medicaid, and any other insurance that I did not associate with, could have a primary care physician to write orders for them. Every patient that pertains to has seen her personally. She has personally seen every patient that receives Schedule II meds. She has approved the medications that they are receiving. Then they continue to see me and she signs their scripts. She has also given me instructions to call scripts in for patients that are schedule III–V. She reviews my notes and signs them. For her supervisory duties, New River Medical Associates pays her $100 per week. We are handling things as if I am a physician extender and she is the supervisory physician * * *
>
> (*Id.* at 3.)

DI Tomaziefski also testified that the dates of the prescriptions written by Respondent that he had obtained and seized as evidence did not match the date that Respondent had her medical license reinstated. DI Tomaziefski testified that on May 28, 2009, he sent a confidential source (''CS'') into New River Medical Associates to meet with Respondent as a patient. As a result of that visit, Respondent's office assistant, [AY],[13] called in a prescription for hydrocodone in the name of the CS to Dublin Pharmacy, Dublin, Virginia. (Tr. 99–100.) The record evidence contains a Dublin Pharmacy record with a handwritten notation including the names ''[AY]'' and ''Schultz,'' and the typed name of the CS, address, cost and quantity of the drug prescribed, along with the name ''Dr. Linda Cheek.'' DI Tomaziefski further testified that the CS wore a ''wire'' during the visit, which DI Tomaziefski listened to and learned that Dr. Schultz did not see the CS, even though the prescription was called in under Dr. Schultz's DEA number. (Tr. 101, 105; Gov't Ex. 14.)

DI Tomaziefski further testified that on June 2, 2009, he participated with the CS in a controlled purchase of the above prescribed hydrocodone from Dublin Pharmacy, and the purchased prescription drug was seized as evidence by DEA. On June 4, 2009, DI Tomaziefski and the CS returned for another controlled visit to Respondent. Respondent and Dr. Schultz confronted the CS with urinalysis results which revealed the presence of buprenorphine, not otherwise prescribed or disclosed by the CS to DEA. As a result, DEA terminated the undercover operation.

DI Tomaziefski next testified to obtaining additional copies of prescriptions issued under Respondent's name and using Respondent's surrendered DEA registration number. (Tr. 109.) On June 26, 2009, a prescription dated May 14, 2009, for ''Ambien 10 mg tablet #30 (thirty)'' with five refills was obtained from Martin's Pharmacy, in Pulaski, Virginia. DI Tomaziefski concluded the prescription had not been filled because it did not contain a pharmacy tag on the prescription. (Tr. 110; *see* Gov't Ex. 11.) On April 6, 2010, DI Tomaziefski obtained from Martin's Pharmacy a prescription dated February 23, 2009, for ''Lortab 7.5–500 mg tablet #120 (one hundred-twenty)'' with two refills and signed with Respondent's name, which was crossed out, and the name ''K Schultz'' inserted. DI Tomaziefski testified this prescription had been filled, as evinced by the presence of pharmacy tags on the record copies. (Tr. 111; *see* Gov't Ex. 12.) DI Tomaziefski further testified that he asked the pharmacist why Dr. Schultz's name was written on the prescription and was told that when the prescription was brought into the pharmacy he called New River and was told by ''someone at New River'' that Dr. Schultz had authorized the prescription. The pharmacist crossed out Respondent's name and wrote in Dr. Schultz's name. (Tr. 112.)

DI Tomaziefski next testified that on June 17, 2009, he spoke with Dr. Schultz by telephone and Dr. Schultz said she was not affiliated with New River Medical Associates but was just helping out until Respondent got her medical license back. Dr. Schultz also stated that she did not allow Respondent to call in prescriptions for any authorized refills under Dr. Schultz's DEA number. (Tr. 115.) The record evidence also reflects that Dr. Schultz only worked at New River Medical Associates on Thursdays. (Tr. 117–18.)

The record evidence includes twenty-two prescription records obtained by DI Tomaziefski from Dublin Pharmacy, in Dublin, Virginia, covering the period from March to April 2009, all reflecting ''called-in'' prescriptions by Respondent or [AY] using Dr. Schultz's DEA number. (Tr. 119; Gov't Ex. 15.) DI Tomaziefski testified that the dates on the prescriptions were significant because most of the prescriptions were called in on dates other than Thursdays. (Tr. 118.)

The record evidence also includes ten prescription records obtained by DI Tomaziefski from Martin's Pharmacy in Dublin, Virginia, covering the period from May to June 2009, all reflecting ''called-in'' prescriptions using Dr. Schultz's DEA number. All but one contained a handwritten notation of either Respondent or [AY]. (Gov't Ex. 16.) DI Tomaziefski testified that he knows these prescriptions are ''call-ins'' because an original prescription would have the identifying prescriber information, including DEA number, and signature of the provider. (Tr. 564.)

[13] As noted below, Respondent's employee [AY] is also a patient of Respondent. To protect patient privacy, only initials are used in this Recommended Decision when referring to Respondent's patients.

The record evidence further reflects seven prescription records obtained by DI Tomaziefski from a Rite Aid pharmacy covering the period May to June 2009, with all but one record reflecting ''called-in'' prescriptions using Dr. Schultz's DEA number. The prescription dated June 29, 2009, is a ''non-called in'' prescription bearing a signature consistent with K. Schultz and written on a prescription form in the name of Kathleen Schultz, D.O., 28 Town Center Drive, Dublin, VA. (Tr. 126–27; *see* Gov't Ex. 17 at 7.)

DI Tomaziefski further testified that on June 23, 2009, he traveled to Dr. Schultz's house with a Virginia State Police investigator for the purpose of serving a subpoena and to clarify information contained on Schedule II prescriptions that had been obtained during the DEA investigation. DI Tomaziefski explained that upon identifying themselves to Dr. Schultz, Dr. Schultz spontaneously stated that ''she didn't authorize anybody to use her DEA number.'' Dr. Schultz further stated that she was somewhat retired and worked one day a week at a clinic ''and that on Thursdays, most Thursdays'' would be at New River Medical Associates and wrote Schedule II prescriptions for patients. (Tr. 132.)

DI Tomaziefski further testified that on June 25, 2009, he received a telephone call from Respondent regarding the status of her application for a DEA COR. During the call, Respondent put Dr. Schultz on the line together with Respondent. Respondent and Dr. Schultz informed DI Tomaziefski that they had a verbal agreement wherein Respondent could call in prescriptions under Dr. Schultz's DEA number. (Tr. 134.)

On cross examination, DI Tomaziefski testified that the normal time to render a decision on an application for a DEA COR is approximately four to six weeks, but DEA is not obligated to adhere to that time period and the time period is longer when there are issues with the applicant. (Tr. 142–43.)

DI Tomaziefski's testimony was fully credible. The witness testified consistently with regard to facts, and his testimony as a whole reflected a recollection of factual events with a reasonable level of certainty.

*III. Respondent's Evidence*

Respondent testified at hearing and also presented testimony from former patients [AZ], [DS] and [ET]. [ET] testified by telephone, with consent of the parties, because [ET] was incarcerated at the time of hearing. Additionally, Respondent presented testimony from an employee and patient, [AY].

[AZ] testified in substance that [AZ] is a resident of Elliston, Virginia and had been a patient of Respondent for approximately three years before Respondent lost her medical license. [AZ] testified to being able to maintain a quality of life and function with pain medications, and believed that [AZ] ''wouldn't be here today if it wasn't for Dr. Cheek helping'' with [AZ]'s pain. (Tr. 178.) [AZ] further testified that after Respondent lost her medical license it was a very difficult time and a constant worry as to how [AZ] would obtain medication. (Tr. 181.) In 2008 [AZ] contacted Respondent's office and learned that Dr. Schultz was available. [AZ] returned to the office as a patient, at first seeing Dr. Schultz. [AZ] further testified that Respondent is not an easy doctor to get medications from, has rules to follow, and expects patients to maintain a healthy diet. [AZ] explained that [AZ] participated in ''cleansing groups'' and last participated several years prior to the hearing. (Tr. 187–88.)

On cross examination, [AZ] testified that it is approximately a twenty minute drive from [AZ]'s home to Respondent's office, and there are no other pain management physicians in the area. [AZ] had been referred to Respondent by another physician who had prescribed the same pain medication that [AZ] has taken for approximately fifteen years, including from Respondent. [AZ] explained that at no time did Respondent double up on [AZ]'s pain medication but was not sure if Respondent may have written extra prescriptions during May or June 2008. [AZ] explained that after returning to Respondent's practice in October 2008, [AZ] saw Dr. Schultz approximately once every three months, obtaining three months' worth of prescriptions per visit, because it was more cost- and environmentally effective than monthly visits.[14] (Tr. 214.) [AZ] stated that Dr. Schultz is [AZ]'s physician but [AZ] also sees Respondent. The last time Dr. Schultz had given [AZ] a physical examination was nine months to a year ago. [AZ] further testified that [AZ] did not make Dr. Schultz [AZ]'s full time physician because ''she has been practicing since back in the '50s, so I know she—but she is also kind of getting up there in age * * * but you know, she is 75 years old, or so. Well I'm not sure about her exact age is.'' (Tr. 220.) I find [AZ]'s testimony credible to the extent that it was internally consistent and the witness was able to recall factual events with a reasonable level of certainty.

Patient [DS] testified in substance to being a patient of Respondent since September 10, 2009, having previously been treated at a VA hospital. [DS] stated that [DS] left the VA hospital after it stopped managing [DS]'s pain for no reason. After discharge from the VA hospital and prior to treating with Respondent [DS] stated that [DS] was ninety percent disabled, suffering from withdrawal, and did not believe [DS] would live another two weeks without treatment. (Tr. 237.) After discharge from the VA hospital [DS] had difficulty finding a physician that would take [DS] given [DS]'s financial means. [DS] further testified that after treating with Respondent and Dr. Schultz, [DS]'s life improved ninety percent or more and [DS] was able to continue attending college. [DS] explained that Respondent is not an easy doctor and only gives pain medicine to someone actually in pain.

On cross examination [DS] indicated that [DS] lives approximately twenty-two miles from Respondent's office. While at the VA hospital [DS] was prescribed methadone and Percocet together, along with Neurontin. [DS] explained that [DS]'s frequency of visits to Respondent's office is once every three months, with the last visit being August 26, 2010. [DS] saw Dr. Schultz in September 2009, which [DS] described as a sit-down discussion. [DS] explained that [DS] believed Respondent was [DS]'s primary care physician. Respondent performed the first physical examination on [DS]'s first visit. (Tr. 254.) I find [DS]'s testimony credible in that it was generally consistent and the witness was able to recall factual events with a reasonable level of certainty.

[AY] testified in substance that [AY] is a certified nursing assistant and receptionist, hired by Respondent on February 5, 2002, initially working as a receptionist. [AY] testified that [AY] currently works as a receptionist and also assists patients. [AY] further testified to being laid off from work in October 2008 and returning to employment with Respondent in February 2009. [AY] stated that Dr. Schultz told [AY] that [AY] could call in prescriptions for the patients based on recommendations of Respondent. [AY] explained that in May 2009 Dr. Schultz put in writing that [AY] was authorized to call in controlled substances under Dr. Schultz's name. (Tr. 261–62.) [AY] further testified that

[14] [AZ] testified that [AZ] gets three months' worth of prescriptions, paying $110.00, ''which comes out to be cheaper than if I would have went monthly, and it is the green thing to do, because I'm not running up and down the road burning gas to get back and forth to the office.'' (Tr. 214.)

from May 2008 to October 2008 many patients called stating they were having a hard time finding physicians to care for them.

On cross examination and redirect examination [AY] further explained that [AY] has called in prescriptions as part of [AY]'s job and on a date uncertain Dr. Shultz gave [AY] verbal permission to call in prescriptions, later reduced to writing in June 2009. (Tr. 272–73.) [AY] further testified that [AY] is prescribed controlled substances by New River Medical Associates, is paid eleven dollars per hour, and the cost of [AY]'s visits is offset as part of [AY]'s employment, in that [AY] does not pay for office visits. (Tr. 277–78, 285–86.) [AY]'s Schedule II medications are prescribed by Dr. Schultz but Dr. Schultz has not performed a physical examination of [AY], only a patient history. (Tr. 278.) [AY] stated that she has only seen Dr. Schultz as a patient ''one time'' within the past year, but did not recall the date. (Tr. 279.) Dr. Schultz only comes into the office one day a week, on Thursdays. [AY] explained that all of the patients at New River Medical Associates are pain patients and all or most pay cash, which includes credit card payments and money orders, ranging from $55.00 to $110.00. [AY] stated that a patient paying $110.00 ''would get their examination of three month's worth of medication.'' (Tr. 284.) [AY] provided contradictory testimony with regard to insurance and Medicare patients, first testifying on cross examination that ''about ten percent'' are insurance patients but on redirect examination that the office does ''not accept insurance.''

[AY]'s testimony at times was not internally consistent and [AY]'s testimony is evaluated in light of [AY]'s employment status with Respondent at the time of hearing. Additionally, [AY] is a patient of Respondent, receiving services at reduced cost. [AY]'s testimony with regard to Dr. Schultz's presence at the office only on Thursdays is consistent with other objective record evidence and credible. [AY]'s testimony with regard to ''call-in'' prescription authority from Dr. Schultz largely mirrors that of Respondent and, as more fully explained below, I do not find that testimony entirely credible.

Patient [ET] testified in substance that [ET] was a patient of Respondent before Respondent lost her medical license in 2008. [ET] began seeing Respondent again in February 2009. [ET] testified that while Respondent was without a medical license [ET] received treatment at a health center in Pulaski, Virginia for depression, and also received heart medication and ibuprofen for pain. Upon returning to Respondent for treatment in February 2009, [ET] testified to receiving prescriptions from Respondent, but later learned from Respondent's office that [ET] had to return the prescription because it needed to be issued by a Dr. Schultz. [ET] further testified that Respondent was a good doctor. (Tr. 296–346.) On cross-examination [ET] testified that [ET] did not think that [ET] ever received a physical examination by Dr. Schultz. [ET] further testified that as of the date of hearing [ET] was taking only ibuprofen for pain. (Tr. 350–51.) I find [ET]'s testimony credible in that it was internally consistent and the witness was able to recall factual events with a reasonable level of certainty.

Respondent testified in substance that she is a resident of Dublin, Virginia, and began her family practice rotation at the University Health Science Center before transferring to Roanoke Memorial Hospital Family Practice Residency. (Tr. 359–60.) Respondent applied for a DEA COR while in residency but did not really use it until becoming a practicing physician in 1995. Respondent stated that she chose family practice in part because of the variety of the work and wanted to work in a rural area where good doctors were needed. Respondent explained that after beginning practice on her own she began studying alternative medicine and saw her first pain patient in the late 1990s. (Tr. 362.) Respondent further testified that she was not taught pain management in residency. Respondent began self-study in alternative medicine in 2000, attending numerous training courses and lectures on a variety of subjects. (Resp't Exs. 7–16.) Respondent further testified that she has become noted well enough as a pain management expert that she has been invited twice by two different drug companies to attend review sessions on how the drug companies could present drugs to the Food and Drug Administration (FDA), and how to market them. (Tr. 375.)

Respondent also testified to developing a multidisciplinary facility called New River Medical Associates, in Dublin, Virginia, which was designed to help fix problems and help people heal. (Tr. 377–78.) Respondent testified that she developed ''cleansing sessions'' which consisted of thirty minutes of exercise or counseling, with remarkable results. (Tr. 378–79.) Respondent explained that she decided to ''simply bill the simplest ENM code * * * because if you bill too simple, the insurance company can say, 'This was worth more than that,' and they can get you for fraud either way. Laws are basically built to cause doctors to be charged with fraud * * *.'' (Tr. 379–80.) Respondent further testified to ending the cleansing sessions in October 2005, after a conversation with an insurance investigator, who told Respondent the sessions were not billable. Respondent stated that as a result of the cleansing sessions taxpayers saved hundreds of thousands or even millions of dollars through improved patient health, concluding: ''If this is fraud, maybe we need more of it.'' (Tr. 382.)

Respondent testified that she signed a plea agreement and pled guilty due to six billing incidents when she was out of the country, stating that the most she was paid extra because of the billings was eleven dollars per hour or a total loss of $66.00. (Tr. 384–85.) Respondent further explained that following her guilty plea in 2008, she lost her medical license and ''[n]inety-nine percent of my patients were unable to find another physician to take care of them, even though I tried to communicate to my colleagues that these people needed a physician * * *.'' (Tr. 388.)

Respondent further testified that her medical license was reinstated on February 13, 2008, and she thereafter resumed seeing patients. Respondent testified that she was aware the Government had sent individuals to her practice, identified herein as confidential sources. In August 2005 Respondent declined to provide treatment to a confidential source after discovering that the individual's medical history was false. More recently, she instructed another confidential source to complete a detoxification program after a drug screen revealed multiple positive results. Respondent described having strict rules and procedures, including drug screens. (Tr. 391–93.)

Respondent next testified to hiring Dr. Kathy Schultz *locum tenans* to work with patients on her own from the ''fall of '08 to February 23rd of '09.'' (Tr. 407.) Respondent testified that Respondent acted in the manner of a family nurse practitioner during this time, to continue the plan established by Dr. Schultz, who ''simply established a continuation of my plan from the previous year.'' (Tr. 412.) Respondent testified to an agreement with Dr. Schultz that Dr. Schultz would see all patients receiving Schedule II drugs and Dr. Schultz did not need to see patients receiving Schedule III to V drugs. On or about June 25, 2009, Respondent had a conversation with Dr. Schultz, who told Respondent that she had a conversation with DEA and told DEA that she had not given anyone permission to use her DEA

number. Respondent testified she informed Dr. Schultz that ''you allow us to call in prescriptions for our patients * * *'' and Dr. Schultz replied that she ''didn't realize that.'' (Tr. 422.) Respondent then asked Dr. Schultz to call DI Tomaziefski to rectify the situation.

Respondent also testified that on June 25, 2009, a written document was created reflecting a February 23, 2009 verbal agreement, along with a June 25, 2009 addendum further describing the arrangement between Respondent, Respondent's staff and Dr. Schultz. (Resp't Ex. 41; Tr. 424.) Respondent also introduced a letter dated July 20, 2009, from Kathleen Schultz authorizing [AY] to call in Schedule III to V medications. (Resp't Ex. 36.)

Respondent further testified that since June 2010 a webcam service was added to allow Dr. Schultz to connect with Respondent's office and has offered Dr. Schultz a service to review computer information or patient records, but this service has not been set up. Dr. Schultz does not have a key to Respondent's practice location. Respondent further admitted to writing two prescriptions in twenty months that she should not have written, and due to a ''comedy of errors'' one prescription was filled. Respondent maintains that ''two prescriptions were written by me for patients on my first day back to work,'' stating that she ''had just completely forgotten in my head about the fact that I could not write the controlled drugs, and I did, luckily to only those two patients.'' (Tr. 432–33.)

On cross examination, Respondent stated that she did not engage in the treatment of patients between May 28, 2008, and February 13, 2009. (Tr. 477.) The evidence also included a Notice of Denial letter dated February 1, 2009, with a facsimile date of February 1, 2009, addressed to Respondent, denying a payment request for enrollee [AZ]. (Gov't Ex. 19.) The evidence also included a Medicare prior authorization for patient [AZ], dated January 30, 2009, signed by Respondent and listing Respondent as the prescribing physician with a fax notation of February 2, 2009 (hereinafter ''Prior Authorization Form''). (Gov't Ex. 20.) Respondent testified that the signature on page two of the Prior Authorization Form was her signature. (Tr. 482; *see* Gov't Ex. 20.) Respondent admitted it was wrong that she signed it and that Dr. Schultz either authorized her to sign or Respondent assumed Dr. Schultz would have authorized her to sign. (Tr. 482–84.)

At hearing, Respondent timely objected to the admission of Government Exhibits 19 and 20, arguing lack of proper notice. (Tr. 485.) To comport with due process requirements, the DEA must ''provide a Respondent with notice of those acts which the Agency intends to rely on in seeking the revocation of its registration so as to provide a full and fair opportunity to challenge the factual and legal basis for the Agency's action.'' *CBS Wholesale Distributors,* 74 FR 36,746, 36,749 (DEA 2009) (citing *NLRB* v. *I.W.G., Inc.,* 144 F.3d 685, 688–89 (10th Cir. 1998) and *Pergament United Sales, Inc.,* v. *NLRB,* 920 F.2d 130, 134 (2d Cir. 1990)). Although non-noticed evidence may not be used for purposes of imposing a sanction, it can be the proper subject of cross-examination to impeach credibility. *Mark J. Berger, D.P.M.,* 62 FR 5842, 5844 (DEA 1997).

I find that prior to hearing, the Government did not disclose the substantive information relating to the January 30, 2009 Medicare Prior Authorization Form for patient [AZ] in the OSC, subsequent pre-hearing statements or list of exhibits. Accordingly, for purposes of this Recommended Decision, I give no weight to that evidence and related testimony other than to evaluate Respondent's credibility.

On further cross-examination, Respondent was shown a prescription dated March 20, 2009, to patient [JB] for ''Lyrica 75 mg capsule #60 (sixty),'' (*see* Gov't Ex. 9), and admitted the prescription was hers and contained her signature. (Tr. 492.) Respondent was shown a prescription dated April 6, 2009, to patient [JS] for ''Lortab 7.5–500 mg tablet #60 (sixty),'' (*see* Gov't Ex. 10), and testified that she could not say it was her prescription or signature. (Tr. 491–92.) Respondent explained that she could not identify the prescription and signature as hers because she suggested it was ''very possible'' the Government may have falsified the document. Respondent further stated that she recalled writing the March 20, 2009 prescription for patient [JB] but not the April 6, 2009 prescription for patient [JS]. (Tr. 491–92; *see* Gov't Exs. 9 & 10.) Respondent moreover testified with regard to a May 14, 2009 prescription to patient [VY] for ''Ambien 10 mg tablet #30 (thirty),'' (*see* Gov't Ex. 11), that she could not verify it as a prescription that she wrote. (Tr. 493.) And with regard to a February 23, 2009 prescription to patient [RL] for ''Lortab 7.5–500 mg tablet #120 (one hundred twenty),'' (*see* Gov't Ex. 12), Respondent equivocated as to whether her signature appeared on the prescription. (Tr. 493–94.)

In a letter dated January 13, 2010, (Resp't Ex. 40 at 1), Respondent stated that Respondent wrote a prescription dated March 20, 2009, to patient [JB] for Lyrica. Respondent further wrote that she did not know Lyrica was a controlled substance. (*Id.*) Respondent testified at hearing that she did not check any resources at the time she wrote the prescription and acknowledged being mistaken. (Tr. 497–99.)

The Government's evidence included eight prescriptions for various medications to [ET], all dated May 27, 2010, in the name of Dr. Schultz.[15] (Gov't Ex. 21.) Respondent testified that she recognized the prescriptions, was [ET]'s primary care physician, and would have consulted Dr. Schultz regarding the prescriptions. The evidence also included sixteen different prescriptions for eleven different patients covering the time period from April 29, 2010, to June 10, 2010.[16] (Gov't Ex. 22.) All were issued in the name of Dr. Schultz. Respondent testified she could not necessarily testify that the signatures on the prescriptions were Dr. Schultz's, although she confirmed that all the prescriptions were written to patients at New River Medical Associates. (Tr. 520–21, 525.) During the Government's rebuttal case, DI Tomaziefski testified that those prescriptions were seized pursuant to a search warrant of Respondent's office on June 14, 2010, and were found in Respondent's office in a printer. (Tr. 567–68.)

Respondent further testified that with regard to the process of preparing prescriptions for patients, Respondent is ''the expert in pain management. Dr. Schultz is not the expert in pain management. I am. So, she relies on me to—to tell her what is needed for the patient.'' (Tr. 523.) Respondent then testified that she is ''recommending'' to Dr. Schultz and ''in many cases'' Dr. Schultz makes the decisions. (Tr. 524.)

In rebuttal, SA Slease testified that he has been employed as a Special Agent with the Department of Health and Human Services since 2005 and has experience in approximately twenty-five fraud related investigations. SA Slease further testified that he is familiar with Respondent's practice location and very familiar with the southwestern Virginia area, to include Dublin, Virginia. SA

[15] Respondent timely objected to the admission of this unnoticed and undisclosed evidence. For purposes of this Recommended Decision, I have only considered this exhibit on the issue of Respondent's credibility.

[16] Respondent initially objected to the admission of this exhibit on grounds other than notice. Respondent's objection was initially sustained for lack of foundation, but the exhibit was later admitted without objection. As this exhibit was unnoticed prior to hearing, for purposes of this Recommended Decision, I have only considered it on the issue of Respondent's credibility.

Slease testified to having conducted an Internet and government Web site search for pain management providers within one hour's drive of Dublin, and located seven providers in the surrounding area that specialize in pain management. (Tr. 540–42.)

**The Parties' Contentions**

*I. The Government's Argument*

The Government argues that Respondent's application for registration should be denied due to her mandatory five-year exclusion from Medicare and Medicaid, pursuant to 21 U.S.C. 824(a)(5). Additionally, the Government argues that Respondent's registration would be inconsistent with the public interest pursuant to 21 U.S.C. 823(f) and 824(a)(4). The Government maintains that factor one of § 823(f), the recommendation of the appropriate state licensing board or professional disciplinary authority, is applicable based on the suspension and later reinstatement of Respondent's Virginia medical license but factor three, the applicant's conviction record relating to the manufacture, distribution or dispensing of controlled substances, is not applicable. As to factors two and four, the applicant's experience in dispensing or conducting research with respect to controlled substances and compliance with applicable laws relating to controlled substances, the Government maintains that Respondent issued prescriptions for controlled substances using her surrendered DEA COR. Additionally, the Government argues Respondent caused controlled substances prescriptions to issue under the DEA COR of another doctor, without permission. The Government further argues that Respondent executed pre-signed prescriptions for Schedule II controlled substances from 2003 through February 2006, in violation of 21 CFR 1306.05(a). Finally, the Government maintains that Respondent has refused to accept responsibility for past misconduct and was not forthright at hearing.

*II. Respondent's Argument*

Respondent argues that she only wrote one prescription for controlled substances on her first day back to work after her medical license was reinstated, a mistake due to habit. Respondent maintains that she has shown professional responsibility by calling the first patient to have the prescription returned, but after learning that it had already been filled ''there wasn't anything else she could do.'' Respondent also argues that she showed professional responsibility by calling the second patient and directing the patient to return the prescription before filling it. Respondent further argues that if ''DEA had done their job in a timely manner and approved Respondent's certificate within the timeframe listed on the DEA certificate Web site, that prescription would not have been a problem.'' Respondent maintains that over a twenty-month time span, only two prescriptions were written, and none in the past eighteen months, demonstrating Respondent's professionalism and accordance with the law. Respondent further argues that the called-in prescriptions for Dr. Schultz were done at Dr. Schultz's direction and not done illegally.

With regard to 21 U.S.C. 824(a)(5), Respondent argues that this particular exclusion from Medicare should not be the sole cause for denying her application for a COR because billing issues are very complex; the billing issues were based on ''incident-to billing by her nurse practitioners when Respondent was out of the country'' for which Respondent took responsibility; and denial of a COR ''on the most minimal felony conviction that could be assessed would be a gross injustice.''

Respondent maintains that her reinstatement by the Virginia Board of Medicine weighs in her favor as to factor one of § 823(f), the recommendation of the appropriate state licensing board or professional disciplinary authority. As to factor two, the applicant's experience in dispensing, or conducting research with respect to controlled substances, Respondent maintains that she has extensive experience and training in pain management, and has been recognized by other pain management specialists as well as pharmaceutical companies. In the case of factor five, Respondent maintains there is no allegation or evidence that any conduct by Respondent would threaten the public health and safety.

Respondent further argues that denying her application for a DEA COR would prevent her patients from receiving pain management treatment in Respondent's geographic area. Respondent questions whether the Government's ''real goal is to deny patient care to the underprivileged, poor, disabled, and elderly,'' among other charges.

**Discussion and Conclusions**

*I. The Applicable Statutory and Regulatory Provisions*

The Controlled Substances Act (''CSA'') provides that any person who dispenses (including prescribing) a controlled substance must obtain a registration issued by the DEA in accordance with applicable rules and regulations.[17] Except when dispensed directly by a non-pharmacist practitioner to an ultimate user, controlled substances that are prescription drugs under the Food, Drug and Cosmetic Act must be dispensed pursuant to a prescription issued by a practitioner.[18] Furthermore, it is unlawful for any person knowingly or intentionally to use an expired registration number in the dispensing of a controlled substance to another person.[19] A prescription for a controlled substance may be issued only by an individual practitioner who is licensed to practice and is either registered or exempted [20] from registration.[21] A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.[22] All prescriptions for controlled substances must be signed on and dated as of the date issued and must bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner.[23]

The CSA specifies in 21 U.S.C. 824(a) five factors that the Deputy Administrator may consider when suspending or revoking a DEA registration.[24] Despite the lack of an explicit provision applying these factors to a denial of an application:

[t]he agency has consistently held that the Administrator may also apply these bases to the denial of a registration, since the law would not require an agency to indulge in the

[17] 21 U.S.C. 822(a)(2).

[18] 21 U.S.C. 829(a) (2006 & Supp. 2010).

[19] *Id.* 843(a)(2).

[20] The exemptions from registration identified in 21 CFR 1301.22(c) (agent or employee of hospital) and 1301.23 (military and certain other personnel) are inapplicable to the facts of this case.

[21] 21 CFR 1306.03(a) (2010).

[22] *Id.* 1306.03(b).

[23] *Id.* 1306.05(a).

[24] That subsection provides that a DEA registration may be revoked upon a finding that the registrant: (1) Has materially falsified an application for DEA registration; (2) has been convicted of a felony under the CSA or any other federal or state law relating to any controlled substance; (3) has had a state license or registration suspended, revoked or denied and is no longer authorized by state law to handle controlled substances; (4) has committed such acts as would render registration inconsistent with the public interest; or (5) has been excluded from participation in a program pursuant to 42 U.S.C. 1320a–7(a). It should also be noted that § 824(a) contains a reciprocal reference incorporating the public interest factors from § 823(f). *See* 21 U.S.C. 824(a)(4).

useless act of granting a license on one day only to withdraw it on the next.[25]

In addition, I conclude that the reference in § 823(f)(5) to ''other conduct which may threaten the public health and safety'' would as a matter of statutory interpretation logically encompass the factors listed in § 824(a).[26]

In an action to deny an application for a DEA COR, the Government has the burden of proving that the requirements for granting such registration are not satisfied.[27] The burden of proof shifts to the respondent once the Government has made its *prima facie* case.[28]

*II. Exclusion From Medicare*

The CSA, 21 U.S.C. 824(a)(5), provides, insofar as pertinent to this proceeding, that the Deputy Administrator may revoke or deny a registration if an applicant has been excluded from participation in a program pursuant to 42 U.S.C. 1320a–7(a).

Under Section 1320a–7(a), the Secretary of the Department of Health and Human Services is required to exclude from participation in any federal health care program any individual convicted of a criminal offense ''related to the delivery of an item or service under [42 U.S.C. 1395 *et seq.*] or under any State health care program,'' § 1320a–7(a)(1), as well as any individual ''convicted for an offense * * * in connection with the delivery of a health care item or service or with respect to any act or omission in a health care program * * * [or a] criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct,'' § 1320a–7(a)(3).

I find that Respondent's Medicare fraud conviction and subsequent exclusion from Medicare are supported by substantial evidence. The evidence at hearing includes a plea agreement and judgment pertaining to Respondent's conviction for violating 18 U.S.C. 1347. (Gov't Exs. 3 & 4.) Additionally, the evidence includes a letter from the Department of Health and Human Services dated September 30, 2008, excluding Respondent from all federal health care programs for the minimum statutory period of five years. (Gov't Ex. 6.) Consequently, exclusion from Medicare is an independent ground for denying or revoking a DEA registration in this case. *See Johnnie Melvin Turner, M.D.,* 67 FR 71,203, 71,204 (DEA 2002).

Respondent does not dispute the evidence of conviction or exclusion, but argues, correctly, that denial of an application for registration on this ground is a matter of discretion. *See Dinorah Drug Store, Inc.,* 61 FR 15,972–03, 15,973 (DEA 1996) (denial of registration under Section 824(a)(5) discretionary so long as granting registration not inconsistent with public interest).

Accordingly, on these facts, the Government has met its burden of proving its Section 824(a)(5) claim, *see* 21 CFR 1301.44(d), placing the burden on Respondent to show that despite her conviction, granting her a COR would not be contrary to the public interest, *see Medicine Shoppe—Jonesborough,* 73 FR 364, 380 (DEA 2008) (burden of proof shifts to Respondent once Government puts on *prima facie* case); *see also Thomas Johnston,* 45 FR 72,311, 72,311 (DEA 1980) (same).

I further find that the record evidence fully supports denying Respondent's application for registration on this ground alone. Respondent's conduct pertaining to her conviction for health care fraud related in substance to improper billing of services. Respondent's sentence included restitution in the amount of $24,210.37. (Gov't Ex. 4 at 2; *see generally* Tr. 45–46, 57, 392.) Respondent argues in part that she ''took responsibility for this action [and] exclusion should not be used as the sole cause of denial of a certificate.'' [29] To the contrary and as discussed below, Respondent's testimony demonstrated a complete lack of acceptance of responsibility,[30] among other things, and I find that granting Respondent a COR would be inconsistent with the public interest.

*III. The Public Interest Standard*

Pursuant to 21 U.S.C. 823(f), the Deputy Administrator may deny an application for a DEA registration if she determines that such registration would be inconsistent with the public interest. In determining the public interest, the Deputy Administrator is required to consider the following factors:

(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.

As a threshold matter, the factors specified in Section 823(f) are to be considered in the disjunctive: The Deputy Administrator may properly rely on any one or a combination of those factors, and give each factor the weight she deems appropriate, in determining whether a registration should be revoked or an application for registration denied. *See David H. Gillis, M.D.,* 58 FR 37,507, 37,508 (DEA 1993); *see also D & S Sales,* 71 FR 37,607, 37,610 (DEA 2006); *Joy's Ideas,* 70 FR 33,195, 33,197 (DEA 2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16,422, 16,424 (DEA 1989).

*IV. The Factors To Be Considered*

Factor 1: The Recommendation of the Appropriate State Licensing Board

As described in the Evidence and Incorporated Findings of Fact Section of this Recommended Decision, Respondent holds a valid state medical license but Respondent's state medical license has been suspended in the past. The suspension of Respondent's medical license, between June 4, 2008, and February 12, 2009, included several findings of fact by the Virginia Board of Medicine regarding Respondent's conduct, her credibility and her conviction for health care fraud. The Board also found that ''[f]rom approximately 2003 until on or about February 28, 2006, at which time a search warrant executed at her practice produced a prescription pad with numerous pre-signed blank prescription sheets, Dr. Cheek pre-signed blank prescription sheets for use by the nurse practitioners if she was not in the office.'' (Gov't Ex. 7 at 3.) Additionally, the Board did not find credible Respondent's testimony at formal hearing that the pre-signed forms were not for medications. The Board also found that Respondent ''continued to prescribe Kadian 20 mg (morphine sulfate, C–II)'' to a patient despite the fact that a urine drug screen was negative for opiates during the relevant timeframe. (*Id.* at 3.) The Board further

[25] *Kuen H. Chen, M.D.,* 58 FR 65,401, 65,402 (DEA 1993) (citing *Serling Drug Co. & Detroit Prescription Wholesaler, Inc.,* 40 FR 11918, 11,919 (DEA 1975)); *accord Scott J. Loman, D.D.S.,* 50 FR 18,941 (DEA 1985); *Roger Lee Palmer, D.M.D.,* 49 FR 950 (DEA 1984).

[26] *See Chen,* 58 FR at 65,402.

[27] 21 CFR 1301.44(d) (2010).

[28] *Medicine Shoppe—Jonesborough,* 73 FR 364, 380 (DEA 2008); *see also Thomas Johnston,* 45 FR 72,311, 72,311 (DEA 1980).

[29] Resp't post-hearing br. at 9.

[30] Respondent's testimony pertaining to the offense conduct included the statement: ''If this is fraud, maybe we need more of it.'' Respondent later stated her belief in the ''unjustness'' of her conviction, claiming overbilling for only $66.00. (Tr. 382, 384–86.)

found Respondent in her testimony ''demonstrated little insight into the practice management and ethical issues regarding fraudulent billing that led to the suspension of her license and the additional patient care concerns. Specifically, Dr. Cheek did not take responsibility for her actions and felt that there was a government conspiracy against her because she practices pain management.'' (*Id.* at 4.)

In mitigation, the Virginia Medical Board reinstated Respondent's medical license on February 12, 2009. (Resp't Ex. 18.) While not dispositive, this reinstatement does weigh in favor of a finding that Respondent's registration would not be inconsistent with the public interest, at least as of February 12, 2009. The weight accorded to the reinstatement of Respondent's medical license, however, is tempered by the fact that on the first day of practice following reinstatement Respondent wrote prescriptions for controlled substances without a DEA registration. (*See, e.g.,* Gov't Ex. 18 at 1.)

Factor 3: Respondent's Conviction Record

As noted above, one of the factors in determining whether Respondent's registration would be inconsistent with the public interest is ''[t]he applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). Respondent argued at hearing, and I find, that Respondent has not been convicted of any laws relating to the manufacture, distribution or dispensing of controlled substances. I therefore find that the third factor under Section 823(f), while not dispositive, does weigh in favor of a finding that Respondent's registration would be consistent with the public interest.

Factors 2 and 4: Respondent's Experience in Dispensing Controlled Substances; and Compliance With Applicable State, Federal or Local Laws Relating to Controlled Substances

''Every person who manufactures, distributes, dispenses, imports or exports any controlled substance or who proposes to [do so] * * * shall obtain a registration unless exempted by law or pursuant to §§ 1301.22–1301.26.'' 21 CFR 1301.11(a) (2010). Although a person may apply for registration at any time, ''*[n]o person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person.*'' *Id.* (emphasis supplied).

Respondent's conduct with regard to compliance with applicable federal, state or local laws relating to controlled substances since regaining her medical license in February 2009 has been dismal, at best. On the same day as her medical license was restored, Respondent admittedly wrote at least two prescriptions without authority. Respondent's testimony at hearing explaining that she had forgotten she was unauthorized to write prescriptions and wrote prescriptions by ''habit'' is simply not credible. The evidence at hearing reflects numerous prescriptions that Respondent wrote in her own name on and after February 13, 2009. The objective evidence of record reflects five prescriptions to different patients for Scheduled controlled substances, signed by Respondent between February 23, 2009, and May 14, 2009. (Gov't Exs. 9–13.) Finally, Respondent wrote a prescription for Lyrica on March 20, 2009, admitting that she did not know or research whether Lyrica was a controlled substance.[31] (Tr. 497–99; Resp't Ex. 40 at 1.)

Respondent's conduct with regard to issuing controlled substance prescriptions under the direction and authority of Dr. Kathleen Schultz was also unlawful. As an initial matter, Respondent's explanation of her arrangement with Dr. Shultz is not credible. Respondent maintains in substance that she reached a verbal and later written agreement with Dr. Schultz for Respondent to prescribe controlled substances, including pain medications, at the direction of Dr. Schultz. Respondent further testified that Dr. Schultz was present at Respondent's practice on Thursdays to see Respondent's patients and issue prescriptions. That testimony stands in sharp contrast to the objective evidence of record reflecting that a significant majority of prescriptions issued at Respondent's practice occurred on other days of the week. For example, DI Tomaziefski testified that ''most of the prescriptions were called in on days other than Thursdays.'' (Tr. 118; *see* Gov't Exs. 15 & 17.) Additionally, patients [DS], [AZ] and [AY] all testified to seeing Dr. Schultz rarely and that Respondent was effectively their primary care physician.

Respondent's testimony with regard to identification of her own signature as well as Dr. Schultz's signature on prescriptions issued from Respondent's office was notably contrived. Respondent testified that she recognized her own signature on a prescription for Lyrica with two refills issued on March 20, 2009. (Tr. 491; *see* Gov't Ex. 9.) Respondent further volunteered that the ''prescription is mine. It is signed. It was not filled. I do not therefore consider a law has been broken.'' (Tr. 491.) Respondent then testified that she did not recognize her signature on a prescription for Lortab issued on April 6, 2009, that had been filled. (Tr. 491–92; *see* Gov't Ex. 10.) Respondent offered that ''I cannot say this is my signature. I am not opposed to the idea the government can do a lot of things . * * *'' (Tr. 492.) Respondent testified she could not ''verify'' a prescription for Ambien dated May 14, 2009, bearing a signature in Respondent's name. (Tr. 493; *see* Gov't Ex. 11.) Respondent testified she could not recognize her signature on a prescription for Lortab dated February 23, 2009. (Tr. 494; *see* Gov't Ex. 12.) Finally, Respondent testified with regard to a prescription dated February 23, 2009, for Ambien, that the signature was hers and that she recalled writing the prescription. (Tr. 495; *see* Gov't Ex. 13.) This testimony as a whole was palpably incredible.

Respondent also testified that she could not recognize the signature of Dr. Schultz with regard to sixteen prescriptions. (Tr. 519–20; *see* Gov't Ex. 22.) This testimony is inconsistent with Respondent's prior testimony and assertion that she was working at the direction of Dr. Schultz, presumably following Dr. Schultz's written and oral directions. This testimony is also markedly at odds with the fact that sixteen prescriptions, eleven of which bore ''a do not fill before'' date in the name of Dr. Kathleen Schultz, were found in a printer in Respondent's office during the execution of a DEA search warrant on June 14, 2010.

The record as a whole supports by substantial evidence a finding that Respondent knowingly wrote prescriptions without authority on and after February 13, 2009, in her own name. Additionally, the record further supports a finding by substantial evidence that Respondent wrote prescriptions unlawfully using Dr. Schultz's DEA registration.

The evidence with regard to whether Dr. Schultz knowingly authorized Respondent and Respondent's assistant [AY] to call in prescriptions under Dr. Schultz's DEA registration number is mixed. DI Tomaziefski testified that in an initial conversation with Dr. Schultz, Dr. Schultz stated she did not authorize anyone to use her number. In a later call initiated by Respondent and with Respondent on the line, Dr. Schultz

[31] Pregabalin (Lyrica) is a Schedule V controlled substance. 21 CFR 1308.15(e)(1) (2010); *Schedules of Controlled Substances: Placement of Pregabalin Into Schedule V,* 70 FR 43,633–01 (DEA 2005).

stated she had authorized the use of her DEA number. Additionally, Respondent introduced a written agreement bearing signatures in the names of Dr. Schultz and Respondent, purporting to memorialize an agreement for Respondent to act under Dr. Shultz's direction for all Schedule II to IV medications, noting in part that Dr. Schultz does not need to see patients receiving Schedule III to V medications. (Resp't Ex. 41.) The written document purports to memorialize a verbal understanding between Dr. Schultz and Respondent as of February 23, 2009. An addendum dated June 25, 2009, notes Dr. Schultz will see ''all patients one time'' because of an inability ''to determine the legality'' of the original agreement. (*Id.*) While the evidence lends some support to a finding that Dr. Schultz may have authorized in some instances the ''call-in'' of Dr. Schultz's prescriptions by Respondent and [AY], as well as the supervision of Respondent, the evidence as a whole demonstrates that this arrangement was used primarily to allow Respondent to issue numerous controlled substance prescriptions with little if any substantive input by Dr. Schultz.

The transparency of the arrangement was quite apparent even from the testimony of Respondent. Respondent testified at one point that she was the pain management expert, not Dr. Schultz. (Tr. 523.) The testimony of Respondent's patients also undermined Respondent's story. All of Respondent's patients who testified indicated that they saw Respondent for treatment and only rarely did Dr. Schultz perform physical examinations or see patients. For example, patient [AZ] testified to last having a physical examination from Dr. Schultz nine months to a year ago, yet visited Respondent's practice approximately once every three months. (Tr. 214.) Patient [ET] testified that [ET] had been a patient of Respondent until Respondent lost her medical license in 2008. [ET] began treatment with Respondent again on February 23, 2009. (Tr. 340.) [ET] further testified that [ET] does not recall having a physical examination by Dr. Schultz. (Tr. 350.) Patient [AY] testified that Dr. Schultz was only present in Respondent's practice on Thursdays. (Tr. 280.) [AY] further testified that Dr. Schultz has never performed a physical examination of [AY] while a patient and that [AY] has only seen Dr. Schultz as a patient one time. (Tr. 278–79.)

The evidence also includes testimony from DI Tomaziefski regarding an undercover visit by a confidential source (''CS'') to Respondent's practice on May 28, 2009. DI Tomaziefski testified in substance that the CS was wearing a ''wire'' and DI Tomaziefski listened to the office visit and learned that the CS was treated by Respondent and not seen by Dr. Schultz. Respondent gave the CS a prescription for hydrocodone, which Respondent's office assistant called in to a local pharmacy using Dr. Schultz's DEA number. (Tr. 99–100; *see* Gov't Ex. 14.)

There is additional evidence of record reflecting inconsistencies with regard to Respondent's claim that she was working at the direction of Dr. Schultz, but further elaboration is unnecessary. The evidence as a whole demonstrates that Respondent's claim that she was working at the direction of Dr. Schultz is not supported by credible evidence. To the contrary, the evidence as a whole reflects a pattern of conduct by Respondent aimed at unlawfully circumventing her lack of a DEA COR to prescribe controlled substances in violation of 21 U.S.C. 822(a)(2) and 843(a)(2).

The Government has introduced evidence and argued that Respondent's history of non-compliance with applicable laws is evident from the October 29, 2008, findings of fact by the Virginia Board of Medicine. The Board found that from ''approximately 2003 until on or about February 28, 2006, at which time a search warrant executed at her practice produced a prescription pad with numerous pre-signed blank prescription sheets, Dr. Cheek pre-signed blank prescription sheets for use by the nurse practitioners if she was not in the office.'' (Gov't Ex. 7 at 3.) Such conduct is contrary to DEA regulations which require prescriptions for controlled substances to be ''dated as of, and signed on, the day when issued * * *'' as well as Virginia law.[32]

As an initial matter, this issue of Respondent's pre-signing of prescription pads between 2003 and 2006 was not specifically noticed by the Government in the OSC or pre-hearing statements. It was, however, addressed in Government Exhibit 7, an exhibit that was provided to Respondent prior to hearing, presumably on or before the September 13, 2010 deadline set by the Prehearing Ruling (ALJ Ex. 4 at 2), and filed on September 27, 2010. At hearing Respondent did not object to the admission of the exhibit. (Tr. 72.) To comport with due process requirements, the DEA must ''provide a Respondent with notice of those acts which the Agency intends to rely on in seeking the revocation of its registration so as to provide a full and fair opportunity to challenge the factual and legal basis for the Agency's action.'' *CBS Wholesale Distributors,* 74 FR 36,746, 36,749 (DEA 2009) (citing *NLRB* v. *I.W.G., Inc.,* 144 F.3d 685, 688–89 (10th Cir. 1998) and *Pergament United Sales, Inc.,* v. *NLRB,* 920 F.2d 130, 134 (2d Cir. 1990)). The DEA has previously held that an issue cannot be the basis for a sanction when the Government has failed to ''disclose 'in its prehearing statements or indicate at any time prior to the hearing' that an issue will be litigated.'' *Id.* at 36,750 (citing *Darrell Risner, D.M.D.,* 61 FR 728, 730 (DEA 1996)). The DEA has also previously found, however, that a respondent may waive objection to the admission of evidence not noticed by the Government prior to the hearing when the respondent does not timely object and when the respondent also raises the issue. *Gregory D. Owens, D.D.S.,* 74 FR 36,751, 36,755 (DEA 2009).

I find in this case that the issue of Respondent's pre-signing of prescription pads between 2003 and 2006 was sufficiently noticed to Respondent in advance of hearing, because the matter was provided to Respondent as an exhibit prior to hearing. Respondent's failure to object to the admission of the exhibit further supports its consideration on the issue of sanction. I find that Respondent's history of pre-signing blank prescription sheets from 2003 to February 2006 to be supported by substantial evidence and contrary to DEA regulation and Virginia law.

The action of the Virginia Medical Board appears to consider issues directly related to this proceeding and therefore should be afforded significant weight. In particular, the Board's consideration of Respondent's lack of responsibility for her actions and belief in a government conspiracy against her practice of pain management was very consistent with the testimony of Respondent at the proceedings in the above-captioned case. It is also noteworthy that the Board did not find Respondent's testimony with regard to material issues to be credible. Respondent's clear disregard of applicable law and regulations prohibiting such conduct over an extended period of time weighs heavily against Respondent's application for registration.

Additionally, the evidence of Respondent's dispensing practice includes an instance on May 20, 2009, when she issued to a patient a prescription for Lyrica, a Schedule V controlled substance, admitting that she

[32] 21 CFR 1306.05(a) (2010). Requirements for prescriptions in Virginia include, among other things, that ''[e]ach written prescription shall be dated as of, and signed by the prescriber on, the day when issued.'' Va. Code Ann. § 54.1–3408.01(A) (2010).

did not know or research whether Lyrica was a controlled substance. Respondent maintained that the ''drug company did not do a very good job of informing'' her of the controlled status of the drug, elaborating that ''I fail to see why it had a controlled status.'' (Resp't Ex. 40 at 1; *see also* Tr. 497–99.) The applicable regulations are specific in placing the ''responsibility for the proper prescribing and dispensing of controlled substances'' on the practitioner, with a corresponding responsibility on the pharmacist.[33] Respondent's conduct in this instance was contrary to applicable regulations and inconsistent with the public interest.

The evidence of Respondent's experience in dispensing controlled substances and compliance with applicable law and regulations weigh heavily in favor of a finding that Respondent's registration would be inconsistent with the public interest.

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

As to factor five, ''Respondent's lack of candor and inconsistent explanations'' may serve as a basis for denial of a registration. *John Stanford Noell, M.D.,* 59 FR 47,359, 47,361 (DEA 1994). Additionally, where a registrant [34] has committed acts inconsistent with the public interest, a registrant must accept responsibility for her actions and demonstrate that she will not engage in future misconduct. *Patrick W. Stodola,* 74 FR 20,727, 20,735 (DEA 2009).[35] Also, ''[c]onsideration of the deterrent effect of a potential sanction is supported by the CSA's purpose of protecting the public interest.'' *Joseph Gaudio, M.D.,* 74 FR 10,083, 10,094 (DEA 2009).

Respondent's testimony at hearing repeatedly and clearly demonstrated that she does not accept responsibility for her actions. For example, Respondent testified that she

> do[es] not know why the government targets me. For some reason or other, the government has it in for Linda Cheek, M.D. It might be why. I am a renegade. I admit it. I always have been. If it weren't for people like me, changes would never be made, and I'm proud of that, and I'll stand by it.

(Tr. 389.) Respondent's testimony about a ''government conspiracy'' against her was also noted by the Virginia Board of Medicine in its Order dated October 29, 2008. ''Specifically, Dr. Cheek did not take responsibility for her actions and felt that there was a government conspiracy against her because she practices pain management.'' (Gov't Ex. 7 at 4.)

Respondent's testimony at hearing regarding her ''mistaken'' issuance of prescriptions because of ''habit,'' along with her testimony regarding the arrangement with Dr. Schultz to issue prescriptions at the direction of Dr. Schultz, is not credible; it is moreover contrary to other objective evidence of record. Equally incredible is Respondent's ability to recognize her signature in one instance, but not in another, for no apparent reason. Further examples permeate the record. I find that Respondent's lack of credibility during numerous material portions of her testimony weighs heavily in favor of denying Respondent's application.

**V. Community Impact Evidence**

Respondent at hearing sought to introduce testimony from several witnesses on the issue of ''community impact,'' maintaining that a denial of her DEA COR would leave southwestern Virginia medically underserved by pain management practitioners.[36] As a threshold matter, there is some question as to whether this issue is relevant at all in a DEA administrative proceeding regarding the registration of a practitioner. Agency precedent has found community impact testimony and evidence relevant with regard to pharmacies but has also rejected community impact evidence altogether in more recent cases. For example, the agency has considered and credited a respondent's argument that loss of registration would severely and adversely impact the local community by eliminating one of two pharmacies serving the poor. *Pettigrew Rexall Drugs,* 64 FR 8855, 8859–60 (DEA 1999). In recent cases, the agency held that ''DEA has never applied [the *Pettigrew*] rule in a subsequent case * * * it would be ill-advised to extend it to the case of a prescribing practitioner.'' *Gregory Owens, D.D.S.,* 74 FR 36,751, 36,757 (DEA 2009); *see also Steven M. Abbadessa, D.O.,* 74 FR 10,077, 10,078 (DEA 2009) (rejecting community impact evidence).

Although not discussed in *Owens,* there are cases since *Pettigrew* that have considered and given weight to community impact evidence, without specifically citing *Pettigrew.* For example, in a 2004 decision the Deputy Administrator explained that ''regardless of any demographic showing as to what proportion of Louisiana's population is medically underserved[,] such information does not detract from the fact that Respondent provides needed medical services to such an area * * * while this provides some support for maintaining registration under the facts of this case, it also has a negative implication for continued registration.'' *Imran I. Chaudry, M.D.,* 69 FR 62,081, 62,083–84 (DEA 2004).

In light of this precedent, I find that community impact evidence as a threshold matter is not entirely irrelevant. That said, the evidence adduced at hearing does not support a finding that denying Respondent's application for registration would have any appreciable adverse community impact. The testimony offered by Respondent and three patient witnesses claimed in substance that Respondent was the only pain management doctor reasonably available in southwestern Virginia. Respondent also introduced an Internet search results query to support her assertion. (Resp't Ex. 43.)

This testimony and evidence was rebutted by testimony from SA Slease, Department of Health and Human Services, who credibly testified that he was very familiar with the southwestern Virginia area to include Dublin, Virginia, and based on an Internet and government Web site search for pain management providers, located seven pain management specialists in the area.

While I have admitted and considered testimony with regard to community impact for the reasons set forth above, I find in this instance that the denial of Respondent's application for registration would have little if any adverse community impact with regard to the availability of pain management physicians.

**Conclusion and Recommendation**

I find the Government has established by substantial evidence a prima facie case in support of denying Respondent's application for registration. I conclude by a preponderance of the evidence that the Government has proved independent grounds for denying Respondent's application for registration pursuant to 21 U.S.C.

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[33] 21 CFR 1306.04(a) (2010).

[34] Although Respondent is not presently a registrant, she was a registrant in the past. (*See* Gov't Ex. 8; Tr. 73–76.) In any event, the extent of Respondent's acceptance of responsibility is unquestionably relevant to the question of whether her pending application should be granted. *See, e.g., Morall* v. *DEA,* 412 F.3d 165, 182–83 (DC Cir. 2005) (discussing several DEA decisions to continue registrations where physician cooperated with DEA investigators).

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

[36] I allowed Respondent to call two of four proposed witnesses on this specific issue, because additional testimony would be unnecessarily duplicative. *See* 21 CFR 1316.59(a) (2010).

824(a)(5), and alternatively, that the balance of the other factors in this case weighs heavily in favor of a finding that Respondent's registration would be inconsistent with the public interest under § 823(f).

Once DEA has made its prima facie case for revocation or denial, the burden shifts to the respondent to show that, given the totality of the facts and circumstances in the record, revoking or denying the registration would not be appropriate. *See Morall* v. *DEA,* 412 F.3d 165, 174 (DC Cir. 2005); *Humphreys* v. *DEA,* 96 F.3d 658,661 (3d Cir. 1996); *Shatz* v. *United States Dep't of Justice,* 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston,* 45 FR 72,311 (DEA 1980).

Additionally, where a potential registrant has committed acts inconsistent with the public interest, she must accept responsibility for her actions and demonstrate that she will not engage in future misconduct. *See Patrick W. Stodola,* 74 FR 20,727, 20,735 (DEA 2009). Also, ''[c]onsideration of the deterrent effect of a potential sanction is supported by the CSA's purpose of protecting the public interest.'' *Joseph Gaudio, M.D.,* 74 FR 10,083, 10,094 (DEA 2009). An agency's choice of sanction will be upheld unless unwarranted in law or without justification in fact. A sanction must be rationally related to the evidence of record and proportionate to the error committed. *See* Morall v. *DEA,* 412 F.3d 165, 181 (DC Cir. 2005). Finally, an ''agency rationally may conclude that past performance is the best predictor of future performance.'' *Alra Laboratories, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995).

I recommend denial of Respondent's application. I find the evidence as a whole demonstrates that Respondent has not accepted responsibility. To the contrary, Respondent maintains without credibility that she is being unfairly persecuted because of her pain management practice. Respondent's past performance, including a felony conviction for health care fraud, past and recent history of non-compliance with applicable laws and regulations, and overall lack of candor while testifying at hearing is fully consistent with a denial of Respondent's application for a DEA COR.

Dated: December 30, 2010.

Timothy D. Wing,

*Administrative Law Judge*

[FR Doc. 2011–28002 Filed 10–27–11; 8:45 am]

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. 10–73]**

### Shawn M. Gallegos, D.D.S., Decision and Order

On May 19, 2011, Administrative Law Judge (ALJ) Timothy D. Wing issued the attached recommended decision. Neither party filed exceptions to the decision.

Having reviewed the entire record, I have decided to adopt the ALJ's findings of fact, conclusions of law and recommended order in its entirety except as explained below.[1] Accordingly, I will order that the Respondent's application be denied.

### Order

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

Dated: October 7, 2011.

**Michele M. Leonhart,**

*Administrator.*

*Theresa Krause, Esq. & Brian Bayly, Esq.,* for the Government

*Shawn M. Gallegos, D.D.S., pro se,* Respondent

### Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge

### Introduction

Administrative Law Judge Timothy D. Wing. This proceeding is an adjudication pursuant to the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.,* to determine whether the Drug Enforcement Administration (DEA) should deny a dentist's application for a DEA Certificate of Registration (COR) as a practitioner. Without this registration the dentist, Shawn M. Gallegos, D.D.S. (Respondent or Dr. Gallegos), of Martinez, California, will be unable to lawfully prescribe, dispense or otherwise handle controlled substances in the course of his practice.

On August 3, 2010, the DEA Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause (OSC) to Respondent, giving Respondent notice of an opportunity to show cause why the DEA should not deny Respondent's application for a DEA COR, filed on or around January 27, 2010, pursuant to 21 U.S.C. 824(a)(4) and 21 U.S.C. 823(f), on the grounds that Respondent's registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 824(a)(4) and 823(f).

In part and in substance, the OSC alleges that Respondent voluntarily surrendered his DEA registration number BG6936491 for cause on December 2, 2009, alleging that during the course of a DEA investigation concerning suspicious orders of hydrocodone and phentermine, Respondent stated the controlled substances were not used in the normal course of his dental practice. The OSC further alleges that on multiple occasions, Respondent failed in his responsibility as a practitioner to ensure that the controlled substances ordered and dispensed by him were for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, in violation of 21 CFR 1306.04(a). Additional alleged violations include the inability to account for the dispensing of the controlled substances in violation of 21 CFR 1304.04(a); the failure to keep a dispensing log for controlled substances, in violation of 21 CFR 1304.03(b); the failure to keep accurate, complete and mandatory records of controlled substances in violation of 21 CFR 1304.21(a); the failure to properly report the theft of hydrocodone and the unauthorized use of Respondent's registration, in violation of 21 CFR 1301.76(b); the failure to establish a valid doctor-patient relationship before issuing and dispensing controlled substances (diet pills), which were for other than a legitimate medical purpose and outside the usual course of professional practice, in violation of 21 CFR 1306.04; and the commission of ''such acts that would render Respondent's registration inconsistent

[1] At page 19 of the slip opinion, the ALJ explained that ''Respondent's statement during the December 2, 2009 audit that the dispensing records were located within his patient records was found to be inaccurate. Even if true, the patient records would not substitute for required copies of DEA Form 222 relating to the Schedule II controlled substance oxycodone, among other recordkeeping requirements.'' To make clear, a DEA Form 222, which is otherwise known as an ''order form,'' must be executed for each distribution of a schedule II controlled substance with the exception of those distributions which are exempt under 21 CFR 1305.03. This form is not required, however, to document a practitioner's dispensing of controlled substances, which must be recorded in a dispensing log. *See* 21 CFR 1304.03(b), 1304.22(c). While the record establishes that Respondent ordered oxycodone only a single time (for which he did not have a copy of the requisite Form 222), Respondent was also required to maintain, for a period of two years, records documenting the receipt of all controlled substances he acquired, as well as an initial inventory when he first engaged in controlled substances activities and biennial inventories thereafter for each controlled substance he acquired. *Id.* 1304.04(a), 1304.11, 1304.21(a). Respondent, however, had no such records.