

and, as remedial measures, stopped dispensing schedule II substances all together.” Resp. Exceptions, at 8. Respondent also argues that, through Respondent’s Owner and PIC, it “accepted the responsibility for not documenting in every instance, its efforts in resolving the red flags and as [a] remedial measure stated that it ‘document[s] everything that’s possible.’” *Id.* It further contends that, “[a]lthough . . . [Respondent’s Owner and PIC] accepted responsibility for the misfiling of the prescriptions, it is easily deuced [sic] from the record and from the instituted corrective measures that the Respondent accepted the responsibility for the missing information as well.” *Id.* at 18 n.19.

I reject Respondent’s contentions. Most significantly, Respondent’s Owner and PIC has entirely failed to acknowledge that Respondent violated the CSA when it knowingly dispensed numerous controlled substance prescriptions which were clearly issued outside of the usual course of professional practice and which lacked a legitimate medical purpose. And even as to the factual matters for which the CALJ found she accepted responsibility, such as failing to adequately document her conversations with prescribers, Respondent’s Owner and PIC immediately equivocated by making excuses for not doing so in the future. She stated, “Now I document every little thing that it’s concerned to the conversation and the dispensing of controlled substances. However, there’s a lot of conversation going on on a daily basis between doctors and offices.” Tr. 1010–11. Similarly, after acknowledging that she filled controlled substance prescriptions for patients who lived a significant distance from the pharmacy, Respondent’s Owner and PIC justified her filling of the prescriptions, asserting, without any evidence to corroborate her claim, that “some of them are working locally and they all had a local doctor.” *Id.* at 1026.

Respondent’s Owner and PIC also testified that, “If the DEA provide me, do not fill for 100 miles, like—that’s why I said, I accepted my responsibility, I took remedial measures. I do not fill schedule II prescriptions in my pharmacy because of these conflicting red flags. Because it’s a practice of Florida to travel.” *Id.* at 1023–24. Respondent characterized this testimony as meaning that Respondent’s Owner and PIC accepted responsibility for filling long-distance prescriptions. Resp. Br., at 36; *see also* Resp. Exceptions, at 8. I specifically reject Respondent’s argument. Notably, this testimony began with the word “if” and

in any event, it does not constitute an acceptance of responsibility for violating the corresponding responsibility rule. Further, the testimony was not offered in the context of addressing Respondent’s filling prescriptions from its Florida customers who travelled long distances to patronize Respondent. Rather, the testimony was offered to address Respondent’s filling of prescriptions for out-of-state customers, specifically customers from Kentucky about whom Respondent’s Owner and PIC testified she had been “clearly instructed” by DEA. Tr. 1023.

Notably, at no point in the hearing did Respondent’s Owner and PIC accept responsibility, let alone accept responsibility unequivocally, for violating the corresponding responsibility regulation. Notably, the testimony of Respondent’s Owner and PIC manifests that she still does not acknowledge the scope of a pharmacist’s obligation under 21 CFR 1306.04(a). As one example, she testified that “[t]he prescription is an order for the pharmacist to fill. For me not to fill that prescription, I have to have a very good reason not to fill it, because it’s an order from the doctor to me to fill that prescription for that patient.” *Id.* at 1168. As the Agency has previously recognized, a registrant cannot accept responsibility for its misconduct when it does not even understand what the law requires of it. *Alexander*, 82 FR at 49,729. I agree with the CALJ’s conclusion that “there is no unequivocal acceptance of responsibility on this record that would be particularly helpful to the Respondent’s efforts to avoid a sanction.” R.D., at 58.

Here, the CALJ concluded that “the paltry nature of the Respondent’s acceptance of responsibility would have rendered remedial measure evidence largely irrelevant.” *Id.* In addition, Respondent’s misconduct included an egregious abdication of the corresponding responsibility requirement involving the dispensing of controlled substances such as Dilaudid 8 mg., a most potent and highly abused schedule II drug; the evidence also shows that Respondent committed extensive violations of other Federal and State legal requirements. Thus, due to the Respondent’s “paltry” acceptance of responsibility and its “intentional decision to decline to notice evidence of remedial steps” leading to the preclusion of that evidence from consideration, the CALJ recommended that “the record supports the imposition of a sanction.” *Id.* I find that this is the

appropriate result on the record in this case.

I agree with the CALJ’s assessment that, “[w]here no understanding is acquired about how the regulated conduct fell short of professional and federal and state legal standards, it would be difficult (even illogical) to predict improvement.” *Id.* at 59. I also agree with the CALJ’s prediction that Respondent “is likely to proceed in the future as it has in the past if not curtailed in its ability to do so.” *Id.* I further agree with the CALJ that the “sheer number of established transgressions of various types, coupled with the refusal to admit that issues existed, would render a sanction less than revocation as a message to the regulated community that due diligence is not a required condition precedent to operating as a registrant.” *Id.*

Respondent has not rebutted the Government’s *prima facie* showing that its continued registration is “inconsistent with the public interest.” 21 U.S.C. 823(f). I will therefore order that Respondent’s registration be revoked and that any pending applications be denied.

#### Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a) and 21 U.S.C. 823(f), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration FP1049546 issued to Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy be, and it hereby is, revoked. I further order that any pending application of Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy for renewal or modification of this registration be, and it hereby is, denied. This order is effective April 12, 2018.

Dated: February 28, 2018.

**Robert W. Patterson,**

*Acting Administrator.*

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## DEPARTMENT OF LABOR

### Office of the Secretary

#### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Voluntary Protection Program Information

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** The Department of Labor (DOL) is submitting the Occupational Safety and Health Administration (OSHA) sponsored information collection request (ICR) titled,

“Voluntary Protection Program Information,” to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

**DATES:** The OMB will consider all written comments that agency receives on or before April 12, 2018.

**ADDRESSES:** A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* website at [http://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=201711-1218-002](http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201711-1218-002) or by contacting Michel Smyth by telephone at 202-693-4129, TTY 202-693-8064 (these are not toll-free numbers) or by email at [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

Submit comments about this request by mail to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL-OSHA, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503; by Fax: 202-395-5806 (this is not a toll-free number); or by email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov). Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor—OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW, Washington, DC 20210; or by email: [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

**FOR FURTHER INFORMATION CONTACT:** Michel Smyth by telephone at 202-693-4129, TTY 202-693-8064 (these are not toll-free numbers) or by email at [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

**SUPPLEMENTARY INFORMATION:** This ICR seeks to extend PRA authority for the Voluntary Protection Program (VPP) information collection. The VPP is a partnership between labor, management, and government designed to recognize and promote excellence in safety and health management. In order to participate in the VPP, an applicant submits an application and an annual self-evaluation containing a detailed description of its safety and health management programs to the OSHA, which uses the information to conduct a preliminary analysis of the worksite's programs and to make a preliminary determination regarding the worksite's qualifications for the VPP. Occupational Safety and Health Act of 1970 section

2(b)(1) authorizes this information collection. *See* 29 U.S.C. 651(b)(1).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1218-0239.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on August 30, 2017 (82 FR 41294).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 128-0239.

The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

*Agency:* DOL-OSHA.

*Title of Collection:* Voluntary Protection Program Information.

*OMB Control Number:* 1218-0239.

*Affected Public:* Private Sector—businesses or other for-profits.

*Total Estimated Number of Respondents:* 3,468.

*Total Estimated Number of Responses:* 3,808.

*Total Estimated Annual Time Burden:* 90,863 hours.

*Total Estimated Annual Other Costs Burden:* \$0.

**Authority:** 44 U.S.C. 3507(a)(1)(D).

**Michel Smyth,**

*Departmental Clearance Officer.*

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**BILLING CODE 4510-26-P**

## DEPARTMENT OF LABOR

### Mine Safety and Health Administration

#### Affirmative Decisions on Petitions for Modification Granted in Whole or in Part

**AGENCY:** Mine Safety and Health Administration (MSHA), Labor.

**ACTION:** Notice.

**SUMMARY:** The Federal Mine Safety and Health Act of 1977 and the Code of Federal Regulations govern the application, processing, and disposition of petitions for modification. This **Federal Register** notice notifies the public that MSHA has investigated and issued a final decision on certain mine operator petitions to modify a safety standard.

**ADDRESSES:** Copies of the final decisions are posted on MSHA's website at <https://www.msha.gov/regulations/rulemaking/petitions-modification>. The public may inspect the petitions and final decisions during normal business hours in MSHA's Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202. All visitors are required to check in at the receptionist's desk in Suite 4E401.

**FOR FURTHER INFORMATION CONTACT:** Barbara Barron at 202-693-9447 (Voice), [barron.barbara@dol.gov](mailto:barron.barbara@dol.gov) (Email), or 202-693-9441 (Telefax). [These are not toll-free numbers].

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

Under section 101 of the Federal Mine Safety and Health Act of 1977, a mine operator may petition and the Secretary of Labor (Secretary) may modify the application of a mandatory safety standard to that mine if the Secretary determines that: (1) An alternative method exists that will guarantee no