investigator who testified at the hearing stated that, ''there was some ambiguity.'' Therefore, the Acting Deputy Administrator does not find Respondent's prescribing of controlled substances with his revoked DEA registration to be of significant concern in assessing the public interest. Particularly since Respondent immediately ceased writing controlled substance prescriptions upon being advised that his DEA registration was not valid.

As to factor five, the Acting Deputy Administrator is quite concerned with Respondent's long history of substance abuse. Respondent admitted to using cocaine and marijuana for 20 years. In the prior administrative proceeding, the then-Acting Administrator adopted the Administrative Law Judge's finding that ''there was insufficient evidence to conclude that Respondent has recognized and dealt with the severity of his problem, or that he has progressed in his recovery to the extent that he should be permitted to continue to hold a DEA registration.'' At the time of the hearing in this matter before Judge Tenney, Respondent had been in rehabilitation for five years. He has been randomly drug tested since 1991 and has not tested positive. He continues to participate in Cocaine Anonymous and Narcotics Anonymous and regularly receives psychological counseling. He has successfully completed his criminal probation, and in August 1994, his medical license was placed on probation for six years by the Medical Board of California. As part of this probation, Respondent is subject to random drug testing and his controlled substance handling is restricted. Respondent testified at the hearing before Judge Tenney that, ''I'm extremely remorseful. But I cannot change what happened.''

The Administrative Law Judge concluded that Respondent's registration would not be inconsistent with the public interest. But given his background of drug abuse, Judge Tenney recommended that Respondent's application be granted subject to his compliance with all of the terms of his probation with the Board.

The Government filed exceptions to the Administrative Law Judge's recommendation. First, the Government took exception to Judge Tenney's conclusion that Respondent was ''exempt'' from the provisions of the Controlled Substances Act due to his good faith prescribing of controlled substances when he was without a valid DEA registration. The Acting Deputy Administrator is confused by this exception, since the Government raised this same proposition in its post-hearing filing, but argued that Respondent had not acted in good faith. However, the evidence is clear that Respondent did in fact act in good faith, believing that he had a valid DEA registration. As discussed above, the Acting Deputy Administrator considers Respondent's good faith assumption that he was properly registered when he issued controlled substances prescriptions between March 3 and May 17, 1994, to be a mitigating factor when considering his compliance with Federal laws.

The Government also took exception to Judge Tenney's recommendation that Respondent's registration be conditioned upon compliance with the probationary terms imposed by the Board. The Government argued that such a disposition would be difficult to enforce since DEA would be unaware if, or when, the probationary terms were violated or removed. Therefore, the Government urged that ''should Respondent be granted any DEA registration, that it be restricted to terms and conditions established by DEA, and independent of any probationary terms currently imposed by the California Medical Board.'' The Acting Deputy Administrator finds that Respondent's efforts at rehabilitation are commendable and the controls imposed by the Board are sufficient to monitor Respondent's handling of controlled substances. Consequently, the Acting Deputy Administrator finds that it is in the public interest at this time to issue Respondent a DEA registration conditioned upon his continued compliance with the terms imposed upon his California medical license. The Acting Deputy Administrator further concludes, however, that should the Board terminate Respondent's probation before August 5, 2000, Respondent's DEA registration will continue to be subject to the same terms as set forth in the Board's August 5, 1994 decision.

The Acting Deputy Administrator finds that Respondent only applied for a DEA Certificate of Registration in Schedules IV and V. The Board's probationary terms restrict Respondent's handling of Schedules II and III controlled substances to inpatients in hospital settings. However, since Respondent has not applied for Schedules II and III privileges with DEA and no request to modify his application was made at the hearing in this matter, the Acting Deputy Administrator can only issue Respondent a DEA Certificate of Registration in Schedules IV and V at this time. Nonetheless, the Acting Deputy Administrator finds that should Respondent apply for Schedules II and III in the future, the application should be granted and Respondent's Schedules II and III handling should be restricted to inpatients in hospital settings, to include emergency room patients, and be conditioned upon compliance with the Board's terms and conditions.

Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 28 CFR 0.100(b) and 0.104, hereby orders that the application, submitted by Stanley Alan Azen, M.D., for a DEA Certificate of Registration in Schedules IV and V be granted subject to continued compliance with the terms imposed upon his California medical license. It is further ordered, that should Dr. Azen's probation be terminated early by the Medical Board of California, his DEA Certificate of Registration will continue, until August 5, 2000, to be subject to the same terms imposed by the August 5, 1994 decision of the Medical Board of California. This order is effective December 9, 1996.

Dated: November 4, 1996.

James S. Milford, Jr.,

Acting Deputy Administrator.

[FR Doc. 96–28765 Filed 11–7–96; 8:45 am]

BILLING CODE 4410–09–M

[Docket No. 95–1]

Margaret E. Sarver, M.D., Suspension of Registration; Reinstatement With Restrictions

On September 7, 1994, the Deputy Assistant Administrator (then-Director) of the Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Margaret E. Sarver, M.D. (Respondent) of Beaver Falls, Pennsylvania, notifying her of an opportunity to show cause as to why DEA should not revoke her DEA Certificate of Registration, AS1667623, and deny any pending applications for registration under 21 U.S.C. 823(f) and 824(a)(4), as being inconsistent with the public interest.

By letter dated October 12, 1994, the Respondent, through counsel, timely filed a request for a hearing, and following prehearing procedures, a hearing was held in Pittsburgh, Pennsylvania on August 15 and 16, 1995, before Administrative Law Judge Paul A. Tenney. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, both sides submitted proposed findings of fact, conclusions of law and argument. On January 29, 1996, Judge Tenney issued his Findings of Fact, Conclusions of Law and Recommended Ruling, recommending

that the Respondent's DEA registration should be revoked in Schedules II and III. On February 16 and 28, 1996, the Government and Respondent respectively, filed exceptions to the Recommended Ruling of the Administrative Law Judge, and on February 29, 1996, Judge Tenney transmitted the record of these proceedings to the Deputy Administrator. Subsequently, on March 1, 1996, Judge Tenney transmitted to the Deputy Administrator a facsimile from the Respondent for inclusion in the record.

The Acting Deputy Administrator has considered the record in its entirety, and pursuant to 21 CFR 1316.67, hereby issues his final order based upon findings of fact and conclusions of law as hereinafter set forth. The Deputy Administrator adopts the findings of fact and conclusions of law of Judge Tenney, except as noted below. However, for reasons explained below, the Acting Deputy Administrator rejects Judge Tenney's recommendation as to the appropriate disposition of this case.

The Acting Deputy Administrator finds that the Respondent is an internist with a general practice in Beaver Falls, Pennsylvania. She was Board Certified in Internal Medicine in 1965, and has maintained an active practice for approximately 31 years. Although, Respondent treats patients with a variety of medical problems, she has a special interest in weight loss.

Sometime prior to November 18, 1991, the Commonwealth of Pennsylvania, Department of Public Welfare, Bureau of Quality Assurance (DPW) identified Respondent as a frequent prescriber of the controlled substances, Seconal, Tuinal, Noludar, Nembutal, and the combination of glutethimide and acetaminophen with codeine. On November 18, 1991, DPW conducted an on-site review at Respondent's office to gather information about her medical practice and to copy 22 patient records. The DPW reviewers found Respondent's office to be ''unclean and unsanitory [sic]'' and discovered that her ''method of record keeping and billing was fragmented and disorganized.'' During the course of the review, Respondent stated that she prescribes sleeping medication upon request and admitted that some patients continue on such medication for months or years. Respondent also admitted that she was aware of the effect of the combination of glutethimide and codeine products, but stated that she prescribes this combination to patients with both legitimate sleeping and pain problems. The combination of glutethimide and codeine products is known as a ''set'' on the streets, and the effect of the two drugs taken together is similar to that of heroin. When asked by the DPW reviewers about her prescribing of this combination, Respondent replied, ''when you get drifters asking for Dilaudid and Demeral [sic], I don't think Tylenol #3 is all that bad.''

Following the on-site review, three physicians conducted a peer review of the 22 medical records copied during the on-site review. This peer review concluded *inter alia* that all of the drug regimens prescribed for these patients by Respondent ''failed to comply with [Medical Assistance] Standards of Practice due to insufficient appropriateness and/or necessity of the drugs prescribed.'' As a result of the investigation, the DPW concluded, in part, that Respondent's treatment for one patient was contrary to medical assistance regulations in that she ''prescribed drugs of high abuse potential . . . in a manner determined after medical record review to be of inferior quality and/or medically unnecessary.'' DPW further concluded that Respondent ''prescribed drug regimens of high abuse potential (Percocet, Vicodin, Tylenol w/codeine, Seconal, Hycotuss, Glutethimide, Tuinal, Noludar) for twenty-two (22) recipients whose medical records failed to sufficiently document the appropriateness and necessity of the drugs prescribed.'' By letter dated June 15, 1992, the DPW proposed to terminate the Respondent as a provider, to preclude Respondent from participation in the Medical Assistance Program for a period of four years. Respondent requested a hearing regarding the proposed sanctions, stating that the DPW did not have the complete medical records on each of the 22 patients whose medical records were reviewed in the course of the investigation. Respondent stated that the DPW reviewer had not told her that they needed all her notes on each patient, and that there was additional patient chart material waiting to be filed in the records. The DPW action against Respondent was settled without sanctions, however, there is no evidence in the record as to the basis for this resolution.

In July 1992, a DEA investigator interviewed a confidential informant who stated that he had once been a patient of Respondent's and had been able to obtain controlled substances, including the combination of glutethimide and Tylenol with codeine, from Respondent without a medical examination. As a result of this information, as well as the DPW investigation, DEA investigators visited approximately 27 area pharmacies to collect prescriptions allegedly written by Respondent. The investigators discovered that some of the pharmacies would no longer fill Respondent's prescriptions due to suspicions that the individuals receiving the prescriptions were drug dependent. At no time did the investigators instruct the pharmacies to stop filling Respondent's prescriptions. Among the concerns expressed by the pharmacists were Respondent's frequent prescribing of the combination of glutethimide and Tylenol with codeine; prescriptions written by Respondent were often from outside the pharmacy's trade area; and Respondent's prescriptions were sometimes post-dated.

In September 1992, the DEA investigators interviewed Respondent, specifically questioning her about her prescribing practices, including the glutethimide and Tylenol with codeine combinations. The investigators informed Respondent of the dangers of taking these medications together, that they produce a heroin-like effect, and that glutethimide should not be taken with narcotics. Respondent stated that if DEA believes that those drugs are dangerous, DEA should take them off the market. Respondent continued to prescribe combinations of glutethimide and codeine products after being warned by both DPW and DEA of the danger and abuse potential.

During the course of the investigation, the DEA investigators interviewed a number of Respondent's patients. In January 1993, they interviewed three of Respondent's patients as they left her office. One indicated that he had been seeing Respondent upon the recommendation of his girlfriend, who informed him that he could get prescriptions for controlled substances from Repondent. Another indicated that she had been a patient of Respondent's for 19 years, and only goes to Respondent now because she is addicted to various controlled substances and is able to get them from Respondent. Each had 4 prescriptions for various Schedule II through IV controlled substances including, glutethimide, Seconal, Tylox, acetaminophen with codeine, Hycodan, Vicodin, Adipex, diazepam and Didrex. One had a prescription written by Respondent for glutethimide for her son. Two indicated that other than being weighed and occasionally having their blood pressure or pulse checked, no other examination was performed during office visits before controlled substance prescriptions were issued. Two indicated that they were not given

instructions on how to take the various medications in combination with one another. Respondent's medical charts on these individuals indicated a variety of medical conditions.

In November 1993, DEA investigators interviewed M.S. and L.O. patients of Respondent. M.S. informed the investigators that he had initially gone to Respondent because he had heard on the street that she would prescribe the drugs people wanted. He admitted that he was addicted to Vicodin, that he was attending a methadone clinic, and that he sometimes sold some of Respondent's prescriptions. In a subsequent affidavit, M.S. denied selling Respondent's prescriptions. M.S. indicated to the investigators that other than having his weight and occasionally his blood pressure and/or pulse checked, Respondent did not perform a physical examination. Records in Respondent's possession indicated that M.S. suffered from dependencies to various drugs, including Dilaudid and Percocet, both Schedule II controlled substances. An investigator testified that L.O. stated that she also was addicted to drugs prescribed by Respondent, including Vicodin and Ativan, a Schedule IV controlled substance. She also was enrolled in a methadone treatment program. However, in a subsequent affidavit, L.O. stated that she did not tell the investigators that she was addicted to her medication. Respondent placed into evidence the medical records for these individuals. The records indicated a variety of medical conditions.

In February 1994, the investigators interviewed a husband and wife who initially went to Respondent for weight loss and back problems. They admitted obtaining prescriptions for controlled substances from Respondent without a medical examination, and sometimes without an office visit. According to the wife, Respondent would sometimes leave them prescriptions behind the office's screen door along with prescriptions for others. They indicated that they were examined on their first visit, but that since then they were only weighed and occasionally their blood pressure was checked. They told the investigators that they received Schedule II through IV controlled substances from Respondent, including Dilaudid, Percocet, Seconal, Hycodan, Vicodin, Adipex, and Soma with codeine. Respondent did tell them that the prescribed drugs were addictive but did not give them any instructions regarding taking the drugs in combination with each other. Respondent's records on these individuals indicated various medical problems/conditions.

In addition to conducting patient interviews, DEA monitored the visits of two of Respondent's patients, B.S. and K.C., who had agreed to cooperate with DEA. On February 16 and March 16, 1993, B.S. went to Respondent's office in an undercover capacity. As was her normal practice, before each visit, B.S. prepared a list of the controlled substances that she wanted Respondent to prescribe for her. On each occasion she obtained prescriptions for 100 dosage units of diazepam, 30 dosage units of Tylox, 60 dosage units of Adipex, 50 dosage units of acetaminophen with codeine (with one refill on the second visit), 60 glutethimide, and 8 ounces of Tussi-Organidin (with five refills on the second visit), a Schedule V cough syrup. On the first visit, B.S. had asked for Hycodan cough syrup, which Respondent did not prescribe, instead substituting Tussi-Organidin, stating that Hycodan was difficult to find at local pharmacies. Other than being weighed, no other physical examination was performed during either visit. On the first visit, B.S. also gave Respondent a list of desired prescriptions, including glutethimide, Darvocet and Vicodin, for her son who would not be present. Respondent did not issue any prescriptions for B.S.'s son since he had not been in for an office visit for quite awhile. At the hearing before Judge Tenney, Respondent admitted, however, that she had issued prescriptions for B.S.'s son without seeing him because he suffers from emotional problems and does not like to go to the office himself.

The second cooperating patient, K.C., went to Respondent's office on January 31 and February 28, 1994. On both occasions, K.C. received several prescriptions for controlled substances. No medical examination was conducted nor was there an inquiry into her medical condition. Respondent merely asked K.C. what prescriptions she needed and how much of each medication she wanted. Respondent put into evidence documents that indicate K.C.'s medical history.

In August 1993, DEA executed a search warrant at Respondent's office authorizing the seizure of 81 patient records. At the hearing before Judge Tenney, Respondent testified that her medical files on each patient consisted of a manila folder stored in a file cabinet, carbon copies of all prescriptions issued to each patient, and a medical card on each patient. During the execution of the warrant, Respondent told the DEA personnel where the medical files were located, and at no time did she indicate that the medical files seized were not the complete medical record on each patient.

A medical doctor, who is a board certified clinical pharmacologist from the University of Pittsburgh Medical School, reviewed seven of the seized patient records, as well as prescription profiles for the seven individuals, and concluded that there did not appear to be a relationship between the drugs prescribed and the established medical problems. He further opined that the drugs were not prescribed in the course of legitimate medical practice and were prescribed in a manner contrary to that utilized by a majority of medical practitioners. Respondent claimed that the reviewer ignored many of the medical diagnoses found in the patients' records. At the hearing, it was revealed that there were several inaccurate dates and amounts/refills noted in the reviewer's report. Respondent further testified that this review was incomplete, and therefore inaccurate, since the reviewer did not have all of Respondent's information regarding the seven patients. The DEA personnel did not seize the card files for each patient when they executed the search warrant. However, she did not inform the DEA personnel about the card files. She testified at the hearing that she knew that the DEA personnel were not getting the complete medical records of the 81 patients, but ''I just let it go.'' In addition, the exhibit that is Respondent's response to the reviewer's report stated that, ''* * * [DEA] did not get my most important records on the patients—they thought they did, and I let them think so. * * *''

Respondent testified that she does not do a complete physical examination of each patient on every visit because many of her patients are long-term patients, that she sees on a regular basis. She also testified that she tells patients how to use prescribed medication and all of her prescriptions have instructions on them. However, if a patient has been receiving prescriptions for a certain medication, she does not explain its use every time she issues a prescription. Respondent was often not aware of the schedule of drugs she regularly prescribed. She admitted at the hearing that she occasionally post-dated controlled substance prescriptions, however, she did not know that that practice violated Federal regulations. See 21 CFR 1306.05(a). Respondent testified before Judge Tenney that she had heard that the combination of glutethimide and Tylenol with codeine was used on the street from one pharmacist and from the DEA

investigators in 1992. She stated that ''I had never heard it from anyone else.''

Respondent also testified that she only prescribes controlled substances if there is a medical indication for the drug. If she suspects that a patient is lying about his or her symptoms, or the patient is abusing or selling the prescribed substances, Respondent will discontinue treatment. In fact, Respondent had terminated the treatment of several of the patients that had been interviewed by DEA or whose medical records were reviewed by the clinical pharmacologist.

In her post-hearing filings, Respondent argues that all or much of the evidence used against her is hearsay, which uncorroborated cannot be substantial evidence. Respondent's Motion to Strike Hearsay Evidence is denied. ''* * * [H]earsay is both admissible and may, standing by itself, constitute substantial evidence in support of an administrative decision.'' Klinestiver v. Drug Enforcement Administration, 606 F.2d 1128 (D.C. Cir. 1979) (citing Richardson v. Perales, 402 U.S. 389 (1971)). It is significant in this case, as it was in Klinestiver and Perales, that Respondent did not subpoena any of the key declarants relied upon by the Government thereby providing herself the opportunity for cross-examination.

Pursuant to 21 U.S.C. §§ 823(f) and 824(a)(4), the Deputy Administrator may revoke or suspend a DEA Certificate of Registration and deny pending applications, if he determines that the continued registration would be inconsistent with the public interest. Section 823(f) requires that the following factors be considered:

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

(2) The applicant's experience in dispensing, 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 or safety. These factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight he deems appropriate in determining whether a registration should be revoked or an application for registration be denied. See Henry J. Schwarz, Jr., M.D., Docket No. 88–42, 54 FR 16,422 (1989).

In this case, factors two, four, and five are relevant in determining whether the Respondent's retention of her Certificate of Registration would be inconsistent with the public interest. As to factor two, the clinical pharmacologist and the three DPW peer reviewers all criticized Respondent's prescribing practices. While it appears that the DPW has settled its investigation of Respondent with no sanctions, there is nothing in the record to indicate the basis for this resolution. There does however appear to be some question as to whether the DPW peer reviewers had Respondent's complete medical records when rendering their opinions, which will be discussed in detail below. Therefore, unlike Judge Tenney, the Acting Deputy Administrator finds the conclusions of the DPW peer reviewers to be of little relevance in determining Respondent's experience in dispensing controlled substances. Respondent argues that the clinical pharmacologist's review was incomplete based upon his failure to consider the medical diagnoses in the records provided; inaccuracies in dates and amounts of controlled substances prescribed; and most importantly, because the reviewer did not have Respondent's complete medical records when rendering his opinion. The reason that the reviewer did not have the patients' complete medical records will be discussed in connection with factor five. However, while not specifically found by Judge Tenney, the Acting Deputy Administrator concludes that the fact that the reviewer did not have the complete medical records does significantly minimize the weight to be given to his conclusions regarding Respondent's prescribing practices. Nevertheless, there is other evidence that seriously calls into question Respondent's dispensing of controlled substances.

At least three area pharmacists expressed concerns about the combination of drugs prescribed by Respondent, the types of patients bringing in prescriptions written by Respondent, and the fact that some of the prescriptions were post-dated. The Acting Deputy Administrator is extremely troubled by Respondent's frequent prescribing of the highly abused combination of glutethimide and codeine produces which produces a heroin-like effect. As Judge Tenney noted, Respondent was repeatedly advised of the effect of this combination and its potential for abuse. In November 1991, Respondent indicated to DPW that she was aware of the effect of this combination of drugs, but stated that, ''when you get drifters asking for Dilaudid and Demeral [sic], I don't think Tylenol No. 3 is all that bad.'' Respondent indicated at the hearing in this matter that a local pharmacist had also called to her attention the dangers of this combination. Then in September 1992, when DEA investigators questioned Respondent about her prescribing of this combination of drugs, Respondent stated that if the DEA does not want people taking these medications, the drugs should not be on the market. Despite these warnings, Respondent continued to prescribe the combination of these drugs to her patients. As the Government noted, in a recent case, the DEA Administrator concluded that:

> [r]egarding factor two, Respondent's experience in dispensing controlled substances is poor based on his prescribing the combination of Tylenol with codeine and Doriden [the brand name for glutethimide] to an individual, *especially when Respondent was aware that this combination was subject to abuse.* Leonard Merkow, M.D., 60 FR 22,075 (1995) (emphasis added).

Respondent's complete disregard for the warnings about the prescribing of this combination, as well as her statements to DPW and DEA personnel about the drugs, reflects poorly on her experience in dispensing controlled substances. As Judge Tenney noted, ''Respondent's prescribing practices in this situation evidences a disregard to the danger to her patients and the community at large by prescribing such a highly abused combination of drugs.''

The Acting Deputy administrator concurs with the Government's contention that Respondent's lack of knowledge, and apparent disinterest, in the schedule of the substances she was actively prescribing is evidence of her cavalier attitude towards the proper dispensing of controlled substances. In addition, Respondent's careless behavior is further evidenced by her prescribing of glutethimide to patients with sleeping disorders. On most of her prescriptions for glutethimide, Respondent indicated a dosage of 1 or 2 tablets at bedtime, yet one of Respondent's patients received prescriptions for a total of 250 dosage units over a 79 day period. In addition, some of Respondent's prescriptions contained the instructions to take one tablet at bedtime ''PRN'', which according to Respondent means ''as needed for pain''. Glutethimide is not a pain medication, and according to Respondent was meant to be used as a sleeping aid. As argued by the Government, ''Respondent's prescribing of and directions for use for powerful controlled substances demonstrate an

alarming lack of experience and lack of concern for her patients' welfare.''

As further evidence of Respondent's casual approach to the handling of controlled substances is the fact that she seems to allow patients to determine what controlled substances they will be prescribed and in what amount. This behavior was clearly evident during the undercover visits by Respondent's patients. Allowing a patient to dictate the drug and drug quantity is a highly suspicious practice and clearly conduct which threatens the public health and safety. See Robert L. Dougherty, Jr., M.D., 60 Fed. Reg. 55,047 (1995). Also, patients stated, and Respondent admitted at the hearing, that she sometimes issues controlled substance prescriptions without even seeing the patient. The Government argued that Respondent would issue controlled substance prescriptions without conducting a physical examination. Respondent testified that she does conduct a physical examination on the initial visit, and when one is medically indicated. The Acting Deputy Administrator concurs with Judge Tenney that, ''when seeing a patient on a frequent basis, a complete physical examination may not be necessary every time.''

Additionally, Respondent has maintained several patients on controlled substances for prolonged periods of time, in contradiction of information contained in the Physician's Desk Reference (PDR). For example, as Judge Tenney noted, five patients were prescribed Hycodan cough syrup for extended periods of time. However, the PDR warns that ''physical dependence, the condition in which continued administration of the drug is required to prevent the appearance of a withdrawal syndrome, assumes clinically significant proportions only after several weeks of continued . . . use, although some mild degree of physical dependence may develop after a few days of narcotic therapy.'' Respondent admitted to prescribing Hycodan for a few patients for periods of approximately two years.

According to the PDR, Adipex is indicated for the ''management of exogenous obesity as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction,'' and ''tolerance to the anorectic effect develops within a few weeks.'' Respondent prescribed Adipex to several of her patients for over a year or two. Regarding Seconal, the PDR states that it is indicated for the ''short term treatment of insomnia, since it seems to lose its effectiveness for sleep induction and sleep maintenance after 2 weeks,'' and ''should not be administered in the presence of acute or chronic pain. . . .'' The recommended dose for sleeping disorders is 100 mg. at bedtime. The record indicates that Respondent issued Seconal prescriptions to several individuals over extended periods of time; she wrote a number of Seconal prescriptions to an individual, who according to Respondent, was suffering from acute back pain; and between May 26, 1992 and September 28, 1992, Respondent prescribed a total of 325 dosage units of Seconal (100 mg.) to an individual, well over the recommended dosage.

The Acting Deputy Administrator is aware that the PDR is a reference tool and that a physician is not bound by its information. However, Respondent's prolonged maintenance of patients on the above-referenced medications, along with the other evidence of Respondent's questionable prescribing practices, raised extremely serious concerns about Respondent's ability to responsibly dispense potentially dangerous and highly abused controlled substances.

As to factor four, ''compliance with applicable State, Federal, or local laws,'' the DPW reviewers concluded that Respondent violated various Pennsylvania Medical Assistance regulations. DPW found that Respondent's prescribing of controlled substances in a manner deemed to be of inferior quality and/or medically unnecessary constituted a violation of 55 Pa. Code 1101.77(a)(10), and that Respondent prescribed drug regimens of high abuse potential for 22 medical assistance recipients whose medical records failed to document sufficiently the appropriateness and necessity of the drugs prescribed in violation of 55 Pa. Code 1101.51(d)(1). However, unlike Judge Tenney, the Acting Deputy Administrator is unable to determine whether Respondent was in fact in violation of these provisions since as discussed above, the DPW reviewers did not appear to have Respondent's complete medical records in rendering their opinions.

The Acting Deputy Administrator does conclude that Respondent violated Federal regulations relating to controlled substances. Respondent admitted that she would on occasion post-date prescriptions which is a violation of 21 CFR 1306.05(a). Respondent testified at the hearing that she was unaware that this was a violation and did it when her patients could not pay for a full month's supply at once or when they would not be available to pick up their prescriptions at a later date.

As to factor five, ''such other conduct which may threaten the public health and safety,'' the Acting Deputy Administrator finds that Respondent's unconscionable failure to turn over her complete medical records during DEA's execution of the search warrant shows a lack of respect for the law. As Judge Tenney found, Respondent was present when the warrant was served. She testified at the hearing that she intentionally did not tell the agents that they were not retrieving the complete records on each patient, and she knew, or should have known that the DEA would require the full medical records in order to complete its investigation. This is especially distressing in light of DPW's earlier review of her prescribing practices, when Respondent complained that the DPW peer reviewers could not accurately review her records for sufficiency, since the reviewers did not have her complete patient records. Nonetheless, Respondent's failure to turn over her complete records to DPW and DEA does in fact call into question the DPW peer reviewers' and the clinical pharmacologist's conclusions that Respondent did not prescribe controlled substances for legitimate medical purposes and that her records were inadequate to justify the prescribing. The Acting Deputy Administrator is not happy that Respondent will benefit from her failure to cooperate with DPW and DEA, but the Acting Deputy Administrator is unable to draw any conclusions as to the legitimacy of Respondent's prescriptions or sufficiency of her medical records based upon the DPW peer reviewers' and the clinical pharmacologist's reviews.

But regardless of the inability of the Acting Deputy Administrator to rely on these reviews, there is ample other evidence in the record that illustrates Respondent's callous disregard for the proper and careful handling of controlled substances. The Acting Deputy Administrator is profoundly troubled by Respondent's unwillingness to recognize the seriousness of her prescribing practices, most significantly regarding the combination of glutethimide and Tylenol with codeine, and allowing patients to dictate what controlled substances they receive. In a previous case, the Administrator found that a pharmacist's ''refusal to acknowledge the impropriety of his dispensing practices . . . even after the initiation of this investigation, give[s] rise to the inference that [he] is not likely to act more responsibly in the future.'' Medic-Aid Pharmacy, 55 FR 30,043 (1990).

In his opinion, Judge Tenney noted as mitigating factors that Respondent has maintained a medical practice for 31 years, during which time the state licensing board has not taken any adverse action against her medical license, and until 1991, neither had DPW or DEA. In addition, Judge Tenney recognized Respondent's efforts to identify and discontinue treatment of patients who she suspected of abusing controlled substances. Judge Tenney recommended that Respondent's DEA registration be revoked in Schedules II and III, the more serious classes of controlled substances.

Both parties filed exceptions to Judge Tenney's recommended decision. In essence, the Government argued that Respondent's DEA registration should be revoked in all schedules, not just in Schedules II and III. In support of its exceptions, the Government contended that Respondent ''indiscriminately prescribed a variety of controlled substances, including Schedule IV and V controlled substances. . . .'' The Government further argued that ''[w]hile revoking Respondent's authority with respect to Schedule II and III controlled substances may prevent the diversion of some dangerous drugs, it will not protect the public from the diversion of Schedule IV and V controlled substances, many of which are highly abused.'' The Acting Deputy Administrator agrees with the Government, that any sanction taken against Respondent's registration should not be limited to Schedule II and III controlled substances, since the practices of Respondent that threaten the public health and safety are not confined to drugs in those schedules.

A significant amount of Respondent's exceptions dealt with the Administrative Law Judge's reliance on the reviews of Respondent's records conducted by DPW and the clinical pharmacologist. As discussed previously, the Acting Deputy Administrator has reluctantly declined to rely on those reviews since they were not based, through no fault of their own, upon Respondent's complete medical records. In addition, Respondent takes exception to Judge Tenney's finding that Respondent knew about the abuse of the combination of glutethimide and Tylenol with codeine prior to November 1991, yet continued to prescribe that combination of drugs to her patients. The Acting Deputy Administrator does not believe that the Administrative Law Judge made such a finding. Instead, Judge Tenney found, and the Acting Deputy Administrator concurs, that the evidence clearly shows that Respondent continued to prescribe this extremely dangerous combination after November 1991, when she acknowledged being aware of its heroin-like effect.

Also as stated in her exceptions, ''[i]t is the Respondent's position that the Administrative Law Judge disregarded the information admitted through her exhibits at hearing.'' The Acting Deputy Administrator has carefully considered all evidence submitted in this proceeding in rendering his decision. Further, Respondent continues to object to the consideration of hearsay evidence. The Acting Deputy Administrator has already addressed and rejected this exception.

The Acting Deputy Administrator concludes that some sanction is necessary against Respondent's DEA Certificate of Registration in order to protect the public interest. This conclusion is based upon Respondent's continued prescribing of the heroin-like combination of glutethimide and codeine products after acknowledging its dangerous nature, her allowing patients to dictate the type and amount of controlled substances to be prescribed, her overprescribing of highly addictive controlled substances in contradiction of the PDR, her refusal to comply with the mandate of a criminal search warrant, and her refusal to acknowledge the impropriety of her prescribing practices. However, the record does not clearly establish that these substances were prescribed for no legitimate medical purposes. Accordingly, the Acting Deputy Administrator does not believe that Respondent's behavior warrants the severe sanction of revocation.

The Acting Deputy Administrator concludes that in order to protect the public interest, Respondent needs to be better educated in the proper handling and effects of controlled substances. Therefore, the Acting Deputy Administrator will suspend Respondent's DEA registration for at least 120 days and until she presents evidence to the Resident Agent in Charge of the DEA Pittsburgh Resident Office, or his designee, of the successful completion of at least 24 hours of training in the pharmacology and/or proper handling of controlled substances. Once Respondent has satisfied this requirement, her DEA Certificate of Registration will be reinstated subject to the following restriction: Respondent shall maintain a separate log of all prescriptions that she issues. At a minimum, the log shall indicate the date that each prescription was written, the name of the patient for whom it was written, the name and dosage of the controlled substance(s) prescribed, and the medical indication for the substance prescribed. The Respondent shall maintain this log for a period of three years from the reinstatement of her DEA Certificate of Registration. Upon request by the Resident Agent in Charge of the DEA Pittsburgh Resident Office, or his designee, the Respondent shall submit or otherwise make available her prescription log for inspection.

Accordingly, the Acting Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. §§ 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that DEA Certificate of Registration, AS1667623, issued to Margaret E. Sarver, M.D., be suspended for at least 120 days and until she presents evidence of the successful completion of 24 hours of training in the pharmacology and/or proper handling of controlled substances. It is further ordered that upon receipt of such evidence, Dr. Sarver's DEA Certificate of Registration will be reinstated subject to the restriction outlined above. This order is effective December 9, 1996.

Dated: November 4, 1996.

James S. Milford, Jr.,

Acting Deputy Administrator.

[FR Doc. 96–28766 Filed 11–7–96; 8:45 am]

BILLING CODE 4410–09–M

Federal Bureau of Investigation

Agency Information Collection Activities: Proposed Collection; Comments Requested

ACTION: Notice of information collection under review; telecommunications carrier reimbursement cost estimate and telecommunications carrier reimbursement request for payment.

Office of Management and Budget (OMB) approval is being sought for the information collection listed below. This proposed information collection was previously published on April 10, 1996, in the Federal Register and allowed 60 days for public comment.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until January 7, 1996. This process is conducted in accordance with 5 CFR 1320.10. Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk