

been used as a vehicle to boycott the new Health Center. Subjecting a messenger model network to a 30% limit on participation, as well as to the other qualified managed care plan limitations, is not only the most effective way to prevent a boycott from being effective, but also makes compliance easily verifiable.¹ Allowing defendants to operate a messenger model that does not require DOJ approval and does not limit the number of physicians who can participate, would be imprudent and would jeopardize the efficacy of the Final Judgment. Consequently, we believe that any network operated by defendants based on a messenger model should be subject to all the limitations placed on a qualified managed care plan.

A 30% participation limitation on the messenger model would also have a significant deterrent effect on any attempts to use the messenger model as a means to coordinate pricing because managed care plans competing with the Woman's Hospital/WPHO qualified managed care plan could exclude the 30% of the doctors involved in the price fix. Consequently, there would be little incentive for only 30% of the physicians to agree on prices. Therefore, the 30% participation limit goes a long way toward preventing such an agreement from taking place.

If it is important to prevent both price fixing and boycott activity via the formation of a managed care plan, it is illogical to address only the price fixing potential inherent in a negotiating organization of physician and hospital providers. The use of the messenger model alone does not address the potential for such a negotiating organization to be the vehicle for organizing a boycott. Without limitations such as those placed on qualified managed care plans, a messenger model could be a vehicle for providers to collectively agree not to deal. Similarly, we cannot see any distinction between a messenger model and qualified managed care plan that justifies not requiring prior written DOJ approval for operating a messenger model. Consequently, we believe that the messenger model should be limited to participation by 30% of the physicians in any relevant market, and should be subject to the other restrictions placed on qualified managed care plans. Finally, we recommend that the defendants and

consenting physicians also be required to obtain prior written approval from the DOJ before forming, operating, owning an interest in, or participation in a messenger model.

Certificate of Service

I, Pamela Girardi, hereby certify that copies of the United States' Response to Public Comments in *U.S. v. Women's Hospital Foundation and Woman's Physician Health Organization*, Civ. No. 96-389-B-MZ were served on the 15th day of August 1996 by first class mail to counsel as follows:

John J. Miles,

*Ober, Kaler, Grimes & Shriver, Fifth Floor,
1401 H Street, NW., Washington, DC 20005.*

Toby G. Singer,

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Pamela C. Girardi.

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Drug Enforcement Administration

Mitchell F. West, D.O., Denial of Application

On January 24, 1996, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Mitchell F. West, D.O., (Respondent) of Bethel Park, Pennsylvania, notifying him of an opportunity to show cause as to why DEA should not deny his application, dated July 7, 1993, for a DEA Certificate of Registration pursuant to 21 U.S.C. 823(f), as being inconsistent with the public interest. The order also notified the Respondent that, should no request for a hearing be filed within 30 days, the hearing right would be deemed waived. The order was mailed by certified mail, and a signed return receipt dated January 30, 1996, was received by the DEA. However, no request for a hearing or any other reply was received by the DEA from the Respondent or anyone purporting to represent him in this matter. Subsequently, on March 25, 1996 the investigative file was transmitted to the Deputy Administrator for final agency action.

Therefore, the Deputy Administrator, finding that (1) thirty days have passed since the issuance of the Order to Show Cause, and (2) no request for a hearing has been received, concludes that the Respondent is deemed to have waived his hearing right. After considering relevant material from the investigative file in this matter, the Deputy Administrator now enters his final order

without a hearing pursuant to 21 CFR 1301.54(e) and 1301.57.

The Deputy Administrator finds that, in July of 1992, the Respondent voluntarily surrendered his DEA Certificate of Registration prior to receiving a misdemeanor conviction in the Court of Common Pleas of Allegheny County, Pennsylvania, for prescribing controlled substances "not in good faith in the course of this professional practice." On July 7, 1993, the Respondent applied for a new Certificate of Registration, disclosing his prior voluntary surrender and for circumstances surrounding that event.

Further investigation disclosed that on September 23, 1993, and on October 8, 1993, the Respondent unlawfully wrote prescriptions without a legitimate medical purpose, and obtained possession of Schedule II controlled substances containing oxycodone. Consequently, on May 16, 1994, the Respondent pleaded guilty to two counts of unlawful possession of controlled substances by misrepresentation, in violation of the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act, (Drug Act) resulting in a state felony conviction. The investigation revealed that the Respondent had a substance abuse problem, and as part of his court sentence, he was ordered to seek evaluation for substance abuse and to "follow all treatment recommendations."

Also, on July 20, 1994, the Respondent pleaded guilty to one count of delivering a controlled substance in violation of the Drug Act, again a felony offense. Consequently, on December 5, 1994, the State Board of Osteopathic Medicine (Board) ordered the Respondent to "cease and desist immediately from the practice of osteopathic medicine in the Commonwealth of Pennsylvania" because of his felony convictions. From these facts, the Deputy Administrator infers that, since the Respondent is not authorized to practice medicine in Pennsylvania, he also lacks authorization to handle controlled substances in that state.

The Drug Enforcement Administration cannot register a practitioner who is not duly authorized to handle controlled substances in the state in which he conducts his business. See 21 U.S.C. 823(f) (authorizing the Attorney General to register a practitioner to dispense controlled substances only if the applicant is authorized to dispense controlled substances under the laws of the state in which he or she practices); and 802(21) (defining "practitioner" as one

¹ While 30% of the physicians in a market could attempt a boycott, it is unlikely they would try because a boycott consisting of only 30% of the physicians in any relevant market would undoubtedly, and obviously fail.

authorized by the United States or the state in which he or she practices to handle controlled substances in the course of professional practice or research). This prerequisite has been consistently upheld. See Dominick A. Ricci, M.D., 58 FR 51,104 (1993); James H. Nickens, M.D., 57 FR 59,847 (1992); Roy E. Hardman, M.D., 57 FR 49,195 (1992); Myong S. Yi, M.D., 54 FR 30,618 (1989); Bobby Watts, M.D., 53 FR 11,919 (1988).

Further, pursuant to 21 U.S.C. 823(f), the Deputy Administrator may deny an application for a DEA Certificate of Registration if he determines that granting the 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 and 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 denied. See Henry J. Schwarz, Jr., M.D., Docket No. 88-42, 54 FR 16422 (1989).

In this case, all five factors are relevant in determining whether granting the Respondent's application would be inconsistent with the public interest. As to factor one, "recommendation of the appropriate State licensing board * * *", the Board, after reviewing the Respondent's unlawful professional conduct, ordered the Respondent to cease the practice of osteopathic medicine in Pennsylvania. It is therefore reasonable to infer, and the Respondent does not deny, that because he is not authorized to practice medicine, he is not authorized to handle controlled substances in Pennsylvania as a result of the Board's order.

As to factor two, the Respondent's "experience in dispensing * * * controlled substances," factor three, the Respondent's "conviction record under Federal or State laws relating to * * * controlled substances", and factor four, the Respondent's "[c]ompliance with

applicable State, Federal, or local laws relating to controlled substances," it is undisputed that the Respondent has received two state felony convictions since September of 1993, for violating the Drug Act by unlawfully possessing controlled substances, and unlawfully delivering controlled substances. Such conduct directly violates the public's interest in the continuation of lawful and safe handling of controlled substances.

Finally, as to factor five, "[s]uch other conduct which may threaten the public health and safety," the Deputy Administrator finds it significant that the Respondent demonstrated a blatant disregard of Federal legal requirements by knowingly handling controlled substances without possessing a DEA Certificate of Registration; in fact, he engaged in such conduct while his application for a registration was pending. Further, the Respondent's failure to respond to the Order to Show Cause, either by requesting a hearing or by submitting a written response, indicates that he is either unwilling or unable to proffer support at the present time for his application.

Therefore, the Deputy Administrator finds that the public interest is best served by denying the Respondent's application. Accordingly, the 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 Respondent's application for a DEA Certificate of Registration be, and it hereby is, denied. This order is effective September 23, 1996.

Dated: August 13, 1996.

Stephen H. Greene,

Deputy Administrator.

[FR Doc. 96-21416 Filed 8-21-96; 8:45 am]

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DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

August 16, 1996.

The Department of Labor (DOL) has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35). Copies of these individual ICRs, with applicable supporting documentation, may be

obtained by calling the Department of Labor Acting Departmental Clearance Officer, Theresa M. O'Malley ((202) 219-5095). Individuals who use a telecommunications device for the deaf (TTY/TDD) may call (202) 219-4720 between 1:00 p.m. and 4:00 p.m. Eastern time, Monday through Friday.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for (BLS/DM/ESA/ETA/OAW/MSHA/OSHA/PWBA/VETS), Office of Management and Budget, Room 10235, Washington, DC 20503 ((202) 395-7316), within 30 days from the date of this publication in the Federal Register.

The OMB is particularly interested in comments which:

- * 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: Employment and Training Administration.

Title: Quarterly Determinations, Allowance activities and Employability Services Under the Trade Act; Training Waivers Issued and Revoked.

OMB Number: 1205-0016.

Agency Number: ETA-563. ETA-9027.

Frequency: Quarterly.

Affected Public: State, Local or Tribal Government.

Form	Re-sponses	Average time per response (minutes)	Total burden
ETA-563.	45 (average 95 reports per quarter).	12	3,420
ETA-9027.	52	15	52

Total Burden Hours: 3,472.

Total Annualized capital/startup costs: 0.