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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Dear Sir or Madame:

The purpose of this letter is to provide comment to the Proposed Rule (Docket No. 98N-0617) revising the Federal regulatory requirements for Opioid Treatment Programs (OTP's). Specifically, the purpose of this letter is to request the Secretary to rescind the proposed rule restricting recognition of State agencies as accreditation organizations to those accrediting at least 50 OTP's and instead promulgate rules to ensure adequate quality of accreditation services and to ensure provision of the core elements of accreditation.

The Proposed Rule states that "...the Secretary is proposing in Sec. 8.3 to limit eligibility to those applicants (including States and political subdivisions of a State) who demonstrate that they will be able to accredit at least 50 OTP's per year. The Secretary believes that this requirement is needed to ensure the quality of the accreditation services performed by accreditation bodies and to minimize the variability in the standards used by accrediting organizations. The Secretary is interested in comments on this restriction and may revisit this requirement after the first 3 years."

The Secretary should revisit this requirement immediately.

It is my understanding that this would tacitly limit recognition of State agencies as accrediting bodies to California, New York, and Texas. I am unaware of any evidence that these three states have accreditation services of greater quality than those of the remaining 47 States, American Samoa, the District of Columbia, the Federated States of

Micronesia, Guam, Puerto Rico, the Republic of Palau, and the Virgin Islands. In the absence of such evidence, the proposed restriction is inappropriate.

The Secretary's concern that accrediting bodies must be recognized only if their accreditation services are of acceptable quality are quite appropriate. However, to address that concern by recognizing only accreditation by the larger states is misguided. The issue at hand is the quality of the accreditation services, not the size of the state. The Secretary instead should specify standards for acceptable quality of accreditation services. The Proposed Rule already contains some such standards, such as requiring the application for recognition to include "policies and procedures that ensure processing for accreditation and applications for renewal of accreditation within a timeframe approved by SAMHSA."

The other concern of the Secretary, to "minimize the variability in the standards used by accrediting organizations" is misguided in its entirety. Variability in standards certainly is reduced by reducing the number of accrediting entities, but this will be of little practical significance as long as accrediting organizations require that service providers maintain compliance with applicable State laws and regulations. And one would certainly hope that no organization would accredit an OTP which is operating illegally.

Reducing variability in accreditation standards by reducing the number of accrediting organizations will remain a misguided effort so long as the states exercise their right to impose requirements upon OTP's more stringent than those imposed by the Federal government. For example, were a state to require that treatment plans of OTP patients be reviewed and revised every 30 days, it would be of little operational significance whether that requirement were imposed by state requirements or CARF accreditation standards. Treatment plans still would need to be reviewed and revised every 30 days

Variability in requirements across states will continue as long as states' rights exist. A more salient issue is whether the diverse requirements for OTP's include appropriate core requirements. The issue is adequacy, not variability. Accordingly, the Secretary should specify the requisite core elements of accreditation.

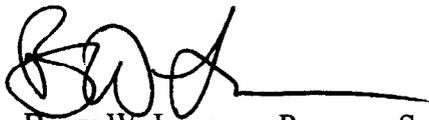
What would not be a misguided effort would be for the Secretary to address variability of accreditation standards *within* rather than *across* states. While requirements across states will vary, there must be a level playing field for OTP's within each state. Thus, the reliability with which an accrediting organization assesses compliance among providers is a critical issue. There may be a single written standard, but if it is interpreted and applied differently at each site the result is an operational multiplicity of standards within the state. In the State of Nevada we have addressed this issue by developing an accreditation instrument which yields a numerical score, making statistical analysis of reliability of accreditation findings by different reviewers feasible. Accordingly, the Secretary should specify minimal standards for the reliability of the accreditation process – a matter subsumed within the recommendation that the Secretary develop standards for acceptable quality of accreditation services.

Finally, and perhaps most significantly, restriction of recognition of State accreditation agencies to those accrediting at least 50 OTP's effectively sabotages in rural and frontier states the enhanced access to OTP's recommended by the Institute of Medicine. The Proposed Rule cites anticipated initial costs of accreditation by private organizations to range from \$5,500 to \$8,000, with an annual average of \$2,600 presuming 3-year accreditations and discounts – presumptions which may or may not be appropriate.

Under the relaxed regulations being proposed, it now may be possible for OTP's to be established in rural communities. For example, Ely, Nevada, does not have sufficient opioid addicts to make establishment of an OTP cost-effective under the current regulations. Accordingly, the nearest OTP is 250 miles away. OTP in Ely may be feasible if the relaxed Federal requirements make economy of scale less of an issue, but such feasibility immediately disappears when the cost of accreditation is literally thousands of dollars.

Accordingly, I ask that the Secretary rescind the proposed rule that restricts recognition of State agencies as accrediting bodies to those accrediting at least 50 OTP's on the grounds that such a restriction does not address quality of the accreditation service, does not restrict variability across states for operation of OTP's, does not address the more salient issue of variability within states for operation of OTP's, and will hamper efforts to increase access to OTP's in rural and frontier states.

Sincerely,



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