Michael D. Maves, MD, MBA, Executive Vice President, CEO

June 6, 2007

Mr. Mark W. Caverly
Section Chief
Liaison and Policy Section
Office of Diversion Control
Drug Enforcement Administration
Washington, DC.20537

Re: ***Controlled Substances and List I Registration and Reregistration Fees Final Rule (Docket No. DEA-266F) and Clarification of Registration Requirements for Individual Practitioners Final Rule (Docket No. DEA-244F)***

Dear Mr. Caverly:

On behalf of the physician members of the American Medical Association (AMA), we want to take this opportunity to share with you concerns we have with provisions in two final rules issued in 2006 that create a significant and disproportionate hardship on physicians. Specifically, we are offering our comments on provisions in the *Controlled Substances and List I Registration and Reregistration Application Fees Final Rule (Docket No. DEA-266F),* and the *Clarification of Registration Requirements for Individual Practitioners Final Rule (Docket No. DEA-244F).* We have received inquiries from physicians on the impact of these two rules and the unintended policy implications.

Controlled Substances and List I Registration and Reregistration Application Fees Final Rule (Docket No. DEA-266F)

The *Controlled Substances and List I Registration and Reregistration Application Fees Final Rule* establishes the fee schedule applied to practitioners/dispensers as well as manufacturers and distributors. The registration fee to obtain the Drug Enforcement Agency (DEA) number is set "to appropriately reflect all costs associated with [the DEA's] Diversion Control Program." The impact of this rule has been onerous for physicians (particularly in light of the rule discussed below requiring multiple DEA numbers) and disproportionate relative to manufacturers and distributors. While the Agency's response to comments includes an analysis of the financial impact on practitioners as a percent of their

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average income, a corresponding analysis of the percent of income the DEA registration fees constitute for manufacturers and distributors was not included. This omission is material given that the comparison would likely underscore the disproportionate impact on practitioners. Furthermore, the newly announced three-year registration fee for physicians ($551) represents a steep and substantial increase over the prior practitioner registration fee, and this was done without any explanation as to what physician activities regulated by the DEA are fueling such a large increase. Physicians should not have to assume financial responsibility for the costs associated with the Drug Diversion program's oversight of manufacturers and distributors. The fee hike for physicians is in marked contrast to the substantial reduction in the announced annual fee for manufacturers and distributors. There is no rational basis for the newly issued fee schedule and the resultant shift in financing of the Diversion Control Program oversight activities from manufacturers and distributors to physicians. The hardship created by the significant fee increases is coupled with the newly announced "clarification" of DEA policy of Registration Requirements for Individual Practitioners (see discussion below). Practitioners, such as locum tenens, who are licensed and practice in more than one state are required to register and pay the registration fee multiple times. This creates irrational outcomes where some individual physicians pay more in registration fees than manufacturers and distributors.

The AMA requests that the DEA revise and re-issue the registration fees in order to re-establish parity between practitioners, including physicians, and manufacturers and distributors. The fee hike will have the impact of reducing the number of physicians who are able to register and will create grossly disproportionate financial burdens on physicians who practice in more than one state. In addition, we request that the DEA issue a clarification whereby physicians are required to pay fees once even where they may need to register more than once, as discussed below.

Clarification of Registration Requirements for Individual Practitioners Final Rule (Docket No. DEA-244F)

The *Clarification of Registration Requirements for Individual Practitioners Final Rule* amends the DEA registration regulations "to make it clear that when an individual practitioner practices in more than one State, he or she must obtain a *separate* DEA registration for *each* State." (Emphasis added.) The Final Rule was issued on December 6, 2006, and went into effect on January 2, 2007. We are concerned about two separate but related issues presented by the "clarification."

The first issue pertains to the application of the clarification to locum tenens practitioners. In the Final Rule, it states that:

> the revision of the regulation will not affect the DEA's approach to locum tenens practitioners. DEA will be addressing policies regarding locum tenens practitioners in other documents to be published in the Federal Register.

However, the DEA has not yet issued the aforementioned policies nor has the DEA made readily available regulatory or subregulatory guidance vis-à-vis locum tenens practitioners.

After inquiries made to the DEA, the AMA was informed that such practitioners are now required to pursue a laborious, time consuming, and *ad hoc* process to obtain a waiver from the requirements contained in the announced clarification. This is a dramatic departure from the prior policy. Previously, locum tenens practitioners who were licensed in multiple states only registered for one DEA number. Now such practitioners must obtain multiple DEA numbers and pay the attendant fee each time.

Second, related to the foregoing, the Final Rule constitutes more than a clarification and is, in fact, a substantive change. Prior to the issuance of this final rule, physicians understood that they were responsible for registering for a single DEA number. In addition to the financial burdens created by this change in policy (as discussed above), the implications for drug control policy are far reaching. This change will create substantial challenges for oversight. (Simply put, it is easier to track a physician's controlled substance prescribing history and pattern if a single DEA number is assigned to the physician.) In addition, the new requirement will increase the administrative burden on physicians. Certainly, the DEA has the discretion to require that a physician pay the fee only once even if the physician is required to obtain multiple DEA numbers.

Finally, we continue to strongly urge the Agency to issue guidance that would allow the use of DEA numbers only for the purpose for which the numbers were originally intended—identifying those practitioners who are authorized to prescribe and distribute controlled substances. We remain deeply concerned that the federal government continues to authorize the sale of the DEA number through the U.S. Department of Commerce. This practice heightens the possibility that individuals will obtain DEA numbers to perpetrate fraud and drug diversion. If this practice was prohibited, the possibility of such abuses would be minimized.

The AMA appreciates your consideration of this important matter. If you have any questions, please do not hesitate to have your staff contact Mari Johnson at (202) 789-7414 or mari.johnson@ama-assn.org.

Sincerely,

Michael D. Maves, MD, MBA