

October 8, 2004

Carolin Lovett
Policy Analyst
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

**RE: *Electronic Orders for Schedule I and II Controlled Substances* –
Final Rule (RIN: 1117-AA60)**

Dear Ms. Lovett:

On behalf of our members, the Healthcare Distribution Management Association (HDMA) would like to convey our support regarding a final regulation submitted by the Drug Enforcement Administration, *Electronic Orders for Schedule I and II Controlled Substances*. We understand this rule is currently undergoing review within the Office of Management and Budget (OMB) prior to final Federal Register publication.

HDMA is the national trade association representing full-service distribution companies responsible for ensuring that billions of units of medication are safely distributed to retail pharmacies, hospitals, nursing homes, clinics, and other provider sites across the United States. Most of HDMA's members are DEA registrants subject to the requirements of the Controlled Substances Act (CSA).

As you know, the CSA requires that a Schedule I or II controlled substance may only be distributed to another person with a written order on a form issued by the Attorney General. To date, these distributions have been accomplished using a paper form, the DEA Form 222 Official Order Form. However, the final DEA regulation is intended to allow registrants to voluntarily issue orders for Schedule I and II controlled substances electronically.

HDMA and its members have encouraged the DEA in this rulemaking. For several years, an HDMA-facilitated industry working group has provided technical, economic and other information to the DEA to aid in the rule's preparation. We believe these cooperative

efforts have fostered development of a simplified ordering system without compromising security, patient safety, or confidentiality.

We are hopeful that the final rule will have a very direct, and positive, impact on HDMA's members and on the DEA. Providing the means for electronic submissions should result in a very large cost savings -- in the multi-million dollar range. Other benefits, such as aiding patient care by facilitating faster receipt of orders and streamlining management of the ordering system, are expected. Moreover, the safeguards built into the electronic system are intended to actually enhance information security over the current paper based system.

Given the substantial benefits anticipated for the final rule and its voluntary nature, we are pleased to indicate our strong support for rapid review and Federal Register publication, consistent with appropriate internal federal government review procedures.

If further communication or information about the rule would facilitate your review, please do not hesitate to contact me at 703-787-0000 ext. 240. Thank you.

Sincerely,

Anita T. Ducca
Director, Regulatory Affairs

cc: John D. Graham, Ph.D.
John Morrall