



September 24, 2008

Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: "Electronic Prescriptions for Controlled Substances"

Dear Secretary Leavitt:

The National Committee on Vital and Health Statistics (NCVHS) is directed by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) to develop recommendations for uniform standards to enable electronic prescribing (e-prescribing) in ambulatory care. This letter will constitute our comments relative to the Department of Justice (DOJ) notice of proposed rule making (NPRM) regarding its Drug Enforcement Administration's (DEA) intent to revise its regulations to provide practitioners with the option of writing prescriptions electronically for controlled substances.

Prescription writing is a critical factor in patient care and patient safety. The National Association of Chain Drug Stores (NACDS) estimated that in 2006, 3.4 billion prescriptions were written, with another 2 billion refills and renewals processed, amounting to \$249 billion spent on prescription drugs. Of these, it is estimated that 11 percent, or 374 million prescriptions, for controlled substances are written each year.

At the present time, it is not possible to prescribe controlled substances electronically. The healthcare industry has identified that the inability to electronically prescribe controlled substances is a major barrier to overall e-prescribing adoption by providers. Based on testimony, the NCVHS made recommendations to you addressing the need to include controlled substances along with other drugs in e-prescribing (see attached letter).

In that letter, we acknowledged that:

- Controlled substances are medications that have traditionally been afforded a higher level of security of prescription writing due to the risk of illegal acquisition and use
- The U.S. Department of Justice (DOJ) Drug Enforcement Administration (DEA) has regulatory authority over the prescribing and dispensing of controlled substances

Various strategies have been considered within e-prescribing to afford continuation of high levels of security over controlled substances. One such strategy was the use of public key infrastructure (PKI). NCVHS stated the problems with this approach in its March 2005 letter to you.



NCVHS is pleased to note that the current NPRM does not include a PKI requirement. However, the proposed rule does contain security and authentication requirements that would appear to have similar negative consequences for the adoption of e-prescribing, including requirements for two-factor identification and identity proofing that appear well beyond the capabilities of current ambulatory care e-prescribing systems in health care today. Accordingly, we urge HHS to work with DEA on alternative solutions to security and authentication that reflect a more balanced, risk-based approach that balances security with functionality and clinical practice—an approach that is more consistent with capabilities present in effective e-prescribing systems today.

Sincerely,

/s/

Harry L. Reynolds, Jr.
Chairman, National Committee on
Vital and Health Statistics

Cc: HHS Data Council Co-chairs