December 8, 2005 **DRAFT**!! Version 3.0

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

Dear Secretary Leavitt:

The National Committee on Vital and Health Statistics (NCVHS) is requested by the
Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) to
develop recommendations for uniform standards to enable electronic prescribing
(eprescribing) in ambulatory care. Additionally, 42 CFR Part 423 Medicare Program; E-
Prescribing and the Prescription Drug Program; Final Rule (on page 67579) asks "the
NCVHS to assess new versions of standards as they are developed, obtain input from
SDOs and other organizations, and provide recommendations to the Secretary regarding
whether the new versions should be adopted." We have sent you two previous letters
(September 2, 2004 and March 4, 2005) with our recommendations. As a result of
hearings we conducted on December 7, 2005, to receive an update on the industry's
development of eprescribing standards, we have two additional recommendations.

Background and Discussion

About a year ago, we heard testimony that improvements to the National Council for
Prescription Drug Programs (NCPDP) SCRIPT standard were in process. We asked
NCPDP to keep us informed of these improvements and report back as progress was
being made. Specifically, we asked NCPDP to show us the differences between the
implementation guidance found in SCRIPT Standard Implementation Guide Version 5.0
(SCRIPT 5.0) and in the new SCRIPT Standard Implementation Guide Version 8.1
(SCRIPT 8.1). On December 7, 2005, we learned that the rapid progress made by the
industry working through NCPDP has resulted in improvements to the standard we
originally recommended (SCRIPT 5.0) and that you adopted as one of the eprescribing
foundation standards.

A newer version (SCRIPT 8.1) was approved by NCPDP and the American National
Standards Institute, and published in October 2005. This newer version of the SCRIPT
standard includes all functions of the foundation standard plus the ability to transmit
medication history information. Furthermore, it provides additional clarification for use
of the standard. We also learned that the industry generally has not implemented
SCRIPT 5.0 and actually is implementing SCRIPT 8.1 to gain its benefits.

Based on the information we received from NCPDP and input from industry
representatives on December 7, 2005, NCVHS concludes that the SCRIPT 8.1 standard is
backward compatible for the foundation standard functions in SCRIPT 5.0.

The preamble of the Final Rule (in Section 10 of Federal Register, 70:214, 67579-80) describes a process by which the Secretary may "waive notice and comment rulemaking under an Administrative Procedure Act exception to the requirement for notice and comment rulemaking." The implementation of SCRIPT 5.0 is mandated for eprescribing beginning January 1, 2006. Without adoption by the Secretary of SCRIPT 8.1 for foundation standard functions, however, the industry is held back from implementing SCRIPT 8.1 for eprescribing.

Recommendation 1

Based on testimony and information received from the industry that SCRIPT 8.1 does not incorporate significant changes from SCRIPT 5.0, and is backward compatible with the foundation standard functions in SCRIPT 5.0, NCVHS recommends the Secretary adopt the new version SCRIPT 8.1 as well as the previously adopted version SCRIPT 5.0 for meeting the eprescribing transaction standard functions.

This means that compliance with either version (5.0 or 8.1) would constitute compliance with the eprescribing standard under MMA.   It further allows the flexibility requested by the industry and the assurance that implementing SCRIPT 8.1 is considered compliant.

Recommendation 2

Because time is of the essence for permitting the industry to implement SCRIPT 8.1, NCVHS also recommends the Secretary waive notice and comment rulemaking under an Administrative Procedure Act exception for the adoption of SCRIPT 8.1 for the foundation standard functions so that it may be implemented as rapidly as is feasible.

NCVHS is pleased to support the process by which the Department of Health and Human Services can improve the efficiency and effectiveness of eprescribing.

Sincerely yours,

Simon P. Cohn, M.D., M.P.H.
Chairman, National Committee on
Vital and Health Statistics