

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-17
Baltimore, Maryland 21244-1850



Office of E-Health Standards and Services

MAN 13 2016

Lee Ann C. Stember
President
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260

Dear Ms. Stember,

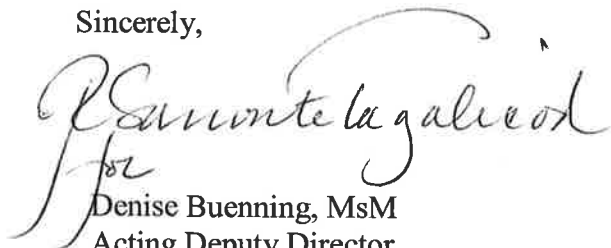
Thank you for your August 16, 2013 letter requesting that the Office of e-Health Standards and Services (OESS) reconsider the requirement that a modification to the NCPDP Telecommunication Standard Version D.0. be published in the Federal Register as a notice of proposed rulemaking (NPRM).. We have considered alternate approaches for adopting the modification but find that the most appropriate approach possible would be through an NPRM.

We appreciate the suggestion to consider a more expedited process to adopt standards, and analyzed your interpretation of a summary of section 1104 of the Patient Protection and Affordable Care Act (Pub.L.111-148) (Affordable Care Act). . However, notwithstanding the summary of section 1104 of the Affordable Care Act that you cited, the text in section 1104(b)(4) mandates that an interim final rule be used for specific new standards and operating rules, and we find no language that permits that the interim final rule be used to adopt new versions of existing standards and operating rules. The exception to this is the reference to a Review Committee in Section 1104(b)(5)(i), the recommendations of which “to amend adopted standards and operating rules” shall be adopted through interim final rulemaking. However, we do not think that the Review Committee approach would be an expeditious avenue with which to consider adopting the NCPDP modification.

Section 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), requires us to publish a notice of proposed rulemaking (NPRM) in the Federal Register. Section 553(b)(B) of the APA authorizes an agency to waive normal rulemaking requirements for good cause if the Department finds that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest. Even in cases in which section 1104 of the Affordable Care Act permits the use of interim final rulemaking to adopt standards and operating rules, the agency must demonstrate that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest before it can waive those procedures. Although we support the intent of the NCPDP modification, we do not believe we can justify waiving the notice and comment procedures as impracticable, unnecessary, or contrary to the public interest.

We apologize for any previous indications from OESS that the modification to the D.0 standard could be adopted through another means.

Sincerely,

A handwritten signature in cursive script, appearing to read "Denise Buenning". The signature is written in black ink and is positioned above the typed name and title.

Denise Buenning, MsM
Acting Deputy Director,
Office of E-Health Standards and Services