



August 27, 2013

Andrew Morgan  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1600-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

Re: Centers for Medicare & Medicaid Services, 42 CFR Parts 405, 410, 411, 414, 423, and 425 [CMS-1600-P], RIN 0938-AR56, Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014

Dear Drew,

The National Council for Prescription Drug Programs is providing the following response to CMS-1600-P.

NCPDP stands ready to assist CMS in the continued success of electronic prescribing. NCPDP members and staff are committed to the actions cited in the MMA, have brought forth standards where available or needed, and facilitated industry task groups dedicated to the implementation of e-prescribing. Thank you for the opportunity to respond to this NPRM.

For direct assistance, please contact  
Lynne Gilbertson  
VP, Standards Development  
National Council for Prescription Drug Programs (NCPDP)  
9240 E. Raintree Drive  
Scottsdale, AZ 85260  
(480) 477-1000 x 108 (AZ office)  
(615) 754-0445 (direct)  
[lgilbertson@ncdpd.org](mailto:lgilbertson@ncdpd.org)

Sincerely,

A handwritten signature in black ink, appearing to read "Lee Ann C. Stember".

Lee Ann C. Stember  
President  
National Council for Prescription Drug Programs (NCPDP)  
9240 E. Raintree Drive  
Scottsdale, AZ 85260  
(480) 477-1000 x 108  
[lstember@ncdpd.org](mailto:lstember@ncdpd.org)

cc: NCPDP Board of Trustees

b. Regulatory History (p 43504)

(3) The NCPDP Formulary and Benefit Standard in the Part D e-Prescribing Regulations The backward compatibility concept has been used extensively to update the NCPDP SCRIPT standard in the Part D e-prescribing program, but it has not yet been used to update the adopted NCPDP Formulary and Benefit Standard. We proposed to update the NCPDP Formulary and Benefit 1.0 standard for the first time in the CY 2013 PFS proposed rule (77 FR 44722), but we did not ultimately finalize those proposals. Specifically, we proposed to recognize NCPDP Formulary and Benefit Standard 3.0 as a backward compatible version of NCPDP Formulary and Benefits 1.0 effective 60 days from the publication of the final rule, and sought comment on when we should retire NCPDP Formulary and Benefits 1.0 as well as when we should adopt NCPDP Formulary and Benefits 3.0 as the official Part D e-prescribing standard As was noted in full notice and comment rulemaking, so, as we didn't wish to publish two e-prescribing rules contemporaneously, we elected to forgo our usual use of our simplified updating process for backward compatible standards (in which we waive notice and comment rulemaking and go straight to final) in favor of putting all of the proposals through full notice and comment rulemaking.

2. Proposals

a. Proposed backward compatible standards (p 43504-5)

As was discussed in the CY 2013 PFS final rule with comment period (77 FR 68892), we were persuaded by commenters to refrain from retiring Formulary and Benefit Standard 1.0 until NCPDP ceased supporting it on July 1, 2014. As further noted in that rule, we believed it best to delay implementing any of our Formulary and Benefits proposals, including recognitions of NCPDP Formulary and Benefit 3.0 as a backward compatible standard, until closer to that July 1, 2014 date. Our actions at that time were based on a belief that an extended period of use of either 3.0 or 1.0 would be ill-advised. Having come within roughly a year of the anticipated date upon which NCPDP will cease supporting NCPDP Formulary and Benefit 1.0, we believe that it is now appropriate to re-propose the recognition of NCPDP Formulary and Benefits 3.0 as a backward compatible version of Formulary and Benefits 1.0 effective 60 days after publication of a final rule until June 30, 2014, and, as discussed below, to propose the retirement of NCPDP Formulary and Benefits 1.0, effective July 1, 2014, and to propose the adoption of NCPDP Formulary and Benefits 3.0 as the official Part D e-prescribing standard effective July 1, 2014. As was discussed previously, while the recognition of backward compatible standards can be done in an interim final rule in which we waive notice and comment rulemaking, in light of other Part D e-prescribing proposals being made in this rule that require full notice and comment rulemaking, we will forgo use of the simplified updating method for backward compatible standards (in which we waive notice and comment rulemaking and go straight to final) in favor of putting all of the proposals through a single notice and comment rulemaking.

Also, as was seen in our prior proposal to recognize backward compatibility using full notice and comment in place of the backward compatible methodology, we must also propose to require users of 3.0 to support users who are still using NCPDP Formulary and Benefit 1.0 until such time as that version is officially retired as a Part D e-prescribing standard and NCPDP Formulary and Benefit 3.0 is adopted as the official Part D e-prescribing standard.

**NCPDP Response:** We wish to clarify that NCPDP does not cease to support NCPDP Formulary and Benefit Standard Version 1.0, meaning that it will be a version in the listings of NCPDP publications. Versions may be retired as the industry determines the versions in active use. In this case, regulations would cite the appropriate version to be used.

2. Proposed Retirement of NCPDP Formulary and Benefit Standard 1.0 and adoption of NCPDP Formulary and Benefit Standard 3.0

As noted in the CY 2013 PFS proposed rule, the NCPDP Formulary and Benefits standard provides a uniform means for pharmacy benefit payers (including health plans and PBMs) to communicate a range of formulary and benefit information to prescribers via point-of-care (POC) systems. These include:

- General formulary data (for example, therapeutic classes and subclasses);
- Formulary status of individual drugs (that is, which drugs are covered);
- Preferred alternatives (including any coverage restrictions, such as quantity limits and need for prior authorization); and
- Copayment (the copayments for one drug option versus another).

Also as noted in that proposed rule, standards are updated over time to take industry feedback and new and modified business needs into account. See the CY 2013 PFS proposed rule (77 FR 45023–45024) for a full discussion of the changes to that were made to the NCPDP Formulary and Benefit 1.0 as it was updated to the NCPDP Formulary and Benefit 3.0. As noted above, having come within roughly a year of the anticipated date upon which NCPDP will cease supporting NCPDP Formulary and Benefit 1.0, we believe that it is now appropriate to re-propose the retirement of NCPDP Formulary and Benefits 1.0, effective July 1, 2014, and to propose the adoption of NCPDP Formulary and Benefits 3.0 as the official Part D e-prescribing standard, effective July 1, 2014.

To effectuate these proposals, we propose to revise § 423.160(b)(5). We propose to place the existing material in a new paragraph (b)(5)(i), which would provide the formulary and benefit standard for Part D e-prescribing until [60 days after publication of the final rule]. We then propose to create a second new paragraph ((b)(5)(ii)) to recognize NCPDP Formulary and Benefit 3.0. as a backward compatible version of the official Part D e-prescribing standard (NCPDP Formulary and Benefit 1.0), effective [60 days after publication of the final rule] through June 30, 2014. Furthermore, we propose to create a third new paragraph ((b)(5)(iii)) to reflect the retirement of NCPDP Formulary and Benefit 1.0 and the

adoption of NCPDP Formulary and Benefit 3.0 as the official Part D eprescribing standard, effective July 1, 2014. Finally, we propose to make conforming changes to § 423.160(b)(1). We seek comment on these proposals.

**NCPDP Response:** We wish to clarify that NCPDP does not cease to support NCPDP Formulary and Benefit Standard Version 1.0, meaning that it will be a version in the listings of NCPDP publications. Versions may be retired as the industry determines the versions in active use. In this case, regulations would cite the appropriate version to be used.

NCPDP recommends that entities can use NCPDP Formulary and Benefit Standard Version 1.0 or Version 3.0 during the period of transition through **June 30, 2015**. **As of July 1, 2015**, only the NCPDP Formulary and Benefit Standard Version 3.0 will be supported.