CMS Response to Public Comments Received for CMS-10137

The Centers for Medicare & Medicaid Services (CMS) received comments from three organizations, including the Citizen Potawatomi Nation, the United South and Eastern Tribes Sovereignty Protection Fund, and the Tribal Technical Advisory Group, related to the CMS-10137. This is the response to the comments.

Comment: All three commenters expressed disappointment that CMS only made "housekeeping" edits but not substantive policy changes to the I/T/U Addendum. This includes the request to require all pharmacy plans to reimburse I/T/U providers at the rates they pay other network providers and to not discount reimbursement for repackaged pharmaceuticals using the Federal Supply Schedule or the 340B program.

Response: CMS appreciates these comments regarding the I/T/U Addendum updates. The Paperwork Reduction Act (PRA) of 1995 (P.L. 104-13, 44 USC, Chapter 35) is a law governing the collection of information by government agencies from members of the public, including forms, instructions or other collection instruments, such as the Part D Application materials. The Part D Application contains detailed instructions and requirements reflecting current rules, regulations, and CMS guidance applicable to Part D plans. The changes specific to I/T/U pharmacy reimbursement rates from insurance companies require substantive policy, and potentially regulatory, changes. As requested, these policies would impact non-Medicare prescription drug plans insurance reimbursement to I/T/U pharmacies as well as the Medicare prescription drug plans. The Solicitation for Applications for Medicare Prescription Drug Plan Contracts (application) is not the vehicle for issuing new policies. We may consider this request as it applies to the Medicare prescription drug program outside of the application PRA.

Comment: All three commenters requested to expand the scope of the I/T/U Addendum beyond Part D plans so that it applies to "other pharmacy plans". Additionally, in the event that the Part D program lacks the authority to expand the scope of the I/T/U Addendum beyond Part D, that HHS develop a new Addendum that incorporates these policy priorities.

Response: CMS appreciates the comments regarding the I/T/U Addendum. The Medicare Prescription Drug Benefit Rule published in the Federal Register on January 28, 2005 (70 Fed. Reg. 4194) established at 42 CFR 423.4 that "Part D plan (or Medicare Part D plan)" means "a prescription drug plan, an MA-PD plan, a PACE Plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage". CMS is unable to expand the scope of the Addendum to cover other "pharmacy plans," as they are not Part D plans as defined in the Part D regulations at 42 CFR Part 423. The PRA package is not the proper vehicle to make these changes.