

**Responses to Comments Received**  
**Federal Register Notice on Revised CMS-179 (State Plan Under Title XIX of the Social Security Act (Base plan pages, Attachments, Supplements to attachments))]**

CMS received one comment on the December 16, 2011 notice on the proposed changes to Attachment 4.19-B that describes the methods and standard for establishing payment rates for prescribed drugs. The commenter was the Minnesota Department of Human Services.

**Comment on the Medicaid State Plan Pre-Print – Attachment 4.19-B – Public Notice**

The commenter noted that the pre-print currently states that “Public notice is required for any changes in payment rates...” It was stated that Federal Regulation 42 CFR 447.205 requires that “... the agency must provide public notice of any significant proposed change in its methods and standard for setting payment rates for services.”

**CMS Response**

CMS agrees and proposes to add verbiage regarding the word “significant” in the public notice requirement for changes on the pre-print for Attachment 4.19-B. We also propose clarifying that a change in reimbursement that is based solely on a change in the underlying reference price on which the reimbursement methodology is based would not be considered a significant change in methodology. However, a change in the formula used to set the reimbursement amount would be considered a significant change.

**Comment on the Medicaid State Plan Pre-Print – Attachment 4.19-B – Pharmacy Payment Methodology**

The commenter states that the proposed new text requires that “States should pay no more than the pharmacy’s actual acquisition cost for 340B drugs.” The commenter requested that the 340B language be removed from the template or that the language be modified to reflect the logistical reality of Medicaid payment for 340B drugs by either incorporating language around the 340B ceiling price or allowing for shared savings arrangements between the 340B entities and the State Medicaid programs.

**CMS Response**

CMS believes that it would be permissible for a State to pay actual acquisition cost for 340B drugs. We have allowed States to pay covered entities the statutory 340B ceiling price even though the possibility exists that the covered entities purchased drugs at a rate that was lower than the ceiling price.

We have never approved a shared saving arrangement between the 340B entities and the State Medicaid programs, so we do not believe it would be appropriate to add such language to the preprint at this time.

### **Comment on the Medicaid State Plan Pre-Print – Attachment 4.19-B – State Plan Amendments**

The commenter noted that the proposed pre-print provides that "...we expect that States provide us with their rationale, data, and analyses when submitting State Plan amendments to substantiate any changes in these payments." The commenter feels that most States have expressed great concerns regarding the cost and practicability of the standards to complete this requirement.

### **CMS Response**

The expectation described in the State plan preprint does not represent a new requirement for States. Based on Federal regulations at 42 CFR 447.518, the State Plan must describe comprehensively the Agency's methodology for prescription drugs.

It is CMS' longstanding practice to request States to provide their rationale and supporting documentation for any proposed change in reimbursement to pharmacies for covered outpatient drugs. Our intention is simply to clarify our existing procedure in this preprint.