Questions and Answers
New Final Rule Posted Friday, October 15, 2010

Question:

1. Do manufacturers still have to complete pricing agreements?

Response:

The pricing agreements signed after issuance of the 2009 final rule will remain in effect when the 2010 final rule becomes effective December 27. For drugs covered by an existing pricing agreement there is no need to execute new pricing agreements under the new final rule.

Also, the following statement previously posted on DoD's website remains in effect under the new 2010 final rule. It continues to apply to current and any new pricing agreements and states as follows:

Questions have arisen about the effect of Section VII.(f) of the pricing agreement template. Section VII.(f) provides: "Nothing in the Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the DoD under the Constitution, the Act or Federal laws." The following will clarify the applicability of Section VII. (f). (The language of Sec. VII. (f) and the following statements may be included in a pricing agreement acceptable to DoD that is not the template for pricing agreements):

1. Executing a pricing agreement does not waive a signatory manufacturer's right to challenge the validity of the Final Rule or DoD's right to defend the validity of the Final Rule;
2. With respect to any prescription transaction (covered by the Final Rule) that occurs before the date that a pricing agreement is executed by a manufacturer and DoD, the executing of a pricing agreement does not establish liability to DoD and is not an admission of liability, or a waiver of any claim for monetary relief, by the signatory manufacturer concerning the transaction; and 3. With respect to any prescription transaction (covered by a pricing agreement) that occurs on or after the date that the agreement is executed by a manufacturer and DoD, all parties to the agreement reserve their claims as to the validity and enforceability of the provisions in the agreement.

Question

2. If a company wants to opt a product out, do they write a letter to TMA?

Response:

Yes. See section 199.21(q)(3)(111)(C) of the rule regarding the voluntary removal, by the manufacturer in writing, of a drug from coverage in the TRICARE Pharmacy Benefit Program.

Question:

3. If a company wants to revise their current waiver/compromise request to a waiver of interest and penalties, is that acceptable?

Response:

Yes.

Question:

4. When will waiver/compromise requests be addressed?

Response:

TMA deferred action on the pending requests until the new final rule was completed. TMA expects to address the pending requests soon.

Manufacturers are free to submit revised compromise requests if they wish.