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Via E-mail

TO: State Affairs Steering Committee
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FROM: Ryan Faden, Assistant Director, State Affairs

SUBJECT: DRA Final Rule

Urgent Handle & Confirm Review & Comment FYI As Requested

This is to advise you that the final rule implementing the Average Manufacturer Price (AMP) provisions of the Deficit Reduction Act of 2005 (the "Final Rule") was published in the July 17th edition of the Federal Register. PPTA continues to examine the Final Rule which covers 105 pages in its official version. At this point, we wanted to make you aware of CMS' responses to the blood clotting factor related comments. Each point is preceded with its page number reference in the Final Rule. We are including those specific pages as an attachment. To access a full copy of the Final Rule go to: <http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/pdf/07-3356.pdf>.

Page 39161

Despite the comment requesting CMS to consider a separate blood clotting factor furnishing fee if it uses the AMP as a benchmark for pharmacy reimbursement, CMS believes that Medicaid programs have other service categories that can reimburse providers for these services and that States can also establish appropriate dispensing fees on an independent basis.

Page 39221

CMS agrees that it incorrectly included Factor VIII Recombinant and Factor VIII plasma-derived in its top 20 multiple source drug list and states it will remove those products from the list on its Web site. This change represents a significant victory for the industry—particularly in our efforts to educate policymakers about the fact that plasma protein therapies are not interchangeable.

Page 39221

In response to the comment urging CMS to include a provision in the final rule to encourage States to provide a furnishing fee for blood clotting factors modeled after that provided by Medicare, CMS states that Medicaid programs have the ability within their own individual Medicaid State plans to determine how they will reimburse adequately for blood clotting factor.

Page 39223

PPTA commented that in order to appropriately reimburse blood clotting factor under Medicaid, AMPs reported to the States under the DRA should reflect the blood clotting factor furnishing fee. CMS disagrees with this assertion. PPTA had contended that if States rely solely on the AMPs in setting their reimbursement levels and do not take into account the furnishing fee payment that Congress recognized as critical, then payment amounts may be too low. The agency argues that according to the existing definition of AMP, it should not include wholesaler or retailer mark-up, dispensing fees, or furnishing fees. CMS again mentions that the States may determine appropriate dispensing fees and that Medicaid has other service categories in which to reimburse the furnishing of factor if appropriate.

As is evident from the responses to the comments, CMS is taking the position that states should retain the authority to determine adequate reimbursement when utilizing the AMP data supplied by CMS. This is not surprising given the historical ability of states to independently set their own Medicaid reimbursement rates with only limited guidance from the federal government. It should be noted that the Final Rule includes a 180 day comment period for the AMP related provisions. The PPTA Federal Affairs Steering Committee is also in the process of reviewing the Final Rule and will play a key role in determining the direction of PPTA's comments. The State Affairs Steering Committee will also have the opportunity to contribute to the comment development process. We hope you find this information helpful.

Should you have any questions, or if you require additional information, please do not hesitate to contact us at the Association.

Attachment: SASC07047a