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August 30, 2006

**MEMORANDUM**

**FROM:** Michelle L. Butler  
Alan M. Kirschenbaum

**SUBJECT:** CMS Proposed Changes to ASP Calculation Methodology

On August 22, 2006, the Centers for Medicare & Medicaid Services (“CMS”) published in the Federal Register a proposed rule entitled “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment Under Part B.”<sup>1</sup> Although the bulk of the proposal is devoted to updates in the physician fee schedule, the proposal also includes provisions relating to payment for drugs and biologics, including proposed changes to the regulation governing the calculation by manufacturers of average sales price (“ASP”).<sup>2</sup> This memorandum summarizes CMS’s ASP-related proposals. As discussed further below, these pertain primarily to (1) the treatment of certain fees, such as administrative and other service

<sup>1</sup> 71 Fed. Reg. 48,982 (Aug. 22, 2006).

<sup>2</sup> See 42 C.F.R. §§ 414.800-414.806. ASP is used by CMS to establish payment rates for most drugs and biologics covered under Medicare Part B. See 42 U.S.C. § 1395w-3a.

fees; (2) smoothing of sales that are exempt from the ASP calculation; (3) smoothing of price concessions for NDC numbers with less than 12 months of sales and redesignated NDC numbers; and (4) the treatment of nominal sales in light of the changes made by the Deficit Reduction Act of 2005 (the “DRA”).<sup>3</sup> The proposed rule also requests comments on these and other topics related to the calculation of ASP. Comments are due no later than October 10, 2006.

1. Bona Fide Service Fees

Responding to requests from manufacturers for clarification regarding the treatment in the ASP calculation of administrative fees, service fees, and fees paid to group purchasing organizations (“GPOs”) and pharmacy benefit managers (“PBMs”), CMS is proposing to clarify that, beginning with ASP reported for sales during the first calendar quarter of 2007, “bona fide service fees” are not considered price concessions that must be deducted in calculating ASP.<sup>4</sup> CMS is proposing to define “bona fide service fees” as

fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.<sup>5</sup>

In the preamble to the proposed regulation, CMS clarifies that fees, including service fees, administrative fees, and other fees, paid to GPOs or PBMs, would not be considered price concessions if they satisfy the definition of a bona fide service fee.<sup>6</sup> The proposal does not address the treatment in ASP of rebates paid to PBMs.

With regard to the meaning of fair market value, CMS also states that its current FAQ and other guidance on this term would continue to apply unless CMS decides on

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<sup>3</sup> Deficit Reduction Act of 2005, Pub. L. No. 109-171, 120 Stat. 4 (2006).

<sup>4</sup> 71 Fed. Reg. at 49,001, 49,082 (proposed 42 C.F.R. § 414.804(a)(2)(ii)).

<sup>5</sup> Id. at 49,082 (proposed 42 C.F.R. § 414.802).

<sup>6</sup> Id. at 49,001.

another approach.<sup>7</sup> The FAQ guidance provides that bona fide service fees are expenses that “would have generally been paid for by the manufacturer at the same rate had these services been performed by other entities.”<sup>8</sup>

CMS is considering providing further guidance on two issues related to services fees: (1) the types of services that may qualify as bona fide services for purposes of the ASP calculation, and (2) the methodology a manufacturer must use to determine the fair market value of bona fide services performed on its behalf and whether a service fee that was paid was passed on in whole or in part.<sup>9</sup> CMS notes that it may implement any such policy either through rulemaking or another form of guidance. To assist CMS in developing such guidance, the agency requests comments on several topics:

- the specific types of services entities perform on behalf of manufacturers and the necessity of those services;<sup>10</sup>
- activities that should not be considered bona fide services;
- the costs and relative costs of services performed on behalf of manufacturers;

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<sup>7</sup> Id. (citing FAQ 4136 regarding service fees paid to buyers, available at [http://www.cms.hhs.gov/mcrpartdrugavgsalesprice/01\\_overview.asp](http://www.cms.hhs.gov/mcrpartdrugavgsalesprice/01_overview.asp)? (last updated Aug. 22, 2006) and Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B, 70 Fed. Reg. 39,022 (July 6, 2005)).

<sup>8</sup> CMS, FAQ 4136 regarding service fees paid to buyers, available at [http://www.cms.hhs.gov/mcrpartdrugavgsalesprice/01\\_overview.asp](http://www.cms.hhs.gov/mcrpartdrugavgsalesprice/01_overview.asp)? (last updated Aug. 22, 2006).

<sup>9</sup> Id.

<sup>10</sup> CMS notes that, in response to its April 6, 2004 interim final rule on the calculation of ASP, groups representing wholesalers, distributors, and specialty pharmacies provided some insight into costs for items such as handling, storage, inventory reporting, shipping, receiving, patient education, disease management, and data that they believed should be excluded from the ASP calculation. Id. However, CMS explains that the comments did not provide enough information for CMS to evaluate the extent to which such activities are bona fide services actually performed on behalf of the manufacturer. Id.

- additional guidance or alternative methods for determining fair market value for service fees;
- whether, and the extent to which, fees tied to performance of a service, fees based on revenue generated by product sales, fixed fees, or fees based on other methodologies may represent fair market prices;
- the appropriate methods for determining if a fee is passed on in whole or in part by the recipient; and
- how CMS's guidance on the treatment of services fees for ASP calculation purposes may differ from the treatment of service fees for financial accounting or other purposes.<sup>11</sup>

## 2. Smoothing Methodology for Lagged Exempted Sales

The ASP regulation currently requires manufacturers to exclude from the ASP calculation those sales that are exempt from the Medicaid Rebate best price ("BP") calculation.<sup>12</sup> To date, CMS has not provided any guidance on how exclusion of such sales is to be achieved where many of the exempted sales are known only on a lagged basis. However, the current ASP regulation does establish a methodology for estimating price concessions that are known on a lagged basis.<sup>13</sup> Consistent with the methodology for lagged price concessions, and in order to implement a uniform approach that more accurately excludes exempt sales from the ASP calculation, CMS is proposing to establish a 12-month rolling average ratio methodology for estimating exempted sales that are known only on a lagged basis.<sup>14</sup>

Specifically, the proposed rule would require manufacturers, for each NDC number, to divide the sum of lagged exempted sales (in units) for the most recent 12-month period available by the sales (number of units after non-lagged exempted sales have been subtracted from total sales units) for the same 12-month period. The resulting percentage would be applied to the sales for the quarter being submitted (i.e., the number of units for the quarter after non-lagged exempted sales have been subtracted from total

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<sup>11</sup> Id.

<sup>12</sup> 42 C.F.R. § 414.804(a)(4).

<sup>13</sup> Id. § 414.804(a)(3).

<sup>14</sup> 71 Fed. Reg. at 49,002, 49,083 (proposed 42 C.F.R. § 414.804(a)(4)(iii)).

sales). The resulting product would determine the estimated lagged exempted sales in units to subtract from the denominator (*i.e.*, ASP-eligible units) of the ASP calculation. A corresponding adjustment to the numerator of the ASP calculation would be made to ensure that the total in dollars for the reporting quarter does not include revenue related to lagged exempted sales removed from the denominator using the estimation methodology.<sup>15</sup> The proposed rule does not specify whether, in adjusting the numerator, each calculated unit should be valued at WAC or valued on some other basis.

With regard to NDC numbers with less than 12 months of sales, CMS is proposing that manufacturers use data from the number of months for which there are sales.<sup>16</sup> However, if a manufacturer has redesignated an NDC number, the manufacturer must use 12 months (or the total number of months if less than 12) of sales data for the prior and current NDC numbers to estimate the lagged exempted sales applicable to the redesignated NDC number.<sup>17</sup> This applies when the NDC number change reflects, for example, a change in labeler code or a modified package design or other non-drug feature.<sup>18</sup>

CMS also proposes that manufacturers exclude lagged exempted sales from their estimates of lagged price concessions.<sup>19</sup> CMS requests comments on the proposed methodology for excluding lagged exempted sales from the ASP calculation and the estimate of lagged price concessions, as well as any suggestions on appropriate methodologies that may be less complex.<sup>20</sup>

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<sup>15</sup> Id. at 49,083 (proposed 42 C.F.R. § 414.804(a)(4)(iii)(A)).

<sup>16</sup> Id. (proposed 42 C.F.R. § 414.804(a)(4)(iii)(B)).

<sup>17</sup> Id. at 49,002-03, 49,083 (proposed 42 C.F.R. § 414.804(a)(4)(iii)(A)).

<sup>18</sup> Id. at 49,003. However, this does not apply to a changed NDC number as a result of a product being repackaged or relabeled by a different manufacturer/relabeler or private labeling of a product. Id.

<sup>19</sup> Id. at 49,083 (proposed 42 C.F.R. § 414.804(a)(4)(iii)(C)).

<sup>20</sup> Id. at 49,002.

3. Smoothing Methodology for Lagged Price Concessions – NDC Numbers with Less Than 12 Months of Sales and Redesignated NDC Numbers

CMS proposes to amend the regulations pertaining to smoothing of lagged price concessions so that they are consistent with the new proposal regarding lagged exempt sales.<sup>21</sup> For NDC numbers with less than 12 months of sales, CMS proposes that manufacturers use data from the number of months for which there are sales.<sup>22</sup> The preamble states that a manufacturer can include the current ASP reporting quarter in the most recent 12-month period, as long as the manufacturer follows this approach for all of the NDC numbers for which it reports ASPs.<sup>23</sup>

As with the proposal for exempted sales, where an NDC number has been changed to reflect a change in labeler code or a modified package design, the manufacturer must use 12 months (or the total number of months of sales of the prior and current NDC numbers if less than 12 months) of sales data for the prior and current NDC numbers to estimate the lagged price concessions applicable to the redesignated NDC number.<sup>24</sup>

CMS requests comments on its proposed revisions to the smoothing of lagged price concessions for NDC numbers with less than 12 months of sales and redesignated NDC numbers.

4. Nominal Sales

In light of statutory changes made by the DRA that will become effective January 1, 2007,<sup>25</sup> CMS proposes to clarify the method manufacturers must use, beginning in 2007, to identify nominal sales for purposes of ASP reporting and exclusion

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<sup>21</sup> Id. at 49,003, 49,083 (proposed 42 C.F.R. §§ 414.804(a)(3)(i)(A), (B)).

<sup>22</sup> Id. at 49,083 (proposed 42 C.F.R. § 414.804(a)(3)(i)(B)).

<sup>23</sup> Id. at 49,003.

<sup>24</sup> Id. at 49,003, 49,083 (proposed 42 C.F.R. § 414.804(a)(3)(i)(A)). This does not apply to a product that is repackaged or relabeled by another entity or privately labeled. Id. at 49,003.

<sup>25</sup> In February 2006, we prepared a memorandum summarizing the DRA amendments to the Medicaid Rebate program. The memorandum is available on our web site at [www.hpm.com](http://www.hpm.com).

from the ASP calculation.<sup>26</sup> Section 1847A(c)(2)(B) of the Social Security Act requires the exclusion from ASP of sales at a nominal charge.<sup>27</sup> The statute defines such sales as sales at a nominal price that are excluded from BP or as the Secretary may otherwise provide.<sup>28</sup> In the preamble to the 2004 interim final ASP rule, CMS referred for the definition of a “nominal price” to the Medicaid Drug Rebate Agreement,<sup>29</sup> which states that a nominal price is “any price less than 10% of [average manufacturer price (“AMP”)] in the same quarter for which the AMP is computed.”<sup>30</sup> The DRA, among other things, amended the definition of AMP such that the AMP calculation will be done without regard to customary prompt payment discounts extended to wholesalers (i.e., such discounts will no longer be subtracted from gross sales dollars in calculating AMP).<sup>31</sup> The DRA also limited the exclusion from BP of nominal prices so that the exclusion will only apply to sales to the following entities: section 340B covered entities,<sup>32</sup> intermediate care facilities for the mentally retarded, state-owned or operated nursing facilities, and other safety net providers as determined by the Department of Health and Human Services.<sup>33</sup>

Despite these changes to AMP, CMS is proposing that nominal sales exempted from the ASP calculation continue to be based on AMP. Specifically, CMS is proposing that manufacturers calculate AMP as defined in 42 U.S.C. § 1396r-8(k) for a reporting quarter, and then identify nominal sales for that quarter that are eligible for exclusion – i.e., those sales made at a price that is less than 10 percent of the AMP to one of the

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<sup>26</sup> 71 Fed. Reg. at 49,002.

<sup>27</sup> 42 U.S.C. § 1395w-3a(c)(2)(B).

<sup>28</sup> Id. § 1395w-3a(c)(2).

<sup>29</sup> 69 Fed. Reg. 17,935, 17,936 (Apr. 6, 2004).

<sup>30</sup> Medicaid Drug Rebate Agreement, § I(s), sample available at <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/Downloads/rebateagreement.pdf>.

<sup>31</sup> DRA § 6001(c)(1)(C).

<sup>32</sup> See Public Health Service Act § 340B, 42 U.S.C. § 256b. These are disproportionate share hospitals and certain clinics that receive grants from the Public Health Service.

<sup>33</sup> DRA § 6001(d)(2).

permissible entities.<sup>34</sup> CMS notes that this approach allows manufacturers to use a single method for identifying nominal sales for both the Medicaid Rebate program and the Medicare program. However, CMS requests comments regarding whether it should use 10 percent of ASP, rather than 10 percent of AMP, as the basis for identifying nominal sales to exclude from the ASP calculation.<sup>35</sup>

5. Other Issues – Bundled Price Concessions and Widely Available Market Price (“WAMP”)

*Bundled Price Concessions:* CMS notes in the preamble that it is aware of some concerns regarding how the ASP guidance on price concessions is to be applied to drugs that are bundled with other drugs or items.<sup>36</sup> CMS states that it has not, to date, provided guidance regarding the issue of apportioning price concessions across drugs that are sold under bundling arrangements. CMS notes that, in the absence of any specific guidance, manufacturers may make reasonable assumptions in their calculations of ASP as long as those assumptions are communicated to CMS in the ASP submissions.<sup>37</sup> CMS is considering providing guidance on this issue, either through rulemaking or other guidance, and therefore requests comments on the following issues relating to bundled drugs:

- the frequency and types of structures of bundling arrangements that include Part B drugs;
- the extent to which sales of Part B drugs are bundled with sales of non-Part B drugs or products;
- what effect bundling arrangements may have on the ASP calculation, beneficiary access to quality care, and costs to the Medicare program and beneficiaries;
- whether additional guidance on apportioning bundled price concessions for purposes of the ASP calculation is necessary;

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<sup>34</sup> 71 Fed. Reg. at 49,083 (proposed 42 C.F.R. § 414.804(a)(4)(ii)).

<sup>35</sup> Id. at 49,003.

<sup>36</sup> Id.

<sup>37</sup> Id. at 49,004.



- potential methodologies for apportioning bundled price concessions for purposes of the ASP calculation; and
- the effect that variation in the structure of bundling arrangements might have on the impact of potential apportionment methodologies of the ASP calculation.<sup>38</sup>

*WAMP and AMP Threshold:* Section 1847A(d)(3)(A) of the Social Security Act states that CMS may disregard an ASP for a drug or biologic that exceeds WAMP or AMP for such product by an applicable percentage.<sup>39</sup> The statute set this threshold percentage at 5 percent for 2005 and permits the percentage to be adjusted in subsequent years.<sup>40</sup> The threshold percentage was set at 5 percent last year (2006), and CMS proposes that it continue to be 5 percent for 2007.<sup>41</sup> CMS also requests comments on the timing and frequency of ASP, AMP, and WAMP comparisons and the effective date and duration of the rate substitution.<sup>42</sup>

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If you have any questions concerning CMS's proposed revisions to ASP, please contact Michelle Butler (202/737-7551), Alan Kirschenbaum (202/737-4283), Jeff Wasserstein (202/737-9627), or Kirk Dobbins (202/737-4583).

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<sup>38</sup> Id.

<sup>39</sup> 42 U.S.C. § 1395w-3a(d)(3)(A).

<sup>40</sup> Id. § 1395w-3a(d)(3)(B).

<sup>41</sup> 71 Fed. Reg. at 49004, 49083 (proposed 42 C.F.R. § 414.904(d)(3)).

<sup>42</sup> Id. at 49,004.