



February 20, 2007

VIA ELECTRONIC SUBMISSION

Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-2238-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 21244-1850

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Dear Ms. Norwalk:

The Healthcare Distribution Management Association (HDMA) appreciates this opportunity to provide public comments on Proposed Rule CMS-2238-P, “Medicaid Program; Prescription Drugs; Proposed Rule (the “Proposed Rule”) published in the *Federal Register* on December 22, 2006.¹

HDMA and its members are committed to patient safety by delivering life-saving health products and services through a secure and efficient healthcare distribution system. These primary, full-service healthcare distributors are responsible for ensuring that billions of units of medication are safely delivered each year to tens of thousands of retail pharmacies, nursing homes, clinics and providers, in all 50 states. HDMA and its members are the vital link in a healthcare system that assures medicine safety, quality, integrity and availability in the marketplace. HDMA and its members focus on providing value, removing costs and developing innovative solutions to deliver care safely and effectively.

HDMA and its members are key stakeholders in the prescription drug market in the United States. We recognize that, in an effort to reduce federal and state spending, the Deficit Reduction Act of 2005 (DRA)² provides for some of the most sweeping changes in the Medicaid program in more than a decade. We expect our members’ customers and vendors to be profoundly affected by the Medicaid reimbursement and price reporting changes detailed in the Proposed Rule. We envision the already competitive marketplace for prescription drugs becoming even more so in the wake of the enhanced pricing transparency that the Proposed Rule promises. As a result, we anticipate significant changes in the market that will reverberate throughout the healthcare distribution system and impact our members’ businesses. We welcome the opportunity to provide CMS with input on the Proposed Rule from the wholesaler perspective.

¹ 71 *Fed. Reg.* 77173 (Dec. 22, 2006).

² Pub. L. 109-171 (Feb. 8, 2006).



EXECUTIVE SUMMARY

HDMA has limited its comments on the Proposed Rule to issues of primary importance to wholesalers. We have endorsed aspects of the proposal with which we agree. We also have pointed out areas of disagreement. Because we intend our comments to be constructive, we have provided explanations for our positions and recommendations for revisions that address our main concerns. A brief summary of the principle suggestions we have made for fine-tuning the Proposed Rule follows:

- **Bona Fide Service Fees:** The Final Rule should reference the discussion of *bona fide* service fees in the preamble to the 2007 Physician Fee Schedule Final Rule,³ and stipulate that CMS intends to apply the *bona fide* service fee definition in the same way in both the ASP and the AMP context. The Final Rule also should clarify whether administrative fees, GPO fees, distribution fees, promotional fees, etc. can qualify as *bona fide* service fees provided that all of the elements of the definition are satisfied.
- **Customary Prompt Pay Discounts:** To avoid confusion, when the Final Rule instructs manufacturers to deduct cash discounts in the AMP and Best Price calculations, the term “cash discounts” should be qualified by the addition of a parenthetical excepting customary prompt pay discounts. In addition, customary prompt pay discounts should be excluded not only from AMP, but also from Best Price.
- **Retail Pharmacy Class of Trade:** The *sine qua non* of the retail pharmacy class of trade is public access. That said, the Final Rule should take a different tack than the Proposed Rule and exclude from AMP the following sales, rebates and other concessions:
 - Sales to mail-order pharmacies
 - Rebates paid to PBMs on retail network sales
 - Sales to hospitals (regardless of whether a drug is used in an inpatient setting or in one of the hospital’s outpatient departments)
- **Lagged Methodology:** To minimize period-to-period variability in AMP, the Final Rule should require manufacturers to implement a 12-month rolling percentage methodology for netting out price concessions and determining lagged unit amounts needed to calculate AMP. The methodology should rely upon data from the four full calendar quarters prior to the reporting period so that the rolling percentage may be used to determine both monthly and quarterly AMPs.
- **Postpone Public Posting of AMPs:** To avoid misleading consumers and commercial payers and to protect pharmacies from misguided reimbursement cuts, CMS should postpone posting AMP data on its Web site until it receives the first AMP reports after the Final Rule has been implemented.
- **Postpone Setting AMP-Based FULs:** To ensure that pharmacies are adequately reimbursed by state Medicaid programs, CMS also should postpone setting FULs based on AMPs until the Final Rule has been implemented.
- **AMPs and FULs Set at the 11-Digit NDC Level:** The Final Rule should require manufacturers to calculate AMPs at the 11-digit NDC level, and report those AMPs along with utilization data to CMS monthly and quarterly. Such reports would permit CMS to continue using AMPs weighted across all package sizes for rebate purposes, but permit FULs to be set at the 11-digit NDC level so that these payment caps for multiple source products may be tied to the most commonly used package size.

³ 71 Fed. Reg. 69623 (Dec. 1, 2006).

- **FUL Outlier Methodology:** In lieu of an outlier methodology, the Final Rule should set FULs based on the weighted average AMP of the therapeutically equivalent products available in the market, not the AMP of the least costly product. If CMS is unwilling to adopt this approach, the Final Rule should include a FUL outlier methodology that examines AMPs on a cumulative market share basis, starting with the lowest AMP, then the next highest and so on, rejecting AMPs until a cumulative market share of 50% has been reached. This approach would allow CMS to set FULs based on a criterion that distinguishes between low-priced NDCs available only on a limited basis and NDCs priced at true market levels and available in quantities sufficient to satisfy retail pharmacy demand. If CMS prefers, as it proposed, to adopt an outlier methodology that uses price as an indirect proxy for availability, the screening percentage used should be set at 50% or less, not 70% or less, of the next lowest AMP and the price comparison test should be applied iteratively until the lowest AMP that is within 50% of the next lowest AMP has been identified.
- **Definition of Wholesaler:** The Final Rule should conform the definition of “wholesaler” to the definitions of “wholesale distributor,” “wholesale distribution” and “distribute” in the FDA regulations at 21 CFR § 203.
- **RSP:** To ensure that RSP data will be – as the statute requires – representative of average “consumer purchase prices” at retail, CMS should engage stakeholders, as soon as possible and in a meaningful way, in the development of the procedures to be used to collect, aggregate and disseminate RSP data.

DETAILED COMMENTS

We have keyed most of our detailed comments to the section headings in the Proposed Rule. We also have included a discussion at the end of our comments keyed to an issue identifier in the Proposed Rule that addresses overarching concern we have with the scope of the proposal.

Definitions – Proposed 42 C.F.R. § 447.502

Bona Fide Service Fee

HDMA applauds CMS’ decision to include a definition of “*bona fide* service fee” in the Medicaid regulations codifying the methodology for calculating AMP and determining Best Price that is identical to the definition included at 42 C.F.R. § 414.802 in the Medicare regulations codifying the methodology for calculating ASP. It would be operationally difficult for a pharmaceutical manufacturer to implement Medicare and Medicaid price reporting regulations mandating different handling of the same fees paid to a wholesaler under a distribution service agreement.

In our view, logic also demands similar treatment of *bona fide* service fees in all price reporting calculations, regardless of whether those calculations support Medicare or Medicaid. Accordingly, we also applaud the instruction in proposed 42 C.F.R. § 447.504((h)(11) establishing that *bona fide* service fees should not be deducted when AMP is calculated and the parallel instruction in the Best Price context in proposed 42 C.F.R. § 447.505(d)(12). These instructions are consistent with the regulation at 42 C.F.R. § 414.804((a)(2)(E)(ii) excluding such fees from the ASP calculation.

We were particularly pleased CMS provided extensive commentary about its interpretation of the *bona fide* service fee definition in the preamble to the 2007 Physician Fee Schedule Final Rule (the “2007 PFS Final Rule”)⁴, where the definition was originally adopted in the Medicare ASP context. That commentary explained that *bona fide* services “encompass any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs.”⁵ They include services “the manufacturer has the capacity to perform, and those that can only be performed by another entity.”⁶ Moreover, the definition of *bona fide* service fee itself makes it clear that such services may be performed either by entities that take title to and possession of drugs from a manufacturer or entities that do not. We are in complete agreement and believe the same analysis should apply for AMP and Best Price purposes as well.

The commentary in the 2007 PFS Final Rule on *bona fide* service fees also stated that fair market value (FMV) fees involve payments at rates generally available in the market from other similarly-situated entities, may be calculated for “a set of itemized bona fide services, rather than . . . for each individual itemized service, when the nature of the itemized services warrants such treatment,” and may be set in terms of percentage of goods purchased.⁷ We note the Proposed Rule requests comments on an appropriate definition for FMV in the section of the preamble that discusses the treatment of administrative and services fees in the AMP calculation. HDMA provided extensive input on this topic in its comments on the 2007 Physician Fee Schedule Proposed Rule⁸. The discussion of FMV in the context of service fees that CMS presented in the preamble to the 2007 PFS Final Rule is consistent with the views we expressed in our comments. The same approach seems appropriate in the AMP and Best Price context.

In the commentary to the 2007 PFS Final Rule on *bona fide* service fees, CMS acknowledged that manufacturers often have no effective way of knowing whether a *bona fide* service fee is passed on to the fee recipient’s customer, and advised that manufacturers may “presume, in the absence of evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of any entity.”⁹ It also clarified that the “treatment of service fees for ASP purposes and financial accounting purposes may be different, and that if a fee meets our definition of a bona fide service fee it can be excluded from the ASP regardless of its treatment for financial accounting purposes.”¹⁰ The same problem exists with respect to the treatment of Medicaid rebates. Under Social Security Act § 1927 and the Medicaid Rebate Agreement, rebates may not be deducted when AMP and Best Price are determined. In contrast, the treatment of Medicaid rebates in accordance with GAAP for financial accounting purposes requires the rebates to be handled as a deduction from revenues (e.g., like a price concessions).¹¹

CMS should stipulate that the commentary explanations applicable to the definition of *bona fide* service fees when manufacturers are calculating ASP also apply when they are determining AMP and Best Price as well. Many pharmaceutical manufacturers do not make products subject to ASP reporting. As a result, some manufacturers may not be familiar with the discussion of service fees in the preamble to the 2007 PFS Final

⁴ 71 *Fed. Reg.* at 69666-70.

⁵ 71 *Fed. Reg.* at 69668.

⁶ *Id.*

⁷ 71 *Fed. Reg.* at 69669.

⁸ 71 *Fed. Reg.* 48981 (Aug. 22, 2006).

⁹ 71 *Fed. Reg.* at 69669.

¹⁰ *Id.*

¹¹ Revenue Ruling 2005-28, published in Internal Revenue Bulletin 2005-19 (May 9, 2005).

Rule. Further, given recent enforcement actions facing drug manufacturers, and the proliferation of multi-million dollar settlements involving Medicaid price reporting issues, we suspect those manufacturers aware of the 2007 PFS Final Rule would prefer to have CMS reiterate its view of the various elements of the *bona fide* service fee definition in conjunction with the Medicaid regulations on AMP and Best Price. In the name of efficiency, we ask that CMS expressly reference the discussion of *bona fide* service fees in the preamble to the 2007 PFS Final Rule when it prepares the preamble for the Final Rule implementing the Medicaid prescription drug provisions of the DRA. We also encourage CMS to make it clear it is adopting the principles and positions applicable to *bona fide* service fees outlined in the 2007 PFS Final Rule in the ASP context for purposes of AMP and Best Price determinations under Medicaid.

Dispensing Fee

HDMA is pleased CMS took a relatively expansive approach to the definition of dispensing fee in the Proposed Rule. We also applaud CMS' decision to recommend that state Medicaid programs "reexamine and reevaluate the reasonableness of the dispensing fees paid as part of a pharmacy claim"¹² if they elect to adopt AMP-driven pharmacy reimbursement formulas.

We urge CMS to consider the results of a recently-completed national survey of dispensing costs when it reviews proposed State Plan Amendments revising Medicaid pharmacy reimbursement formulas. Grant Thornton LLP obtained cost data from nearly half the retail pharmacy outlets in the United States for the six-month period from March through August 2006 and determined that the mean cost of dispensing per prescription was \$10.50 and the mean cost of dispensing per pharmacy was \$12.10.¹³ For the 65 million Medicaid prescriptions included in the sample, the mean cost per prescription was \$10.51 and the mean cost per pharmacy was \$12.81. Given these cost data, it will no longer be acceptable for states to reduce payments for dispensing services to Medicaid recipients once they take steps to trim the margins on ingredient costs that have been subsidizing Medicaid dispensing.

We also recommend including a few additional elements in the list of services detailed in proposed 42 CFR § 447.502 that must be considered when a dispensing fee representative of fully loaded costs is developed. We are hesitant to rely on the "[p]harmacy costs include, but are not limited to" language currently used to preface the list because of the inadequacy of dispensing fees paid by state Medicaid programs over the years. The revised definition also needs to include the time pharmacists spend entering billing information into their computer systems and communicating by telephone, fax and e-mail with state Medicaid agencies and PBMs about coverage and billing questions. More importantly, the Proposed Rule must include as an element of pharmacy costs the important health, safety and counseling services community pharmacists routinely provide – typically based on an individualized understanding of the customers' medical needs and personal preferences – to ensure that each physician's prescription leads to the best drug regimen for the patient.

Innovator Multiple Source, Multiple Source and Single Source Drugs

¹² Medicaid Drug Rebate Program Release for State Medicaid Directors No. 144 (December 2006).

¹³ *National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies*, prepared for The Coalition for Community Pharmacy Action by Grant Thornton, LLP (January 2007), available at http://www.rxaction.org/publications/COD_Study.cfm. The cost of dispensing per pharmacy treats every pharmacy equally, regardless of prescription volume. It is higher than the cost of dispensing per prescription because high-volume, lower-cost stores are weighted more heavily in this statistic.

The proposed definitions of an innovator multiple source drug and a multiple source drug require there to be two or more drug products that are therapeutically, pharmaceutically and bio-equivalent on the market in the United States. Furthermore, although the definition of a single source drug recognizes products approved by the FDA under a new drug application (NDA), a biologics license application (BLA) or an antibiotic approval, the definition of an innovator multiple source drug only reaches products initially marketed under an original NDA. None of these definitions reaches the situation where, at the end of the life cycle of a particular drug product, the only covered outpatient drug remaining on the market in the United States happens to be a version of the product that was originally approved by the FDA under an abbreviated new drug application (ANDA). CMS should revise the definitions to correct this oversight.

The Proposed Rule also does not define “covered outpatient drug” but rather lets stand without elaboration the definition of covered outpatient drug in the Medicaid Drug Rebate Statute at Social Security Act § 1927(k)(2). That statutory definition reaches beyond drugs approved by the FDA under NDAs, BLAs, antibiotic approvals or ANDAs to over-the-counter (OTC) products that have been prescribed by a physician. To capture the full breadth of the Medicaid drug benefit, we recommend including a definition of covered outpatient drug in the Final Rule that addresses both OTC and prescription drug products. The statutory definition of covered outpatient drug also incorporates grandfathered products and drugs still undergoing the DESI review process. The Proposed Rule’s definitions of single source, innovator multiple source and multiple source drugs do not, however, reach all of the products that came to market before 1962, and remain commercially available today. To avoid any ambiguities, HDMA suggests CMS revise the definitions of multiple source, innovator multiple source and single source drugs to address these gaps.

National Drug Code

The Proposed Rule defines NDC at 42 C.F.R. § 447.502 to mean “the 11-digit numerical code maintained by the FDA that indicates the labeler, product, and package size.” We would like to point out that the FDA maintains 10-digit NDCs configured in three segments (i.e., 5-4-1, 5-3-2, or 4-4-2 formats), not 11-digit NDCs, to identify drugs.¹⁴ Manufacturers create the 11-digit NDCs that are used by Medicaid by inserting a place-holding zero in the official 10-digit numerical codes maintained by the FDA to permit proper computer manipulation of product NDCs.

HDMA recognizes CMS has administered the Medicaid drug rebate program since 1991 using 11-digit NDC codes. We also realize federal and state systems for processing manufacturer price reports, pharmacy claims

¹⁴ 21 CFR § 207.35(b)(2)(i) and (ii) state:

(i) The first 5 numeric characters of the **10-character code** identify the manufacturer or distributor and are known as the Labeler Code...

(ii) The last 5 numeric characters of the **10-character code** identify the drug and the trade package size and type... [emphasis added].

Further, FDA has recently proposed changes in its regulations regarding the NDC system, including assignment and use of the NDC number (*Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs*. Docket No. 2005N-0403, 71 *Fed. Reg.* 51276, (August 29, 2006)). To define the code number, FDA proposed the following language in 21 CFR § 207.33(a):

What is the NDC number? The NDC number is a unique **10 digit number** with 3 segments. The three segments are the labeler code, the product code, and the package code... [emphasis added].

and rebate invoices all run off 11-digit NDCs. We are not proposing that CMS or the states move away from the 11-digit NDC format in their Medicaid systems. We know, for technical reasons, the 11-digit format has become the standard for all commercial and industrial purposes. Our members also use NDCs formatted as 11-digit numbers for the same reason Medicaid does – because computers cannot read spaces or hyphens and cannot adequately distinguish between drugs coded using a segmented 10-digit system. Nonetheless, we recommend that, for the sake of clarity, CMS revise the definition of NDC in the Proposed Rule to more accurately reflect the current regulatory landscape. A better approach would be to define NDC as “the segmented, 10-digit numerical code maintained by the FDA that indicates the labeler, product and package size, and that for commercial and technical reasons, must be converted to an unsegmented 11-digit number by inserting a place-holding zero”.

More importantly, we also wish to draw to CMS’ attention to a recently published FDA proposed rule¹⁵, which contemplates changes in the NDC system maintained by the FDA. Specifically, FDA noted it may consider switching from the 10-digit code to an 11- or 12-digit code because the FDA is concerned it may “run out” of numbers. In its public comments to FDA, HDMA pointed out that any changes to the current 10-digit FDA configuration will have enormous repercussions throughout the supply chain, including, but not limited to, compliance with international standards and existing regulations that govern the bar coding of pharmaceutical products. Additionally, we pointed out that the discrepancy between the FDA and CMS NDC definitions suggests any change by FDA to an 11- or 12-digit code could, at a minimum, result in confusion as to the appropriate code to use to meet Medicaid reporting requirements. We would like to make CMS aware of this concern and recommend to CMS, as we have to FDA, that the agencies consult with one another prior to finalizing their rules so that, to the extent possible, they determine how best to harmonize their use and definition of the national drug codes.

Determination of AMP – 42 C.F.R. § 447.504

Customary Prompt Pay Discounts

Express Exclusion from AMP.—The DRA changed the statutory definition of AMP at Social Security Act § 1927(k)(1) by deleting a phrase in the original definition stipulating that customary prompt pay discounts (CPPDs) paid to wholesalers were to be deducted. We were concerned that CMS might take a similar tack and remain silent about the handling of CPPDs in the Proposed Rule, implying, because they were not discussed, that the discounts should not be considered as part of the AMP calculation. We, therefore, applaud the decision to include language in the Proposed Rule expressly instructing manufacturers not to deduct CPPDs given to wholesalers when they determine AMP.

Definition of CPPDs.—We endorse the definition CMS has crafted for the term “customary prompt pay discount.” We are particularly pleased the agency resisted the temptation to integrate specific payment amounts or time terms in the definition. We suspect that some manufacturers may ask CMS to further define what is “routine” (e.g., how frequently and consistently does a discount have to be offered to be routine? Can prompt pay terms be routine if they are regularly used with one customer only, or must the same terms apply to multiple customers? Most customers? All customers?), what is “prompt?” (e.g., 30 v. 60 v. 90 days?) and possibly even whether what is prompt may vary depending on the circumstances (e.g., product launch v. ongoing sales), etc.

¹⁵ 71 Fed. Reg. 51276 (August 29, 2006).

Although we would welcome discussion of such issues in the preamble, we encourage CMS to maintain the proposed definition in the Final Rule. This approach allows manufacturers and wholesalers enough flexibility to negotiate payment terms, including CPPDs, appropriate to their particular situations and to changing commercial conditions, such as interest rate fluctuations. Flexibility also will foster continued competition in the healthcare distribution business – competition that has promoted consistent gains in productivity and driven down the cost of distribution significantly over the last decade.

Cash Discounts v. CPPDs—We recognize the Proposed Rule explicitly instructs manufacturers to exclude customary prompt pay discounts extended to wholesalers when they calculate AMP. We note, however, that many in the industry have historically referred to “prompt pay discounts” as “cash discounts.” We are concerned that some could inadvertently read certain provisions of the Proposed Rule instructing the deduction of cash discounts too broadly. We ask that you guard against this contingency by adding a parenthetical reading “(except customary prompt pay discounts extended to wholesalers) after the term “cash discount” in proposed 42 C.F.R. § 447.504(d) and 447.504(i). Further, if you accept our recommendation, discussed below, to completely exclude CPPDs extended to wholesalers from the determination of Best Price, similar clarifying language would be needed in 42 C.F.R. § 447.505 (e)(1).

Definitions of Wholesaler and Retail Pharmacy Class of Trade

Wholesaler Definition. – Proposed 42 C.F.R. § 447.504(f) defines “wholesaler” in an overly expansive fashion, including within the reach of the definition not only traditional full-service wholesalers and specialty distributors but also pharmacy chains, pharmacies and PBMs. This definition is inconsistent with the provisions of the Food Drug and Cosmetic Act incorporating the Prescription Drug Marketing Act (PDMA)¹⁶, and with the definitions of “wholesale distributor,”¹⁷ “wholesale distribution”¹⁸ and “distribute”¹⁹ in the FDA regulations that govern prescription drug marketing. Read together, the FDA regulatory definitions – although in their own right, quite broad – limit wholesalers to entities engaged in selling, offering to sell, delivering, or offering to deliver drugs to persons other than a consumer or patient.

We agree that warehousing pharmacy chains and warehousing mass merchant and supermarket pharmacy operations should be treated as wholesalers. They, like traditional wholesalers and specialty distributors, buy drugs directly from manufacturers and/or other wholesalers, consolidate orders for products from a variety of sources, and distribute the drugs, often by the single bottle or vial, to pharmacies within their chain that, in turn, resell the drugs at retail to consumers who present a prescription. Warehousing chains and warehousing mass merchants and supermarkets are licensed as wholesalers under state laws implementing the requirements of the PDMA.

We object to identifying individual pharmacies, including mail-order pharmacies operated by PBMs, as wholesalers. Simply put, these entities sell drugs to consumers and patients, and they rarely function as or are licensed as wholesalers. Their inclusion in the proposed definition of wholesaler is antithetical to the concept of wholesale distribution, as that term has been defined by Congress and the FDA.

¹⁶ P.L. 100-293.

¹⁷ 21 CFR § 203.2(dd).

¹⁸ 21 CFR § 203.2(cc).

¹⁹ 21CFR § 203.2(h).

We recognize the Medicaid Drug Rebate Agreement has characterized pharmacies as wholesalers since 1991, but, in our view, that definition was added to the Agreement to clarify that manufacturers should include direct sales, as well as indirect sales to pharmacies, in the calculation of AMP in light of a statute that defines AMP as the “average price paid to the manufacturer . . . by wholesalers for drugs distributed to the retail pharmacy class of trade. . . .”²⁰ The way CMS chose to structure the definition of “wholesaler” in the Rebate Agreement demonstrates CMS’ belief it has the statutory authority to capture both direct and indirect pharmacy sales in AMP, despite the words of the statutory definition, because such an approach reflects Congressional intent.

We agree with CMS’ interpretation of Congressional intent. We also recognize the logic of requiring the inclusion of both direct and indirect retail pharmacy sales in AMP. After all, beginning this spring, AMP likely will be the pharmacy reimbursement metric for most multiple source drugs. Moreover, depending on the actions of state Medicaid programs, AMP could become the pharmacy reimbursement metric of choice over the next few years in many, if not most, jurisdictions for single source drugs as well.

We note the CBO recently reported that independent pharmacies purchase 98% of their drugs through wholesalers.²¹ We ask that CMS incorporate direct retail pharmacy sales in AMP without adopting a strained, overly broad definition of wholesaler. It should be sufficient to include a provision in the Final Rule expressly stating that net sales to retail pharmacies are to be included when AMP is calculated, but CMS could avoid all ambiguity about the requirement to include direct pharmacy sales in AMP by adding the parenthetical “(direct and indirect)” after the word “Sales” at the beginning of proposed 42 C.F.R. § 447.504(g)(5).

We are particularly troubled by the inclusion of PBMs in the definition of wholesaler. We view the mail-order pharmacies that are operated by many PBMs as an ancillary PBM line of business, and we have already explained above why individual pharmacies, including PBM mail-order operations, should not be classified as wholesalers. That said, at their core, we consider PBMs to be health plan contractors tasked with: (1) developing and administering prescription drug formularies, (2) organizing networks of retail pharmacies that will accept plan enrollees’ drug cards and dispense drugs to them under coverage and co-pay terms dictated by the plan and (3) adjudicating and processing claims for drugs submitted by those network pharmacies. Because the use of formularies permits health plans and the PBMs with which they contract to drive market share, PBMs are able to negotiate concessions from manufacturers of single source drugs in competitive therapeutic categories in exchange for formulary position and enhanced market volume. Those concessions are paid to the PBMs on sales of formulary drugs made through their retail pharmacy networks in the form of rebates because the plans and their PBMs do not buy, take title to, deliver, or otherwise distribute drugs.²²

PBMs are only involved with paying network pharmacies for the drugs they dispense to enrollees in the health plans the PBMs serve. PBMs play no role in the arrangements manufacturers, wholesalers and group purchasing organizations make with brick-and-mortar pharmacies for the sale of drugs used to stock in-store inventories. PBMs neither purchase nor take possession of drugs dispensed by the pharmacies in their retail pharmacy networks. Given that PBMs are not part of the supply chain, it is a perversion of the concept of

²⁰ Social Security Act § 1927(k)(1).

²¹ *Prescription Drug Pricing in the Private Sector*, Congressional Budget Office (January 2007), p 5, available at <http://www.cbo.gov/ftpdocs/77xx/doc7715/01-03-PrescriptionDrug.pdf>.

²² *Id.* at p 2.

wholesale distribution, as the term has been defined by the FDA – and as the term is generally understood in virtually all other industries aside from pharmaceuticals – to characterize PBMs as wholesalers.

We urge CMS to rethink the definition of wholesaler at proposed 41 C.F.R. § 447.504(f). We advocate aligning that definition with the definitions of wholesale distributor, wholesale distribution and distribute in the FDA regulations implementing the PDMA. We also suggest including a statement in the preamble to the Final Rule saying CMS has conformed its definition to the approach taken by the FDA in the PDMA regulations. Our recommended approach would require CMS to eliminate pharmacies, including mail-order pharmacies and PBMs, from the parenthetical expounding upon the meaning of the term “entity” in the definition of wholesaler. It would be appropriate, instead, to clarify the meaning of entity in an explanatory parenthetical listing full-service wholesalers, specialty distributors, warehousing chain, and warehousing mass merchants and supermarkets that operate in-store pharmacies in some or all of their outlets. Depending upon whether CMS has made clear the connection between its definition for wholesaler and the FDA definitions in the PDMA regulations, CMS also could include the other types of entities detailed in 21 C.F.R. § 203.2(dd) in the explanatory parenthetical. As discussed above, CMS could then expressly capture direct sales to retail pharmacies in the calculation of AMP simply by modifying 42 CFR § 447.50(g)(5).

Retail Pharmacy Class of Trade. – We agree with CMS that the *sine qua non* of the retail pharmacy class of trade is public access. For that reason, as we will explain in more detail below, we disagree with including sales to mail-order pharmacies (or the PBMs that own them) in the list of entities in 42 CFR § 447.504(e) that define the retail pharmacy class of trade.

We also object to the inclusion of PBMs in that list. PBMs contract with retail pharmacies to offer pharmacy services at prearranged prices to enrollees in the health plans they represent. Negotiating insurance payment terms is not the same thing as arranging for the purchases of drugs that pharmacies make from their manufacturer and wholesaler vendors. Retail pharmacies hold two sets of contacts – one with vendors for the purchase of drugs and another with payers setting reimbursement terms. These two sets of contracts are negotiated independently. Reimbursement terms in pharmacies’ payer contracts do not affect the prices they pay manufacturers and wholesalers for the drugs they dispense. Similarly, the contract terms manufacturers negotiate with PBMs and, indirectly, with the health plans they represent, are independent of the chargeback contracts the manufacturers hold with pharmacies. They simply do not affect the net prices manufacturers are paid by wholesalers and retail pharmacies for drugs dispensed to the general public. Accordingly, under the controlling statutory definition of AMP, the contract terms between manufacturers and PBMs should not be factored into the determination of AMP. The statutory definition of AMP does not permit CMS to focus on the amount realized by a manufacturer on a drug sale net of all expenses, including PBM rebates, associated with the sale. Rather, the statute requires CMS to look to the amount actually paid to the manufacturer by customers in the retail pharmacy class of trade to define AMP. Those customers are, in our view, independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies – a definition that currently encompasses some 55,000 retail pharmacy locations.

Long-Term Care Facilities, Including Nursing Home Pharmacies

HDMA agrees long-term care (LTC) facilities and the pharmacies that serve them do not sell prescription drugs to the general public and should not be considered entities involved in the retail pharmacy class of trade under the definition CMS has put forward for that concept in proposed 42 C.F.R. § 447.504(e). We, therefore, strongly support CMS' decision to reverse the position taken in Manufacturer Release No. 29 and to exclude sales to LTC entities from the calculation of AMP.

Mail-Order Pharmacies

We are opposed to the inclusion of sales to mail-order pharmacies in the calculation of AMP. The definition CMS has suggested for retail pharmacy class of trade at proposed 42 C.F.R. § 447.504(e) turns on drugs being sold or provided to the general public. Indeed, the reason CMS gave for excluding sales to LTC pharmacies from the calculation of AMP was that those pharmacies are closed operations that serve only the residents of specific LTC facilities, not pharmacies that are open to the general public. The same is true for mail-order pharmacies, the vast majority of which are affiliated with PBMs or with health plans that administer pharmacy benefits internally. These mail-order pharmacies are not open to the general public. Access to any particular mail-order pharmacy is limited to individuals enrolled in a health plan with a mail-order option that is sponsored by the organization that operates the pharmacy or that contracts with the PBM that operates the pharmacy. In other words, mail-order pharmacies are closed operations in the same way that LTC pharmacies are closed operations. CMS can verify the closed nature of mail-order pharmacies by assessing the operations of PDPs and MA-PDs under contract with Medicare Part D, or by checking with OPM staff responsible for contracting for and overseeing the pharmacy benefits available to enrollees in Federal Employee Health Benefits Plans.

Mail-order pharmacies fail the public accessibility test in another important way. Because of the turn-around time on order processing and delivery, mail-order operations cannot adequately meet the acute pharmacy care needs of the limited population of individuals permitted to use them. Even those health plan enrollees with mail-order access need to turn to a conventional brick-and-mortar pharmacy for antibiotics and other drugs when treatment needs to begin immediately or when the expected treatment regimen involves only a single course of therapy lasting a matter of days to a few weeks.

If access available to the general public is the *sine qua non* for the retail pharmacy class of trade, mail-order pharmacies simply do not fit the class because they are closed operations. It seems illogical to us to include mail-order sales in AMP when sales to HMOs and managed care organizations (MCOs) are excluded. After all, most of the health plans that offer a mail option, either through an internal pharmacy operation or under contract with a PBM, are MCOs. Furthermore, even for those health plan enrollees eligible to use them, mail-order pharmacies are incapable of providing the full range of their pharmacy care needs. We believe these operational facts give CMS little choice but to reverse the position it took in Manufacturer Release No. 29 and in the Proposed Rule and, instead, add sales to mail-order pharmacies to the list of sales that must be excluded from the AMP calculation. Of course, doing so would also eliminate the need for manufacturers to net out rebates paid to PBMs and health plans on sales of drugs to their mail-order operations when they determine AMP.

We understand most manufacturers currently code mail-order pharmacy sales and brick-and-mortar pharmacy sales as sales to different classes of trade because mail-order pharmacies buy in pallet quantities, not the bottle and vial quantities that conventional pharmacy outlets need to stock their shelves. As a result, a decision to exclude mail-order pharmacies from the AMP calculation should not present operational difficulties for manufacturers.

PBM Rebates

CMS acknowledges in the preamble to the Proposed Rule that it has been criticized by both the GAO and the OIG for failing to provide clear instructions to manufacturers about the proper handling of rebates paid to PBMs in the calculation of AMP. It declares, however, that its historic position has always been that “PBMs have no effect on the AMP calculations unless the PBM is acting as a wholesaler as defined in the rebate agreement.”²³ Since the Rebate Agreement defines wholesaler as “any entity . . . to which the labeler *sells* the Covered Outpatient Drug . . . (emphasis added)”²⁴ and since PBMs do not purchase drugs to support the retail pharmacy side of their operations, we must conclude that historically CMS did not intend for manufacturers to include in AMP rebates paid to PBMs on sales made through their network pharmacies.

The Proposed Rule reverses the position CMS claims to have taken in the past. In addition to the proposed definition of wholesaler that expressly, but inappropriately, includes PBMs (discussed above), the Proposed Rule contains a provision at 42 C.F.R. § 447.504(g)(6) mandating that the AMP for a covered outpatient drug “shall include . . . discounts, rebates, or other price concessions to PBMs associated with sales for drugs provided to the retail class of trade.” The preamble explains CMS’ reversal of position by saying the agency is concerned that its previous position “exclude[s] from AMP certain PBM prices and discounts which have an impact on prices paid to the manufacturer. We believe that AMP should be calculated to reflect the net drug price recognized by the manufacturer, inclusive of any price adjustments or discounts provided directly or indirectly by the manufacturer.”²⁵

CMS’ explanation for its proposed handling of PBM rebates focuses on the total costs that manufacturers incur to market their single source drugs. It combines discounts on drug sales to the retail pharmacies that actually buy branded products to dispense to their customers with payments manufacturers elect to make to PBMs for formulary placement and market share - even though the CBO concluded “[p]harmacies do not benefit from the rebates that manufacturers give to PBMs.”²⁶ Rather, the PBM rebates are shared with the PBM’s health plan customers.²⁷

²³ 71 *Fed. Reg.* at 77179.

²⁴ Medicaid Drug Rebate Agreement at Art. I(ee).

²⁵ 71 *Fed. Reg.* at 77179.

²⁶ *Prescription Drug Pricing in the Private Sector* at p 12 (footnote 22).

²⁷ *Id.* at p 2 stating “Retail pharmacies . . . negotiate drug prices with wholesalers or pharmaceutical manufacturers. In the retail pharmacy market, there are two additional negotiations: one between health plans or self-insured employers and the manufacturers and the other between health plans or self-insured employers and retail pharmacies. The health plans or self-insured employers often contract out those two additional negotiations to pharmacy benefit managers (PBMs). PBMs that organize a large number of patient under a formulary . . . obtain discounted prices on many brand-name drugs in the form of rebates from manufacturers, which are in turn *shared with health plans or self-insured employers* (emphasis added).”

CMS' focus on the net revenues realized by manufacturers is misplaced. The Proposed Rule implements the DRA, a statute that was intended, in large part, to reduce Medicaid reimbursement to retail pharmacies, directly by revamping the formula for setting the FULs that cap payments on multiple source drugs and indirectly by providing states with data that will permit them to integrate AMPs into reimbursement formulas for both brand and multiple source drugs. The intended objective of the DRA is to reform Medicaid drug reimbursement in a way that reflects the actual acquisition costs of the pharmacies that serve Medicaid recipients. In most instances, these are chain or independent pharmacies with stores in communities where Medicaid beneficiaries live. Including rebates paid to PBMs on pharmacy networks sales in the AMP calculation defeats the purpose for the single source drugs subject to such rebates.

CMS' proposal for deducting PBM rebates when AMP is calculated also is contrary to the statutory definition of AMP at Social Security Act § 1927(k)(1) (as amended by the DRA), and to the definition of AMP in the Rebate Agreement. Both definitions say AMP is "the average price *paid to* the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade (emphasis added)." Rebates *paid by* the manufacturer to a PBM that does not buy or take possession of drugs simply do not qualify. They are not part of the price paid to the manufacturer by the pharmacies in the PBM's retail pharmacy network because those pharmacies do not share in the PBM rebates. CMS does not have the statutory authority to reinterpret the definition of AMP to focus on the net revenues realized by manufacturers instead of the net costs incurred by retail pharmacies for the drugs they dispense.

CMS ignores the change it made in instructions for handling PBM rebates completely in the Proposed Rule's impact analysis. Rather, it estimates only the reductions in reimbursement for multiple source drugs that retail pharmacies will experience because of the changes in the way FULs are set. The impact of the Proposed Rule's handling of PBM rebates on pharmacies likely would be significant, however. AMPs for single source drugs probably would be lower, on average, by more than \$6.00 per prescription.²⁸ Moreover, even though about half the prescriptions paid for by Medicaid are for multiple source products,²⁹ those prescriptions only constitute about 15% of the program's total drug spend.³⁰ Pharmacy revenues are largely attributable to single source drugs even though pharmacy margins may be higher on generics.

Finally, although PBMs only collect rebates on single source drugs,³¹ CMS' position on the handling of these rebates will have a negative impact on state Medicaid budgets. The OIG found that some manufacturers do not currently view transactions with PBMs as sales and, therefore, do not net PBM rebates out when they calculate AMP.³² It observed, too, that other manufacturers only include a portion of their PBM rebates in AMP.³³ As a result, the Proposed Rule's treatment of PBM rebates will lead to lower AMPs and lower rebate payments on some single source products. We do not have access to the data needed to estimate the total revenue reduction, but we are confident the losses will be significant, since the CBO recently reported state Medicaid programs

²⁸ *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, FTC (August 2005), available at <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf>.

²⁹ *Generic Drug Utilization in State Medicaid Programs*, OIG (OEI-05-05-00360) (July 2006), p 9.

³⁰ *Payments for Prescription Drugs under Medicaid*, CBO Testimony of Douglas Holtz-Eakin, Director, before the Special Committee on Aging, United States Senate (July 20, 2005), available at <http://www.cbo.gov/showdoc.cfm?index=6564&sequence=0>.

³¹ *Prescription Drug Pricing in the Private Sector* at p 12; *Pharmacy Benefit Managers* at 50-55.

³² *Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005*, OIG (A-06-06-00063) (May 30, 2006).

³³ *Id.*

received rebates in 2003 on single source drugs that were, on average, equal to 31.4% of AMP.³⁴ Further, the CBO observed that the percentage of state Medicaid revenues tied to rebates on single source drugs has been trending upward.

Outpatient Hospital Sales

Those hospitals that operate pharmacies open normal commercial hours for walk-up business from the general public typically contract separately for drugs used in these retail pharmacy operations. We agree sales to such pharmacies – which in our experience are more the exception than the rule – should be aggregated with sales to more conventional brick-and-mortar retail pharmacy outlets and treated as sales to the retail pharmacy class of trade for purposes of the AMP calculation.

That said, we disagree with categorizing other prescription drug sales to hospitals as sales to the retail pharmacy class of trade unless the drugs are used in the inpatient setting. The Proposed Rule makes access to the general public the *sine qua non* of the definition of the retail pharmacy class of trade. Hospital outpatient departments simply do not fit that definition because they are not publicly accessible. Rather, they are served by institutional pharmacies that only dispense drugs furnished to patients who have been admitted to the hospital for either inpatient or outpatient services. The Medicare Hospital Conditions of Participation, which apply to the vast majority of acute care hospitals in the United States, support treating inpatient and outpatient drug sales to hospitals in a uniform fashion for purposes of the AMP calculation in that they require hospital outpatient services to be “appropriately organized and integrated with inpatient services.”³⁵

Aside from being inconsistent with the definition of the retail pharmacy class of trade, the proposed distinction in the treatment of hospital sales based on where in the facility a drug is furnished is highly impractical and cost-inefficient. The pharmacy management practices of 340B disproportionate share (DSH) hospitals should not influence CMS’ thinking about the reasonableness of treating outpatient hospital sales as retail sales for AMP purposes because all outpatient and inpatient sales at 340B prices are excluded from the AMP calculation for other reasons. In our experience, however, unless hospitals are 340B Covered Entities, they do not buy or contract separately with pharmaceutical manufacturers or with GPOs for drugs intended for patients admitted for inpatient care and those admitted for outpatient care. They do not order separately from our members for inpatient and outpatient uses and they do not inventory drugs separately for such uses. As a result, we suspect that most manufacturers do not currently operate granular enough contract administration systems to distinguish hospital sales used in the inpatient setting from hospital sales used in the outpatient setting. Our member companies certainly anticipate a Final Rule that distinguishes between inpatient and outpatient hospital sales will result in additional work for wholesalers. Wholesalers would need to set up separate accounts; maintain more contracts; submit and track more chargebacks; and pick, pack and ship more deliveries. Such work would inevitably reduce efficiency and increase the cost of distributing drugs to our hospital customers. We suspect our hospital customers have similar concerns about the potential impact on their operating costs.

Before CMS moves forward with a Final Rule that treats hospital sales differently depending upon where in the hospital a particular unit of drug is administered, it should assess the impact on the hospital industry. Any increase in costs attributable to hospitals having to negotiate twice as many drug purchase agreements, process

³⁴ *Payment for Prescription Drugs under Medicaid* at Table 2.

³⁵ 42 CFR § 482.54.

twice as many drug purchase orders and maintain two different drug inventories merely to support the price-reporting needs of their pharmaceutical vendors will flow, in significant measure, to the Medicare and Medicaid programs.

CMS also needs to consider another practical implication of treating inpatient and outpatient hospital sales differently for AMP purposes. Because many hospital contracts for the purchase of prescription drugs would have to be renegotiated and because data on sales under new contracts would take time to work through the chargeback system, we doubt most manufacturers would be in a position to reliably report on hospital sales in accordance with the provisions of the Proposed Rule for six months to a year. This reality could necessitate a delay in the implementation of the AMP rule that we suspect CMS and Congress would find unacceptable.

Administrative, Service and Distribution Fees

The Proposed Rule includes a provision at 42 C.F.R. § 447.504(i)(1) that purports to further clarify elements of the AMP calculation. That provision states:

AMP includes cash discounts, free goods that are contingent on any purchase requirement, volume discounts, PBM price concessions, chargebacks, incentives, administrative fees, service fees, [sic] (except bona-fide service fees), distribution fees, and any other discounts or price reductions and rebates, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to the retail pharmacy class of trade.

We are troubled by three aspects of this instruction. We encourage CMS to address all three concerns when it publishes the Final Rule.

First, this provision again combines fees, discounts and other concessions offered to purchasers of drug products with payments made to third parties like PBMs and GPOs that do not purchase or take possession of drugs and that, in the case of GPOs, are not even a payer for drugs. The provision suggests all concessions to non-purchasers should be deducted when AMP is calculated. As we discussed earlier in our comments on the Proposed Rule's inclusion of PBMs in the definitions of wholesaler and retail pharmacy class of trade and its handling of PBM rebates, payments that manufacturers make to entities that are not purchasers of their products are outside the bounds of the statutory and Rebate Agreement definitions of AMP, and should not be deducted when AMP is calculation. For that reason, we find this provision overly broad in its reach. We hope CMS will limit the provision to price reductions and other payments that flow to purchasers, and expressly exclude payments that flow to third parties not involved in the purchase transaction.

Second, the provision clouds the issue of the proper handling of *bona fide* service fees and appears to create distinctions between administrative fees, service fees and distribution fees that do not always exist. Although it is a minor point, the placement of the comma between "service fees" and the parenthetical that excludes *bona fide* service fees from the AMP calculation leaves the reader wondering what the parenthetical modifies. In most instances, *bona fide* service fees paid to wholesalers and distributors include compensation for distribution services. Furthermore, administrative fees – a term typically used to describe fees manufacturers pay to GPOs and PBMs to support the contracting functions those entities perform on behalf of numerous buyers or health plans – meet the definition of a *bona fide* service fee under a variety of circumstances. Other fees paid to PBMs

for administering fill compliance and other programs also may comport with all the elements of the *bona fide* service fee definition. We recommend that CMS clarify, either in § 447.504(i)(1) itself or by adding a new paragraph to the subsection, that all fees that manufacturers pay to customers or third parties meeting the definition of a *bona fide* service fee are to be excluded from the calculation of AMP.

Third, as we discussed earlier in our comments on customary prompt pay discounts extended to wholesalers, the Final Rule needs to clarify, by the inclusion of a parenthetical after the term “cash discounts”, that only those cash discounts that fail to qualify as wholesaler customary prompt pay discounts are to be deducted when AMP is calculated.

Returns

HDMA commends CMS’ decision to exclude returns from the calculation of AMP. We agree that doing so will help smooth out period-to-period variations in AMP that are incompatible with the use of the statistic as a reimbursement metric.

Nominal Sales

We agree with the Proposed Rule provision directing manufacturers to exclude nominal sales from the AMP calculation. It would be unfair to allow deeply discounted prices offered only to safety-net providers, and not available in commercial transactions, to put downward pressure on AMPs and, in turn, depress Medicaid reimbursement available to retail pharmacies.

Determination of Best Price – 42 C.F.R. § 447.505

Customary Prompt Pay Discounts

We were surprised by CMS’ decision to require manufacturers to consider CPPDs extended to wholesalers when they determine the Best Price of single source or innovator multiple source drugs. CMS justified its decision by saying it “can find no evidence in the legislative history of the DRA that Congress intended to change the definition of best price to exclude customary prompt pay discounts.”

We acknowledge the DRA did not change the definition of Best Price at Social Security Act § 1927(c)(1)(C). We also recognize the statute says Best Price is “the lowest price available from the manufacturer . . . to any wholesaler, . . .” However, we are of the view that CPPDs extended to wholesalers are not price concessions and, therefore, should not have to be deducted under the statutory definition of Best Price. Rather, wholesaler CPPDs are payments to the wholesaler that recognize the time value of money to the manufacturer. In addition, CPPDs compensate wholesalers for assuming the credit risks associated with the sale of the manufacturer’s drugs to customers that dispense the products at retail, or use them in their healthcare operations. In essence, CPPDs are more akin to *bona fide* service fees that they are to price concessions. Thus, in our view, the lowest price available to a wholesaler is not a price net of CPPDs, but rather the stated contract price, which is typically WAC.

HDMA was very involved in the legislative debate over the DRA, and it was particularly focused on the CPPD issue. We understood Congress ultimately decided to amend the Medicaid Drug Rebate Statute to exclude CPPDs extended to wholesalers from the calculation of AMP because it recognized the discounts were retained by wholesalers and not passed on to end-consumers as price concessions. Simply put, Congress wanted AMP to be a transactional price that reflects the prices available to end-customers in the market. Congress recognized that including CPPDs in AMP would distort AMP as a measure of average end-customer costs. This same logic suggests that manufacturers should not be required to include wholesaler CPPDs in Best Price either.

If CMS cannot see its way clear to completely excluded wholesaler CPPDs from the determination of Best Price, it should expressly indicate that manufacturers should not aggregate CPPDs paid to wholesalers with contract discounts offered to end-customers but administered through the wholesaler's chargeback system when they determine Best Price. Rather, they should look only to the contract prices in their chargeback contracts when they assess whether the Best Price for the rebate period was set by a particular contract sale. If CMS elects this approach, we would prefer to see such a clarification incorporated into proposed 42 C.F.R. § 447.505(e) as a separate numbered paragraph reading:

When Best Price is determined, customary prompt pay discounts extended to wholesalers should not be aggregated with price concessions available to an end-customer under a contract administered through a wholesaler chargeback arrangement, regardless of whether the manufacturer negotiated the contract directly with the end-customer or with a third-party buying group.

Requirements for Manufacturers – Proposed 42 C.F.R. § 447.510

Monthly AMP Calculation Methodology

The Proposed Rule provides scant guidance on how manufacturers should determine monthly AMP values. This lack of specificity is problematic from the perspective of pharmacies, since monthly AMPs will determine the FULs that will cap their payments for multiple source drugs dispensed to Medicaid recipients beginning sometime this spring. It also is problematic, in our view, to instruct manufacturers to devise their own procedures for estimating end-of-quarter rebates and allocating them to each month in a quarter. Such an approach puts manufacturers at risk of enforcement actions for estimation and allocation methodologies deemed inappropriate by government authorities after years of consistent good faith use. Moreover, the approach in the Proposed Rule fosters the very type of methodological variability from company to company that Congress intended to eliminate when it mandated the promulgation of an AMP regulation in the DRA. We offer as a reasonable solution the 12-month rolling percentage methodology discussed in our comments immediately below about a methodology for the handling of lagged data in the AMP calculation.

Methodology for Handling Lagged Data

The Proposed Rule does not set forth a methodology for dealing with lagged unit data or lagged discounts when monthly or quarterly AMPs are calculated. This deficiency is particularly troubling given that the Proposed Rule, in a reversal from prior instructions, directs manufacturers to consider sales and associated price concessions extended to SCHIPs and SPAPs when they determine AMP. Manufacturers have no way of knowing how many units of drug were dispensed to enrollees in these programs, or what their program rebate

liabilities will be until they receive quarterly rebate invoices from the states. Unfortunately, these invoices never arrive until long after the deadline for filing quarterly AMP reports under the Proposed Rule. Depending on the plan, Part D rebate demands also may arrive too late to be properly included in quarterly calculations. The same could be true about PBM rebate demands if CMS decides to continue requiring their inclusion in AMP under the Final Rule. It seems to us the only practical way to address the inevitable delays in the receipt of data critical to AMP calculations is to build instructions for processing lagged data into the Final Rule. We strongly recommend using a 12-month rolling percentage methodology, similar to that required in the ASP rule.

The current instructions for calculating AMP (and ASP) are silent on whether chargebacks, rebates and other lagged discounts should be accounted for on an as-paid or an as-earned basis. As a result, different manufacturers have adopted different approaches. Some use the as-paid methodology for both chargebacks and rebates. Others use as-paid for chargebacks because the amount of chargebacks paid during a period is readily available within a few days after the period closes, but use an accrual approach for rebates. Still others accrue for both chargebacks and rebates. Even if the Final Rule adds a methodology for handling lagged discounts, it will fail to eliminate all the variability in different manufacturers' AMP calculations unless the methodology expressly stipulates whether chargebacks, rebates or both are to be considered lagged data and whether discounts are to be accounted for on an as-paid or an as-earned basis.

Many large purchasers often buy pharmaceuticals – particularly multiple source drugs – in bulk and then sell from inventory for many months. This buying pattern can result in periods when a manufacturer's sales outstrip price concessions accounted for on an as-paid basis, leading to an artificially high AMP, followed by one or more periods when discounts outstrip sales, leading to an artificially low AMP. Monthly reporting of AMP could exacerbate this problem. If a manufacturer elects to address the problem by accounting for lagged discounts on an accrual basis, it must periodically true-up AMP and Best Price reports to address accrual errors. The instructions in the Proposed Rule for handling bundled sales also will necessitate true-ups in some instances. Such true-ups likely will tax the capabilities of the rebate processing teams at the state Medicaid programs. They definitely will tax the price reporting teams at the manufacturers now that they will be called upon to make at least 16 price-report filings a year, instead of the four that had been due for Medicaid.

More importantly, the true-up approach, while it does allow for the eventual payment of the correct amount of Medicaid rebates, is inconsistent with the use of AMPs prospectively as the reimbursement metric that will set FULs for multiple source drugs. True-ups also will complicate the use of AMPs by state Medicaid programs as a reimbursement metric in the formulas that determine payment amounts to retail pharmacies for single source and multiple source drugs dispensed to Medicaid patients. The need for true-ups becomes particularly troubling in the face of a Proposed Rule that stipulates manufacturers may not – barring extraordinary circumstances and only with permission from CMS – restate monthly AMPs, but notes, in the preamble, that CMS intends to use those monthly AMPs to set and update FULs.

Because upfront discounts on large purchases meant to be sold out of inventory over an extended period of time also can distort pricing available to retail pharmacies in the market when they are factored into the AMP calculation on an as-paid basis, HDMA encourages CMS to build a well-defined smoothing methodology for handling all price concessions – not just lagged concessions – and for handling lagged unit data that must be considered when AMP is determined. Ideally, that methodology would operate much like the 12-month rolling percentage methodology specified for quantifying lagged discounts under the ASP rule. However, for AMP

purposes, we suggest instructing manufacturers to look to the four full calendar quarters before the reporting period to calculate the rolling 12-month percentage. A similar rolling percentage approach should be used to deal with lagged unit data needed to calculate AMP. The price and unit percentages could then be used to determine all three monthly AMPs and the quarterly AMP.

If CMS is not inclined to include upfront discounts in a smoothing methodology for AMP, it is imperative, particularly for multiple source products, that chargebacks be singled out for lagged treatment on a routine basis along with rebates because chargebacks often relate back to sales several periods prior. Because of the complexities involved, CMS should provide examples showing how the methodology should be applied in both the monthly and the quarterly context. Those examples also should take into account the proper treatment of the various types of bundled sales.

Posting of AMP Data

HDMA suspects that making AMP values publicly available on the CMS Web site before all the regulatory changes have been finalized and manufacturers given sufficient time to update their systems could mislead consumers about the appropriateness of the prices they are charged for drugs at retail pharmacies. It also could mislead commercial carriers about the drug costs experienced by network pharmacies. The simplest way to avoid possible confusion and data misuse would be to delay Web site postings until the new AMP rule becomes effective. We strongly encourage CMS to take this step.

We understand CMS believes it does not have the statutory authority to delay posting AMP data beyond the point when it has January AMPs in hand. Nonetheless, HDMA knows that executive branch agencies occasionally miss statutory deadlines without suffering legal repercussions, particularly when there is a valid reason for delay and the delay is reasonably short. We note, too, that CMS failed to meet the statutory deadline included in the Medicare Prescription Drug, Improvement, and Modernization Act of 2005 for implementing the competitive acquisition program (CAP) for drugs covered under Medicare Part B because it needed to work out problems with its initial program design, and attract a CAP vendor.

We realize the DRA sets an effective date of January 1, 2007, for the posting of AMP data. We appreciate the decision to read the law as applying to data related to sales occurring on or after January 1st and CMS' commitment not to post AMP data until it can process January monthly AMPs due to be filed by March 2, 2007. This timing ensures that posted AMPs will at least reflect the DRA's removal of customary prompt pay discounts extended to wholesalers from the calculation. That said, it does not fully resolve the potential problems associated with AMP postings that do not fully reflect the impact of the regulatory changes that will be implemented once the Proposed Rule is finalized.

If CMS decides to go forward with AMP postings this Spring, we hope that, at a minimum, the agency will review the January monthly reports carefully before placing the data on its Web site or downloading it to the states. Moreover, we hope any posting will be prefaced by a warning indicating that limited instructions were provided to guide manufacturers' January AMP calculations. Many manufacturers may have been unable to update or complete updating their government price reporting systems prior to reporting. Moreover, methodologies for calculating AMP are likely to change again mid-year when CMS promulgates a Final Rule codifying the AMP calculation methodology. Accordingly, posted data should be viewed as preliminary and

may not accurately reflect prices available in the market to retail pharmacies. Similar disclaimers should be sent to the states with their download tapes or new electronically-transmitted price report files. These disclaimers also should be reiterated in a State Medicaid Director Letter.

HDMA is pleased the Proposed Rule requires states to amend their state plans before changing their Medicaid pharmacy reimbursement formulas. We also applaud the caveats about the AMP data currently being downloaded to the states that CMS included in State Medicaid Director Letter No. 144 released in mid-December. We were pleased the letter recommended that states revise their dispensing fees when they implement changes in their formulas for reimbursing pharmacies for ingredient costs. We remain concerned, however, about states prematurely using AMP data for reimbursement purposes and inappropriately cutting pharmacy payments to levels that could reduce access to pharmacy services for Medicaid beneficiaries. We strongly urge CMS to use its authority to review and approve State Plan Amendments to prevent states from making precipitous changes before the Final Rule has been implemented and the “new” AMP data assessed.

Upper Limits for Multiple Source Drugs – 42 C.F.R. § 447.514

Monthly FULs

HDMA appreciates CMS’ decision to wait until AMPs have been calculated without prompt pay deductions before it begins distribution of revised FULs. Ideally, however, for reasons similar to those discussed earlier concerning why CMS should delay posting AMPs on the Web, we encourage CMS to extend the delay in setting new FULs until the regulations defining AMP have been finalized and pricing statistics calculated under them submitted.

We are particularly concerned about the potential for underpayments to pharmacies if FULs are set prematurely based on AMPs that may be lower than the “new” AMPs reported under the Final Rule. Even if CMS makes no changes to the Proposed Rule, we would expect the exclusion of sales to long-term care pharmacies from AMP to increase the AMP for those products used heavily by residents in those facilities. AMP likely would be further increased if CMS accepts our recommendations to exclude mail-order pharmacy sales and PBM rebates as well.

Schedule for Establishment and Dissemination of Monthly FULs

The Proposed Rule does not discuss CMS’ plans for using AMP data to set FULs beyond saying it intends to revise FULs monthly based on monthly AMP reports. Because FULs will be determinative of the maximum reimbursement amounts available on multiple source drugs to pharmacies in many states, we view the establishment of a predictable update schedule as critical. We recommend explaining what that schedule will be in the Final Rule. We also suggest coordinating the posting of AMP data on the CMS Web site with the effective date of updated monthly FULs based on the posted monthly AMPs.

FULs Representative of the Most Commonly Purchased Package Size

We understand the Proposed Rule would require FULs to be set at 250% of the lowest AMP (calculated without regard to customary prompt pay discounts) whenever two or more suppliers have A-rated therapeutic

equivalents listed in national pricing compendia. AMPs calculated at the nine digit NDC level will be used even though this approach will preclude tying FULs to the package sizes most frequently purchased by pharmacies.

We are strongly opposed to using nine digit AMPs to set FULs because applying a nine digit price likely will lead to reimbursement rates too low to fairly reimburse pharmacies for some products. CMS' collection and use of only of nine digit weighted average AMPs will become problematic when the weighted average is controlled by a high volume of sales of a larger-sized package with a lower per-unit cost, compared with smaller package sizes of the same drug, strength and dosage form. For example, the weighting could result in an AMP based largely upon pricing for a 500-tablet bottle even though retail pharmacies typically stock 100-tablet bottles to deal with shelf-space limitations and to control inventory costs. The problem with nine digit AMPs likely will become particularly acute with topicals and other products commonly distributed in unit-of- use packages (such as eye drops). The per-unit cost of an ointment in a larger 60-gram tube may be substantially less than the unit cost of the same product in 15-gram tube. Nonetheless, pharmacies have no choice about dispensing the small tube, regardless of the cap the product's FUL places on reimbursement if, as is frequently the case, the physician writes a prescription that specifies the unit-of-use package size.

To address this problem, we urge CMS to modify the Proposed Rule to require manufacturers to calculate and report AMPs routinely at the 11-digit level. Such reports would permit FULs to be set based on the most commonly purchased package sizes, as has been the practice in the past. If manufacturers also were required to report the number of units of each package size sold, as they do now when they report ASP values to Medicare, then CMS could calculate weighted nine digit AMPs that the states could continue to use for rebate purposes. CMS also would be in a position to permit states interested in reworking their pharmacy reimbursement formulas to select whether they want to receive 11-digit AMP data in addition to or in lieu of the nine digit AMPs that CMS has historically used to calculate Unit Rebate Amounts. We are of the view that pharmacy payments based on 11-digit data would more appropriately match reimbursement to per-store ingredient costs, since it is not always reasonable or appropriate for every retail outlet to buy drugs in the size container that promises the lowest per-unit price.

Reporting of 11-digit AMPs could also improve the utility to some consumers and commercial payers of the AMP data CMS will make publicly available through web postings. Finally, having 11-digit AMP data and accompanying unit sales information would permit CMS to set FULs based on weighted-average AMPs, instead of the lowest AMP, should Congress change the law in this regard. As we will discuss below, requiring manufacturers to report 11-digit AMPs and unit sales would permit CMS to address the problem of AMP outliers effectively when it determines FULs by using an approach that takes price and market share information into account simultaneously.

Eliminating Outliers From FUL Calculations

HDMA applauds the decision to carry out the FUL determinations without considering the AMPs reported for drugs once manufacturers have terminated a product. We understand current sub-regulatory guidance, which we presume will remain in effect after the Final Rule is issued, requires manufacturers to continue reporting the AMP calculated for the last quarter a product was marketed until one year after the last-batch expiration date of

the freshest product the manufacturer distributed. Obviously, since such AMPs could be several years old and no longer reflective of market pricing, using them could inappropriately skew FULs.

HDMA also commends CMS for adding a procedure to its methodology for setting FULs intended to ensure that caps on multiple source drug reimbursement are based on pricing keyed to that for a product available in quantities sufficient to meet national distribution demands. Eliminating the sale of product that is extremely short-dated or otherwise distressed avoids setting an artificially low FUL based upon AMP prices that do not reflect true market conditions.

We would prefer to see FULs calculated using the weighted average AMP of the therapeutically equivalent products available in the market, not the AMP of the least costly product. The DRA does not specify that FULs must be set at 250% of the lowest AMP for a product family, as the Proposed Rule would require. Rather, the DRA merely directs CMS to change the regulation at 42 C.F.R. § 447.332(b) to substitute “250 percent of the average manufacturers price (as computed without regard to customary prompt pay discounts extended to wholesalers)” for “150% percent of the published price.”³⁶ Since Congress never expressly mandated tying FULs to a multiple of the lowest AMP for a product family, we are of the view that CMS still retains the discretionary authority first granted it under Social Security Act § 1927(e)(4) to change other aspects of the FUL regulation. We urge CMS to use that authority to base the FUL on 250% of the weighted average AMP. Otherwise, we fear that pharmacies will be underpaid for many of the multiple source drugs they dispense to Medicaid beneficiaries perhaps leading many pharmacy owners to withdraw from providing prescription drug services to Medicaid beneficiaries, thereby reducing access to the most needy Americans.

If CMS is unwilling to amend the existing regulatory language setting FULs based on the least costly therapeutic equivalent, we encourage it to adopt, by regulation, an outlier methodology that uses market-share as the fundamental criteria for determining whether a low AMP should be rejected as non-representative in lieu of the price-based outlier approach detailed in the Proposed Rule.

We support requiring manufacturers to report, along with monthly AMPs, data at the 11-digit level (as discussed above) on the volume of product sold during each reporting period. CMS could then classify monthly AMPs associated with low market shares as outliers that do not represent widely available prices in the market. Specifically, we recommend examining AMPs on a cumulative market share basis, starting with the lowest reported AMP, then the next highest AMP and so on, rejecting AMPs until a cumulative market share of at least 50% has been reached. In contrast to the indirect price-based approach described in the Proposed Rule, this approach will allow CMS to focus directly on whether a low-priced NDC is available only on a “limited basis.”³⁷ Doing so should “ensure that a drug is nationally available at the FUL price”³⁸ because the market-share-based outlier methodology will disregard AMPs that, despite the low price, were only able, collectively, to satisfy less than 50% of market demand during the reporting period. Simply put, such AMPs are not indicative of true market conditions because product priced at such levels is in limited supply and cannot be said to be available for sale nationally.

³⁶ DRA § 6001(a)(5).

³⁷ 71 *Fed. Reg.* at 77188; *see also* proposed 42 CFR § 447.514(c).

³⁸ *Id.*

The example in the following table illustrates the outlier methodology we endorse.

Table 1 - Scenario:

Product at 11-Digit NDC Level	Price	Units	Cuml. Units	Cuml. Share
A	\$ 0.30	100	100	0.1%
B	\$ 1.50	400	500	4.76%
C	\$ 4.50	6000	6500	62.2%
D	\$ 5.00	3500	10000	95.24%
E	\$ 5.50	500	10500	100%

Market Share Sensitive AMP = \$4.50 (lowest price @50% market share (5250 units))
FUL per Proposed Regulation = \$3.75 (250% x \$1.50)

The table illustrates a reporting period for which manufacturers submitted monthly AMPs for five NDCs of a given drug/strength/dosage form of a multiple-source product of \$0.30, \$1.50, \$4.50, \$5, and \$5.50, with corresponding sales volumes of 100 units, 400 units, 6,000 units, 3,500 units, and 500 units. Under our recommended outlier methodology, the first two AMPs would be classified as outliers because collectively these NDCs represent less than 5% of the cumulative market demand. The FUL would be set based on the \$4.50 price because the 6,000 units available at that price, added to the previous 500 units (100 + 400) sold at lower AMPs would cross the 50% market share threshold. In other words, \$4.50 is the lowest AMP for product that is available for sale nationally. This contrasts with a FUL of \$3.75 (250% x \$1.50) under the price-based outlier methodology described in the Proposed Rule – a FUL that, in this example, would not be representative of prices for more than 95% of the market, and would likely result in actual losses on most Medicaid sales.

If CMS prefers to rely on an outlier methodology that uses price as a proxy for national availability rather than a methodology that relies directly on market share data, it would be more appropriate, in our view, to reject as an outlier any AMP that is 50% or less of the next highest AMP. As the Proposed Rule now stands, if the lowest AMP for a product were \$0.31 and the next lowest AMP were \$1.00, the outlier procedure would not be triggered despite the fact that the product's FUL would be only \$0.78 – an amount less than the next lowest AMP. Under the revision to the price-based approach that we have suggested, when an AMP of \$0.51 is accepted as the basis for setting FUL in the face of a next lowest AMP of \$1.00, the FUL of \$1.28 may or may not be enough to permit a pharmacy to sell product to Medicaid recipients without losing money. Further, any price outlier test should be applied iteratively until the lowest AMP that is not more than the specified percentage below the next lowest AMP is selected, even if satisfying that criteria requires rejecting a number of lower AMPs.

Even with these suggested modifications, we are convinced that a price-based approach to outlier identification will be inadequate. Suppose for example the AMPs on a particular multiple source product were \$0.30, \$0.50, \$0.90, \$3.00, \$3.25, and \$3.50 in one reporting period. Even with the modifications we have suggested for improving the price-based outlier methodology, this product's FUL would be set at \$0.75 (250% x \$0.30) simply because the most deeply discounted prices is less than 50% below the next lowest AMP. While it is

likely that most of the product on the market would cost at least \$3.00, pharmacies would be left facing a cost cap that covers a quarter or less of their acquisition costs for the product.

Background – Retail Survey Price

We had hoped CMS would address implementation issues related to DRA § 6001(e) in the Proposed Rule. We were looking forward to the opportunity to comment on how and from what sources data underlying RSP should be collected and how the data should be used to determine “a nationwide average of consumer purchase prices, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available)”³⁹ since the DRA defines RSP but provides little other substantive guidance on RSP-related issues. For example, because RSP is supposed to be representative of “consumer purchase prices” at retail, we wanted to talk about how CMS and its vendor would ensure only pharmacies within the retail class of trade are surveyed. We wanted to speak to how CMS would ensure valid results by structuring surveys to include an appropriate sample size and geographic distribution. We also wanted to discuss other steps that could be taken to ensure that RSP data is true to the statutory requirement to capture the out-the-door prices pharmacies charge consumers.

We note Medicaid Drug Rebate Program Release No. 144 for State Medicaid Directors dated Dec. 15, 2006 – a week before the Proposed Rule was published in the *Federal Register* – advises states that CMS will begin disseminating a monthly national survey of retail prices beginning in January 2007. We take that promise to mean CMS is moving forward with plans to implement DRA § 6001(e). That said, we strongly urge CMS to engage stakeholders, as soon as possible and in a meaningful way, in the development of the procedures the RSP contractor will be tasked with using when it collects, aggregates and disseminates RSP data. Including stakeholders in the regulatory and sub-regulatory processes relating to the implementation of DRA § 6001(e) likely will allow the development of RSP policies and procedures that anticipate issues associated with data availability and adequacy, reflect a more nuanced approach to data collection and analysis, and, in the end, result in the dissemination of RSP data that is – as the DRA mandates – representative of consumer purchase prices at retail for outpatient prescription drugs.

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In closing and on behalf of HDMA and our member companies, thank you for this opportunity to provide our comments on Proposed Rule CMS-2238-P. As you know, we are grateful for the opportunity to engage in substantive discussions with CMS officials about supply chain issues, and we continue to stand ready to address any questions you may have about the issues, concerns, and suggestions discussed above.

Sincerely,



Scott M. Melville
Sr. Vice President
Government Affairs

³⁹ DRA § 6001(e) adding Social Security Act § 1927(f)(1)(A).