HDMA
Healthcare Distribution
Management Association

April 2, 2012

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-2345-P
200 Independence Avenue SW
Washington, DC 20201

Re: CMS-2345-P: Medicaid Program; Covered Outpatient Drugs

Dear Ms. Tavenner:

HDMA appreciates the opportunity to present detailed comments on "CMS-2345-P: Medicaid: Covered Outpatient Drugs," which CMS published in the *Federal Register* as a Proposed Rule on February 2, 2012.[1] We have focused our comments on the definition and treatment of *bona fide* service fees and numerous aspects of the Proposed Rule, including the proposed switch to a presumed exclusion methodology for average manufacturer price (AMP) and the failure to provide for exclusions from the inhalation, infusion, instilled, implanted and injectable (5i) AMP, that would, if finalized as proposed, compromise the adequacy of pharmacy reimbursement under Actual Acquisition Cost (AAC)-based state Medicaid program prescription drug payment formulas and AMP-based federal upper limits (FULs). Our comments also address the proposed change to the definition of bundled sales and the request for input about the adequacy of the proposed definition of wholesaler.

Revise and Clarify Definition and Treatment of Bona Fide Service Fees

Background

The Proposed Rule revises the existing definition of *bona fide* service fees (BFSF) by limiting the definition to fees paid to wholesalers, retail community pharmacies (RCPs), other entities that provide pharmacy services to the general public (e.g., specialty pharmacies, home infusion pharmacies and home health providers) and group purchasing organizations (GPOs). It also clarifies that to qualify as a BFSF, any fee paid to such entities, whether it is for the specific services listed in Affordable Care Act (ACA)[2] §2503(a)(2)(B)(i)(II)[3] or other necessary services, must be a fair market value (FMV) payment for a *bona fide*, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise have to perform (or contract for) in the absence of the service arrangement and that is not passed on, in whole or in part, to the recipient's end customer (hereafter, for simplicity "the four-prong test"). This aspect of the BFSF definition involves the same four-prong test currently codified at 42 CFR §447.502.

The Final Rule Should Provide a Definition of Fair Market Value

Neither the text of the BFSF definition in the Proposed Rule nor the discussion of that definition in the preamble provides a definition of FMV. Rather, the preamble advises that manufacturers should "appropriately determine fair market value and make reasonable assumptions consistent with adequate documentation that will support their payment for these services at fair market rates sufficient that an outside party can determine the basis for the fair market value determination."[4]

[1] 77 *Fed. Reg.* 5318 (Feb. 2, 2012).
[2] Pub. L. 111-148, as amended by Pub. L. 111-152.
[3] ACA recognizes that fees such as distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs can qualify as BFSF.
[4] 77 *Fed. Reg.* at 5332.

HDMA has long encouraged CMS to adequately define BFSF. Unfortunately, the provision in the Proposed Rule falls short. We are disappointed with the decision not to provide substantive guidance on the concept of FMV. We fear the preamble discussion of manufacturers' FMV documentation responsibilities, without more specificity about what CMS regards as reasonable, could encourage some manufacturers to adopt unrealistic, overly restrictive FMV assumptions that could undermine our fee-based distribution business model and inappropriately complicate negotiations over the fees that permit us to provide needed services to manufacturers and bring efficiencies to the supply channel. CMS could supplement the definition in the Final Rule by further clarifying how manufacturers are expected to determine and document FMV. Doing so undoubtedly would facilitate increased uniformity in price reporting between manufacturers. Therefore, we strongly recommend that CMS provide a more robust discussion of FMV in the Final Rule, including a more detailed description of the nature and scope of documentation sufficient in CMS' view to substantiate the *bona fides* of manufacturers' service fees arrangements. We believe that documentation of hard-fought negotiations between wholesalers and manufacturers over service fee amounts should be sufficient.

At the very minimum, as was the case in the preamble to the Deficit Reduction Act (DRA) Final Rule,[5] this Final Rule should reference the discussion of *bona fide* service fees and FMV in the preamble to the 2007 Physician Fee Schedule Final Rule[6] and stipulate that CMS intends to apply this discussion in the same manner in both the Medicare and the Medicaid context. Doing so would offer some clarity regarding FMV. Just as importantly, such a reference would resolve the issue regarding CMS' current interpretation of the "not passed through" requirement that remains in this version of the BFSF definition.

The Final Rule Should Identify Three Additional Wholesaler Services as *Bona Fide*

We are concerned the Final Rule does not call out three key categories of services that wholesalers provide in addition to the distribution services listed in ACA §2503(a)(2)(B)(i)(II) – namely financial services, marketing and sales services, and data management services – nor explicitly state that fees for such services can qualify as BFSF if they meet the four-prong test. Because wholesalers purchase drugs from manufacturers and resell them, they routinely assume the credit risk associated with dealing with myriad pharmacies, both large and small, that dispense prescription drugs to Medicaid beneficiaries. Wholesalers also furnish financial services when they manage manufacturers' contracted discounts, process chargebacks, and handle credits and re-bills to correct for mistakes in the assessment of 340B or Federal Supply Schedule (FSS) eligibility. We recommend that the Final Rule identify that payments for such financial services can be structured as BFSF. Wholesaler data management services, which already include the provision of chargeback data and various reports, including reports on inventory movement, will need to expand greatly if the Final Rule requires a presumed exclusion approach to the calculation of AMP. The costs of providing these expanded services as well as the data services currently available should be identified in the regulations as being BFSF eligible. The role AMP will play in reimbursement for multiple source drugs under ACA makes it essential for the Final Rule to acknowledge that the sales and marketing services our members offer to generic manufacturers are candidates for BFSF treatment. After all, wholesalers devote significant resources to building networks of independent pharmacy customers that will consistently purchase the bulk of their generic drug needs from the wholesaler's portfolio of preferred multiple source products.

The Final Rule Should Stipulate that BFSF Are To Be Excluded from 5i AMP

Although proposed 42 CFR §504(c)(14) provides for the exclusion of BFSF from the calculation of RCP AMP, we are concerned that the Proposed Rule does not detail any exclusions from the AMP for 5i drugs beyond that for customary prompt pay discounts to wholesalers set forth in proposed 42 CFR §447.504(e). We hope this omission is an inadvertent oversight. If that is not the case, we strongly recommend reconsidering the decision, particularly in the context of BFSF. Our arguments for making what we would like to think of as predictable corrections are detailed in the section entitled "Supplement Comments" at the end of this letter.

CMS included a BFSF definition that did not have a recipient limitation in the regulations at 42 CFR §447.502 promulgated to effectuate the DRA and excluded all qualifying service fees from both AMP and Best Price[7] without the benefit of any statutory directive to do so. The Agency also did the same when it promulgated the regulations governing the calculation of average sales price (ASP) for Medicare Part B purposes.[8] CMS should do so again when it finalizes the regulations implementing ACA §2503. Regardless of who receives a *bona fide* service fee, the payment is FMV compensation for work done and not a price concession that should be deducted from any pricing statistic designed to represent prices available to certain groups of customers in the marketplace. We are concerned that it is potentially operationally difficult to expect manufacturers to recognize the very same fee as a discount in some government price reporting contexts but as a legitimate fee for service in others.

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[5] 72 *Fed. Reg.* 39140, 39182 (July 17, 2007) (stating "we are adopting the 2007 final ASP reporting rule's interpretation of the definition of bona fide service fees and how manufacturers may apply the definition for the purposes of AMP and best price" [citation omitted]).
[6] 71 *Fed. Reg.* 69623 (Dec. 1, 2006).
[7] 72 *Fed. Reg.* 39140 (July 17, 2007).
[8] *See* 42 U.S.C. §1395w-3a(c) and 42 CFR §414.802 and §414.804(a)(2)(ii).

We strongly encourage CMS to continue to use identical definitions of BFSF in the Medicaid and Medicare price reporting regulations – a definition that mirrors those currently codified at both 42 CFR §447.502 and 42 CRF §414.802 – and to exclude all BFSF regardless of recipient from RCP AMP, 5i AMP, Best Price and ASP. CMS could still supplement the BFSF definition in the new Medicaid regulations with examples of the types of services that can qualify as *bona fide* – a list we would argue should include a broader range of wholesaler services than those listed in ACA and the Proposed Rule – without comprising the consistency of the definition between Medicare and Medicaid.

Switch to Presumed Exclusion is Impractical and Not Needed

Background

The Proposed Rule would require manufacturers to make a profound change to the basic approach they have used to calculate AMP since the beginning of the Medicaid Drug Rebate Program in 1991. Instead of starting with gross sales and subtracting from those sales any transactions that can be identified with adequate documentation held internally by the manufacturer – meaning, in most instances, either manufacturer direct sales data or chargeback reports – as going to an entity in a class of trade not eligible for AMP, the Proposed Rule would require manufacturers to use a build-up methodology in which they would attempt to capture in the calculation of AMP only those sales they can trace to entities in the classes of trade included in the AMP calculation. This change from the previously used "presumed inclusion" methodology to a "presumed exclusion" methodology is far more complicated than CMS appears to assume.

HDMA is strongly opposed to this proposed change because, for many products, particularly brands, it is tantamount to the imposition of price reporting responsibilities on wholesalers and other downstream customers in the supply chain without statutory authority. As we see it, presumed exclusion inappropriately splits the Medicaid price reporting function between wholesalers and their customers, who would be called upon to develop and implement complex and costly new systems to provide detailed tracking data, and manufacturers, who then would be required to use wholesaler-provided data combined with other data from the wholesalers' customers, some of whom may have no direct relationship with the manufacturer, not their own internal data, to calculate AMPs. Such a split in responsibility for government price reporting is inconsistent with the requirements of Social Security Act §1927, which tasks manufacturers alone, with responsibility for the calculation and reporting of AMP and Best Price and the payment of Medicaid rebates based upon those reports.

Presumed Exclusion Is Contrary to the Congressional Goal of Ensuring Adequate Pharmacy Reimbursement Because It Would Reduce AMPs

CMS seems to justify the proposed change in the treatment of wholesaler sales in the face of what it acknowledges are possible data limitations on manufacturers' ability to trace those sales to end customers[9] by positing that the currently used presumed inclusion approach could result in lower AMPs "because it could include sales to entities (for example, mail order pharmacies and hospitals) that are able to buy the drugs at lower prices than retail community pharmacies."[10] We disagree with this supposition and believe it is an incorrect assessment.

The majority of non-chargeback sales – those indirect sales that manufacturers currently cannot trace and that CMS assumes would inappropriately reduce AMP under a gross-to-net methodology – are made to the full-service wholesalers in HDMA who distribute nearly 87 percent of the prescription drugs sold in the U.S.[11] Moreover, those non-chargeback sales to the wholesalers – the first and the only purchaser the manufacturer can identify with internal data – are typically priced at Wholesale Acquisition Cost (WAC), not at a discounted price that would pull AMP down below the prices available to RCPs. As we understand it, under the current presumed inclusion approach, AMP calculations would include only the WAC price to wholesalers, not a wholesaler's price to its customers. Thus, by potentially removing WAC-priced non-chargeback wholesaler sales from the AMP calculation, the switch to presumed exclusion that CMS is espousing would, in the vast majority of cases, lead to lower AMPs for products sometimes subject to discounting in the marketplace such as multiple source drugs and certain single source brands in therapeutically competitive classes. For those brand products that are not subject to discounting, all sales are priced at WAC, meaning a shift to presumed exclusion would have little, if any, impact on AMP despite the substantial operational and cost burdens that the switch would carry for wholesalers and, we assume, for manufacturers as well.

Presumed Exclusion Would Cause Delays and Inaccuracies Likely to Exacerbate the Already Unacceptably High Period-to-Period Volatility in Draft Weighted AMPs and FULs

Presumed exclusion would cause delays and inaccuracies in the calculation of AMP. Today, upon sale of a product to a wholesaler, a manufacturer has information about units and price and, essentially, is in a position to immediately report an AMP (subject only to

[9] 77 *Fed.Reg.* at 5329.
[10] *Id.*
[11] 2011-2012 HDMA Factbook, Center for Healthcare Supply Chain Research, p. 1; *see also* http://www.healthcaredistribution.org/about_hdma/about_hdma.asp.

subsequent adjustments, chargebacks and rebates), which can be estimated using the prescribed lagged methodology. Switching to presumed exclusion would cause delay because manufacturers would not be able to calculate AMPs until they could establish the class of trade of the wholesaler's end customer to whom the unit was sold or the class of trade in which that customer used the unit. Furthermore, presumed exclusion would cause inaccuracies as well if the manufacturer could not tie the wholesaler's sale of a unit to the correct unit sold to the wholesaler. For example, this new system would require that if a wholesaler placed a large order for several months' worth of product, the manufacturer would have no AMP to report until a unit is sold by the wholesaler. At a later point, these sales would eventually be reported to the manufacturer, but anytime there is a change in the manufacturer's price, the manufacturer would need to correctly tie together its sale to the wholesaler with the wholesaler's sale to its customer. However, besides the concerns over tracking the class of trade, this data exchange is not how current systems can operate because today inventory movement reporting systems to manufacturers do not tie back to specific purchases and doing so would require substantial system upgrades by our members. Adopting such an accounting assumption, such as "first in/first out," would fail unless manufacturers received – and processed – more information than that which our members are currently able to provide. The complexity of the necessary data exchanges is increased by the reality that wholesalers are constantly making purchases to replenish inventory before the sale of existing inventories has been exhausted.

As a result, for many products, particularly those that are multiple source, we would expect the presumed exclusion approach to the calculation of AMP to reduce the number of units identified as AMP-eligible during certain months. Currently, manufacturers count the entire sale to a wholesaler for AMP purposes at the time of the initial sale and units distributed to non-AMP-eligible classes of trade are deducted from gross sales at some later point when the sales out occurs and a charageback is reported. Under presumed exclusion, the manufacturer would not be able to count any sale until our members or others further down the supply chain make tracing data availability over time showing an AMP-eligible sale. Because such lags in data availability likely would reduce the number of identifiable AMP-eligible units in some periods – meaning AMP would be calculated likely using both a lower net price numerator and a lower units denominator, presumed exclusion likely would tend to increase what we see as already unacceptable levels of period-to-period variability in AMPs, weighted AMPs and FULs.

Presumed Exclusion Would Require Wholesalers to Develop Complicated, Expensive New Computer Systems to Accommodate the Data Needs of Manufacturers

Under presumed exclusion, our members would be required to build complicated, expensive new data management systems to meet our vendor's demands for tracing data. Our existing systems for tracking inventory movement (867 reports) only capture units sold, not the type of information about the costs of the products distributed to different classes of trade that manufacturers would need to calculate AMP. We currently have no systems in place for systematically identifying and sorting customer purchases by class trade. We certainly cannot distinguish between not-for-profit and for-profit pharmacy customers. We are not even sure we know how to identify a "specialty pharmacy" since there is no uniform, widely accepted industry definition. One PBM recently distributed a definition that is both controversial and somewhat circular in that it identified specialty pharmacies based on whether more than 25 percent of the prescriptions dispensed were for specialty drugs. We have no systems capable of collecting and reporting the net price that is associated with each unit of drug sold to a particular customer, nor do we know whether it would be more appropriate to use "first-in, first-out" or "last-in, first-out" accounting to support such a system. As another example of the complexities involved, we or the manufacturers would have to develop a way to determine what proportion of the goods sold to customers identified as specialty pharmacies or as chain warehouses are ultimately used to support the customer's mail-order operations since the Proposed Rule stipulates that such sales must be excluded from RCP AMP. No information systems or electronic data exchange formats currently exist for sharing this type of information between wholesalers and manufacturers, much less between our end customers and manufacturers.

Focus Should Be on Non-Contracted Sales

Balancing the concerns of the supply chain community and the importance of adequate reimbursement, HDMA believes CMS should clarify that manufacturers include "non-contracted" sales to wholesalers where the manufacturer does not pay chargebacks and does not otherwise know, or should know, whether the drugs will be distributed to entities that are not retail community pharmacies. We believe this policy on presumed inclusion would address the concerns of all stakeholders.

Presumed Exclusion Would Expose Wholesalers and Others Downstream in the Supply Chain to False Claims Risk Because of the Role They Would Be Required to Assume

Even if our members and others downstream in the supply chain could somehow manage to improve the tracing data to the level sufficient for manufacturers to report under the presumed exclusion methodology, we have concerns about providing this level of data when we have no control over processing or submitting it. More specifically, given the prevalence of whistleblower-initiated false claims actions, the tendency of whistleblowers to identify every possible defendant in the hope of increasing their potential recovery, and the cost of defending even unmeritorious False Claims Act cases, our members fear they would be inappropriately and unfairly

exposed to false claims risks if the Final Rule were to require manufacturers to rely in part on wholesaler data to enable a presumed exclusion methodology when they calculate AMP.

In the end, presumed exclusion would increase the cost, complexities and administrative burden on all parties throughout the supply chain, and would likely yield a lower, more variable and probably less accurate AMP. We recommend that CMS retain the presumed inclusion in the Final Rule, as it did in the DRA Final Rule,[12] as manufacturers should include all wholesaler sales that cannot be identified with adequate data as going to an RCP or another entity that furnishes pharmacy services to the general public in both the RCP and 5i AMP. The purpose of AMP is to assess prices available to RCPs in the marketplace, meaning the only issue is whether a manufacturer has issued a discount to a pharmacy either directly or indirectly in the form of a chargeback contract. Manufacturers already have all the details necessary to correctly calculate a measure of average market prices without having to switch to presumed exclusion from the currently used gross-to-net approach to the aggregation of that data for AMP purposes.

Revise 5i AMP Methodology to Protect Adequate Pharmacy and Physician Reimbursement

HDMA is extremely concerned about the lack of instruction for the calculation of 5i AMP in the Proposed Rule to include exclusions beyond that for customary prompt pay discounts in proposed 42 CFR §447.504(e). The vast majority of the entities entitled to purchase off the Federal Supply Schedule and all of the entities eligible to enroll in the Public Health Service's 340B program are in classes of trade that manufacturers are to include in the calculation of the 5i AMP under the Proposed Rule. As a result, it appears the AMPs for all 5i products would be reduced by the statutory discounts that must be made available under the provisions of the Veterans Health Care Act. Such a reduction is inappropriate since these mandatory discounts to government entities and grantees are not available to RCPs or to the other commercial classes of trade paid for these drugs by various state Medicaid programs. Coupled with the fact that BFSF on such products would also have to be deducted when AMP is calculated, it is unlikely that any 5i products covered by Medicare Part B would escape AMP substitution for ASP.

We sincerely hope the Proposed Rule's lack of a subsection detailing exclusions from the 5i AMP calculation is an inadvertent oversight, not an intentional decision on CMS's part to lower AMP. We believe it is essential for the Final Rule to require manufacturers to exclude federal government sales, BFSF, non-contingent free goods and all forms of patient assistance eligible for exclusion from RCP AMP from 5i AMP as well. Otherwise, pharmacies and physicians would be grossly unpaid for multiple source 5i drugs furnished to Medicaid recipients, possibly exacerbating certain drug shortage situations. Because of the inevitability of AMP substitution as a result of the mismatched treatment of government sales and BFSF under the applicable ASP and AMP rules, physicians also would be reimbursed at levels likely well below their acquisition costs for both brand and multiple source products administered to Medicare Part B patients in what we would argue constitutes an unlawful end-run around the ASP payment rules in Social Security Act §1847A.

Refine AAC and AMP-Based FULs to Ensure Adequate Pharmacy Reimbursement

By entitling ACA §2503 "Providing Adequate Pharmacy Reimbursement," Congress signaled its intent to ensure that pharmacies would be compensated by Medicaid for the drugs they dispense and the services they provide at a level sufficient to encourage the continued participation in the Program of enough RCPs to serve enrollees effectively and conveniently. Our comments on the requirements CMS has set out in the Proposed Rule related to states' pharmacy reimbursement formulas, manufacturers' calculation of AMP and CMS' setting of FULs are reflective of our understanding of Congressional intent and our sensitivities to the concerns of our pharmacy customers. We hope these same understandings and sensitivities will guide the decisions CMS must make as it finalizes the Proposed Rule.

<u>Additional Safeguards Are Required to Ensure AAC Remains Reflective of Market Pricing and Professional Dispensing Fees Remain Sufficient Over Time</u>

We commend CMS's recognition that pharmacy reimbursement for drugs ingredient costs and professional dispensing services must be adjusted in tandem. We understand the drive to require states to move away from ingredient cost payments based on Average Wholesale Price (AWP) or Wholesale Acquisition Cost (WAC) reimbursement algorithms and to substitute instead a requirement that they adopt Actual Acquisition Cost (AAC) payment formulas. We also understand ACA requires pharmacy payments for multiple source products to be subject to AMP-based FUL caps. Given the proposed change to AAC-based pharmacy reimbursement formulas, we would like to see regulatory provisions in the Final Rule that obligate states to supplement survey-based approaches to the setting of AAC with procedures designed to ensure that timely adjustments to AAC are made when prices in the market increase or decrease. Such procedures will be necessary to meet Congress' objective of paying pharmacies adequately – a term which we read as meaning in a manner consistent with currently available pricing in a dynamic market – since surveys inherently generate outdated information.

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[12] 42 CFR §447.504(g)(1) of the DRA Final Rule, which has now been withdrawn, stated "AMP for covered outpatient drugs shall include the following sales and associated rebates, discounts, or other price concessions –(1) Sales to wholesalers, except for those sales that can be identified with adequate documentation as being subsequently sold to any of the excluded entities as specified in paragraph (h) of this section."

We are pleased CMS has committed itself to ensuring, through the State Plan Amendment process, that no state will be allowed to reduce drug reimbursement to the required AAC-based levels without assessing the costs of dispensing and increasing professional dispensing fees accordingly. We remain concerned, however, because the definition of "actual acquisition cost" in the Proposed Rule captures only the "*actual prices* paid to acquire drug products marketed or sold by specific manufacturers (emphasis added)" and that of "professional dispensing fee" contemplates a fee based only on the "*costs* associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary (emphasis added)." Thus, it appears to us the Proposed Rule, if finalized as drafted, would tie both components of pharmacy reimbursement to cost-based measures without recognizing that most pharmacies in the United States are for-profit enterprises that must earn sufficient margins to support investments in quality and efficiency improvements and to otherwise sustain their businesses. Particularly in light of the planned expansion of Medicaid in 2014 under Title II of ACA, failure to allow expressly for the inclusion of profit in either component of pharmacy reimbursement on Medicaid business will likely lead, for those pharmacies that elect to continue their participation in Medicaid, to store closings and patient access problems. It is just such results that Congress was trying to avoid when it enacted ACA §2503.

Since Oregon already reduced the initial dispensing fees that were set based on surveys when that state changed its pharmacy payment algorithms to AAC a little over a year ago, we strongly urge CMS to add provisions to the Final Rule that will ensure the combined level of Medicaid ingredient cost and dispensing fee payments to pharmacies remain adequate over time. Such a provision should consider a reasonable margin as an element of the dispensing fee definition, require at least annual AAC and dispensing fee updates based on surveys conducted using a methodology that has been thoroughly vetted through a public comment process, and establish rules defining requirements for timely adjustments to AAC when market prices change. CMS also should strengthen State Plan Amendment oversight procedures to ensure states cannot unilaterally make changes over time to pharmacy ingredient cost algorithms and professional dispensing fee levels that are inconsistent with the Congressional goal of providing adequate pharmacy reimbursement for drugs and dispensing services provided to Medicaid recipients.

We understand the requirements for pharmacy reimbursement spelled out in the Proposed Rule apply to fee-for-service Medicaid. That said, as part of the implementation of health reform, we expect most states to move higher proportions, or even all, of their Medicaid enrollees to managed care delivery systems over the next several years. Moreover, now that the Medicaid drug rebate program applies to Medicaid managed care utilization, we suspect states will choose to include the pharmacy benefit in such plans because of the perceived value of improved care coordination under "carve in" arrangements. To achieve the objection of adequate pharmacy reimbursement in the face of such a trend, CMS also must take steps to ensure the commercial plans taking on Medicaid managed care business respect the need to guarantee adequate pharmacy reimbursement. They too must move away from the historical model of deeply discounted dispensing fees if their drug cost payments are pegged to acquisition cost levels. After all, the actual cost of dispensing remains the same regardless of the insurance coverage available to the customer being served.

AMP Volatility Undermines Confidence in Reimbursement Benchmarks

There has been enormous period-to-period variability in the weighted AMPs and draft FULs that have been posted to date on the CMS website – a fact recognized by CMS itself in the Proposed Rule.[13] No less than half of the draft FULs changed by at least 10 percent in each subsequent release. Such volatility in a reimbursement metric would be highly problematic, particularly for pharmacies that serve a high proportion of Medicaid recipients, because it would lead to erratic cash flow and undermine sound business planning.

Changes to the Proposed Requirements for Calculating AMP Are Needed To Ensure AMP-Based FULs Support the Goal of Adequate Pharmacy Reimbursement

We are concerned that several aspects of the RCP and 5i AMP methodologies called for by the Proposed Rule will tend to inappropriately lower AMPs and increase AMP period-to-period volatility. Key among these concerns is the proposed switch to presumed exclusion and the omission of exclusions from the 5i AMP methodology. We already have discussed these issues in detail earlier in our comments. We have, however, identified other concerns with the proposed AMP methodologies that we expect to have similar effects. That said, since we are not experts in the processes used to calculate AMP and since we expect our manufacturer trading partners to address these concerns in depth in their comments, we have decided to include our more detailed discussions of the additional methodological problems that are obvious to us in the section entitled "HDMA's Supplemental Comments" at the end of our letter. Suffice it to say here that the apparent instruction to include transfer prices of authorized generics and private-label products in AMP, the failure to exclude discounted pricing to state pharmaceutical assistance programs from AMP, and the ambiguity that surrounds the inclusion of specialty pharmacy and chain warehouse sales in AMP while mail-order sales are excluded fall into this category. Additionally, we are concerned about the likely impact of the 90/10 5i AMP test on AMP, weighted AMP and FUL volatility because we anticipate some products will flip-flop back and forth between the RCP AMP and the 5i AMP methodologies, skewing weighted AMPs and FULs when one manufacturer reports an RCP AMP and another a 5i AMP.

[13] 77 *Fed. Reg.* at 5349.

CMS Should Reserve Judgment on the Weighted AMP Multiplier to Be Used to Set FULs and Reassess Its Approach to the Determination of National Availability

ACA §2503(a)(1) permits CMS to set FUL reimbursement limits at "no less than 175 percent of the weighted average . . . of the most recently reported monthly average manufacturer prices for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis." According to the Proposed Rule, based largely on the close alignment between the currently available draft FULs and the Indiana State Maximum Allowable Cost (SMAC) limits, CMS never intends to exercise its authority under the statute to sometimes use a weighted AMP multiplier in excess of 175 percent. We urge CMS to reserve judgment on this point.

If the Proposed Rule is finalized as drafted, AMPs for some products, particularly those that are 5i products, likely will be lower than the AMPs currently being reported by manufacturers. We also note that our comparisons of draft FULs to Alabama AAC values indicate some FULs are below that reimbursement benchmark. Moreover, a comparison by the investment bank, Lazard Capital Markets, of the posted September FULs for the top 20 prescribed drugs to current SMACs for the 10 states representing the greatest number of Medicaid prescriptions[14] found that 72 percent of the draft FULs were lower than the corresponding SMACs.[15] Setting FULs at such low levels would certainly be contrary to Congress' goal of ensuring adequate pharmacy reimbursement.

The Proposed Rule calls for a fundamental change in the way in which manufacturers calculate AMP. Neither we nor CMS can quantify the potential impact that replacing the current gross-to-net approach with a build-up methodology will have on either the magnitude or the volatility of weighted AMPs and FULs. The period-to-period variability observed to date makes it clear that the smoothing of lagged price concessions is not sufficient to dampen the inappropriate swings likely to occur in multiple source drug reimbursement under FULs caps when, on occasion, we are seeing tenfold or greater changes from month to month. Accordingly, we encourage CMS to reconsider its decision not to develop and implement a FUL smoothing methodology or at least to postpone making a final decision on the point until it has an opportunity to assess the impact of the Final Rule on weighted AMPs and FULs.

In addition, because it would permit CMS more flexibility to ensure that pharmacies are adequately reimbursed, we strongly encourage CMS to reserve its right to adjust the weighted AMP multiplier upward in appropriate situations. CMS also should include a provision in the Final Rule requiring state Medicaid programs to develop and implement a process under which pharmacies could alert the state to situations in which a FUL needs to be lifted or adjusted to address supply issues or to prevent pharmacies from being paid for ingredient costs at less than market values. Any such system should include a process through which pharmacies paid based on a discredited FUL can reverse and re-bill the affected claims.

We suspect this type of alert system will be necessary as well to address localized access issues. We are concerned about the Agency's conclusion that all multiple source drug families with enough equivalent products listed in the Orange Book to justify the setting of a FUL will meet the statutory standard of national availability and, therefore, be accessible to every pharmacy for purchase at prices in line with published FULs.[16] CMS posits that when a drug has at least one approved equivalent, the drug is generally sold on a nationwide basis, but while such products may be sold nationwide, they may not be available to all retailers. For instance, if a manufacturer has production capacity to meet only 10 percent of nationwide market demand, 90 percent of the country would not have access to the product. Nevertheless, under CMS' approach, the product could be sold across the country and considered to be "available nationwide."

There are a variety of reasons why drugs in multiple source product families with draft FULs may be in short supply and not available for purchase by all retailers nationally even though they appear to be appropriate for FUL-capped reimbursement under the reasoning CMS has articulated in the preamble to the Proposed Rule. For example, the Proposed Rule would require manufacturers to report a monthly AMP for a terminated product until the first month after the expiration date of the last lot sold. Furthermore, CMS has directed manufacturers to carry forward the last reported positive AMP if they have no product sales in a given month.[17] Some manufacturers likely understand this instruction to require carrying forward the last reported positive AMP units too now that AMP-eligible unit reporting has been added by ACA. Orange Book listings are tied to notifications from the manufacturer that a drug is no longer marketed.[18] It is our understanding that many manufacturers have no incentive to terminate NDC numbers but rather prefer to

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[14] The 10 states—New York, Texas, Illinois, California, Ohio, Florida, North Carolina, Wisconsin, Missouri, and Indiana—account for 57% of total Medicaid prescriptions in the U.S

[15] Adam J. Fein, Drug Channel Blog, Tuesday Sept. 27, 2011 "The Pharmacy Reimbursement Hit from AMP-Based FULs," available at http://www.drugchannels.net/2011/09/pharmacy-reimbursement-hit-from-amp.html.

[16] 77 *Fed. Reg.* at 5347 (stating "Further, we believe that when a drug product has at least two FDA-approved, pharmaceutically and therapeutically equivalent drug products, that all retail community pharmacies would be able to purchase at least one of the drug products through a pharmaceutical market channel of distribution, including, but not limited to, a national, regional or specialty drug wholesalers, chain warehouse, group purchasing organization, or directly from the drug manufacturer.").

[17] *See* DRA Policy Questions at http://www.cms.gov/DeficitReductionAct/Downloads/DRAPolicyInquiries.pdf

[18] A product is designated as "discontinued" in the Orange Book when it is no longer marketed. There are no specific instructions that relate to the last-lot expiration date, but from a practical standpoint, that is an appropriate time point for a company to declare a product is no longer marketed. *See* Orange Book Preface about discontinued products, available at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm.

keep NDCs as assets for use at a later date. That said, supplies of many multiple source products will sell out long before the product's last-lot expiration date or before the product's NDC is discontinued in the Orange Book. In addition, manufacturers routinely continue to report AMPs calculated based on limited sales for products in short supply because of raw material supply disruptions or carry forward AMPs (and perhaps AMP units) for products on back order because of manufacturing disruptions if they intend to continue marketing the product after the supply problem is resolved.

Regardless of the reason(s), it is clear to us that at least on occasion; pharmacies in some locations will not be able to purchase products in certain FUL groupings through authorized distributors of record because those products will not be nationally available. CMS needs to address this eventuality in the Final Rule. Congress has authorized CMS to contract with a vendor to provide it with "notification . . . when a drug product that is therapeutically and pharmaceutically equivalent and bioequivalent becomes available."[19] Despite retaining Myers & Stauffer LLC to conduct NADAC surveys, it does not appear CMS has engaged a contractor to assess product availability. Given the clear requirements of ACA that multiple source drugs be available to RCPs on a nationwide basis before a FUL is set and the clear evidence that CMS' current assumption about availability is flawed, retention of such a contractor seems justified. In any event, CMS should modify its methodology for setting FULs to ensure it only includes drugs actually available nationally in adequate supply to ensure that all pharmacies will be able to access the product. At the very minimum, states must have procedures in place for lifting FUL caps on product reimbursement after they have verified pharmacy complaints about access issues. Those procedures should include ways for pharmacies to have previously under-reimbursed claims reprocessed. CMS also should consider how it could better identify product families where drugs are in limited supply before its sets FULs.

HDMA supports the decision not to count products that are designated with a "B" code in the FDA Orange Book when CMS decides whether there are enough equivalent products on the market to justify the setting of a FUL. We agree too that it would be inappropriate to apply a FUL to a B-rated alternative formulation to the reference listed product for a FUL family. Our position on these issues is informed by our experience. Simply put, B-rated products typically compete in different markets characterized by different pricing than that applicable to the A-rated drugs that are pharmaceutically equivalent to the reference listed product.

Other Proposed Changes of Note

Definition of Bundled Sales

We suspect the proposed change in the definition of bundled sale could have an adverse impact on our contractual relationships with certain manufacturers. Since those concerns are based merely on supposition, we have elected to address them in more detail in the "Supplemental Comments" section at the end of this letter.

Definition of Wholesaler

We have also chosen to include our response to CMS' request for input regarding the proposed definition of wholesaler in our "HDMA's Supplemental Comments."

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HDMA would welcome the opportunity to meet with you to discuss further our concerns and answer any questions you may have about our positions on issues associated with BFSF, pharmacy reimbursement, or the definitions of bundled sales and wholesalers under the Proposed Rule revising the price reporting processes that support the collection of Medicaid drug rebates and the payment requirements for covered outpatient drugs applicable to state Medicaid programs. Please do not hesitate to contact me at (703) 885-0233 or pkelly@hdmanet.org if we can provide additional information that may be useful to you.

Sincerely,

Patrick M. Kelly
Senior Vice President, Government Affairs

Attachment

[19] 42 USC §1396r-8(f)(1)(A)(ii).

Numerous Reasons Justify the Exclusion of BFSF from 5i AMPs

Since many 5i drugs are covered by Medicare Part B, it would be patently unfair to require the substitution of 103 percent of AMP for 106 percent of ASP using the substitute rules in the 2012 Physician Fee Schedule Final Rule[20] and codified at 42 CFR §414.904(d)(3)(ii) unless BFSF are excluded from 5i AMPs. Given that distribution services fees are higher for drugs requiring the types of special handling typical of many, if not most, 5i products, the Proposed Rule's treatment – or lack thereof – of BFSF in the 5i AMP calculation greatly increases the potential for ASP to exceed AMP by the threshold amount, thus triggering AMP substitution. In many situations, the differential treatment of BFSF in AMP and ASP could side-step the statutory requirement to use ASP as the reimbursement metric for most prescription drugs covered by Medicare Part B.

The limitation on acceptable recipients of BFSF in the Proposed Rule also is troubling from the perspective of the 5i AMP. The problem stems from the fact that administrative fees that otherwise would qualify as BFSF will not be eligible for AMP exclusion when they are paid to PBMs, managed care organizations or other entities, such as mail-order or long-term care pharmacies, that are not wholesalers, RCPs, non-RCP entities that provide pharmacy services to the general public or GPOs, but are entities included in the 5i AMP calculation. The prevalence of PBM administrative fees in the context of rebate agreements between brand manufacturers and commercial insurers, including those serving Medicare Part D, suggests finalization of the Proposed Rule as written would have the unintended consequence of further reducing 5i AMPs. We suspect our manufacturer trading partners are equally upset about the impact of the recipient limitation on BFSF in the context of Best Price.

It seems illogical to us to exclude BFSF paid to GPOs from AMP and Best Price but not to extend the exclusion to other entities such as PBMs and insurers that, like GPOs, are outside the supply chain in that they do not purchase prescription drugs. Similarly, we see no justification for treating payments for medication compliance and patient education programs or other legitimate care management services as BFSF when the service is provided by an RCP or other type of pharmacy that serves the general public but as price concessions when the same work is undertaken by a long-term care or mail-order pharmacy. The payments are, after all, compensation for needed services actually preformed regardless of the type of pharmacy providing them.

CMS clearly has the authority to require the exclusion of fees that satisfy the four-prong test for a BFSF from all pricing statistics regardless of the recipient of the fee. The Proposed Rule itself demonstrates that the statutory directive in ACA §2503(a)(2)(B)(i)(II) to ensure that BFSF paid to wholesalers and RCPs are excluded from AMP does not prevent CMS from proposing a BFSF exclusion when such fees are extended to other entity types. After all, the Proposed Rule would obligate manufacturers to exclude BFSF from RCP AMP when those fees are paid to non-RCP entities deemed to dispense drugs to the general public or to GPOs. The Proposed Rule also would expand the BFSF exclusion from RCP AMP to Best Price even though BFSF are not listed as a statutory exclusion from Best Price under the Medicaid Drug Rebate Statute[21] or any other statute.

Sales to Other Manufacturers That Relabel Should Be Excluded from AMP

The Proposed Rule would instruct manufacturers to include "[s]ales to other manufacturers who act as wholesalers for drugs distributed to retail community pharmacies"[22] in AMP. Despite the ambiguity in the limitation on the inclusion of manufacturer sales only when those sales are to manufacturers who act as wholesalers, CMS provides an explanation of the concept in the preamble that needs some additional clarification because it merely states that manufacturers should read the provision "in concert with the definition of wholesaler"[23] – a definition that circularly defines a wholesaler in part by saying a manufacturer is a wholesaler.

We are concerned that the proposed inclusion of manufacturer sales in RCP AMP could be read as requiring a primary manufacturer to include the transfer price of an authorized generic to a secondary manufacturer in the calculation of AMP. This treatment of transfer price would be the reverse of that required under the DRA Final Rule, which instructed manufacturers to exclude "sales to wholesalers or distributors where the drug is relabeled under the wholesalers' or distributors' NDC number."[24] The approach adopted in the DRA was logical since it avoided the incorporation of transfer price – a price that is not available to customers in the marketplace – in AMP. The proposed change in treatment would inevitably lead to a lower AMP for any brand that licenses the rights

[20] 76 *Fed. Reg.* 73026 (Nov. 28, 2011).
[21] *See* 42 U.S.C. §1396r-8(c)(1)(C).
[22] *See* proposed 42 CFR §447.504(b)(2).
[23] 77 *Fed. Reg.* at 5330.
[24] 42 CFR §447.504(g)(14) (2007) (now withdrawn).

to market an authorized generic to another company and, thus, to a lower weighted AMP and FUL for any FUL grouping containing an authorized generic. We view this result as inconsistent with Congressional intent to provide adequate reimbursement to pharmacies for multiple source drugs. To address the problem, we encourage CMS to clarify the language of the Proposed Rule to stipulate that sales of a product to another manufacturer are eligible for inclusion in RCP AMP only if the other manufacturer will sell the drug under the primary manufacturer's NDC.

The wording of the proposed provision addressing the treatment of sales to other manufacturers in RCP AMP also raises an issue when it is considered in the context of CMS' proposal to require manufacturers to use a presumed exclusion approach to the treatment of wholesaler sales. It appears CMS would expect a primary manufacturer to obtain tracing data from a secondary manufacturer to permit the primary manufacturer to limit the inclusion in AMP of its sales to the secondary manufacturer to that portion of those sales subsequently distributed to an RCP. Such a tracing requirement would raise both an operational issue and a legal concern. From an operational perspective, the proposed rule would require manufacturers to build new systems capabilities to permit the sharing of necessary tracing data. Perhaps more importantly, from a legal perspective, if the primary and secondary manufacturer both sell the same product into the marketplace, the required sharing of the secondary manufacturer's end customer information with the competing primary manufacturer could raise significant antitrust concerns. The clarification we recommended earlier of excluding other manufacturer sales from AMP when the product is relabeled with the secondary manufacturer's NDC would resolve this concern in the context of authorized generics and many private-label sales. The only resolution to the data-sharing problem when the issue is private-label sales of product that will still carry the primary manufacturer's NDC is reversion to the currently used presumed inclusion methodology.

Further Clarity Is Needed about the Treatment of Certain Mail-Order Sales in AMP

The Proposed Rule would direct manufacturers to include sales to specialty pharmacies in AMP because such pharmacies dispense drugs that do not qualify as 5i products to the general public. It also would stipulate that manufacturers should exclude mail-order sales from AMP. There is no recognition in the rule or the preamble discussion of the reality that the vast majority of specialty pharmacies are mail-order operations. CMS needs to clarify in the Final Rule whether the instruction to include special pharmacy sales in AMP always trumps the instruction to exclude mail-order sales or whether manufacturers are to capture only those specialty pharmacy sales that do not involve mail delivery. Failure to provide such a clarification will exacerbate problems with AMP variability because different manufacturers inevitably will make different reasonable assumptions about this issue. The same consideration arises in the context of sales to certain chain warehouses that distribute product to both the chain's retail outlets and its mail-order operations.

Rebates Paid to State Pharmaceutical Assistance Programs Should Be Excluded from AMP

Beginning with the publication of Manufacturer Release #29 in 1997, CMS has instructed manufacturers to exclude pricing to states under qualified state pharmaceutical assistance programs (SPAPs) from their calculations of AMP. The DRA Final Rule clarified that SPAP utilization should be included in the calculation of AMP because the products are dispensed by RCPs but that the rebates should be excluded because they are paid to the SPAP and not available to the pharmacy to reduce its acquisition cost.[25] The Proposed Rule does not provide for the exclusion of SPAP rebates when RCP AMP is calculated even though, consistent with the statutory requirement at 42 USC §1396r-8(c)(1)(C)(III), it does instruct manufacturers that such sales do not set a price point for the determination of Best Price. HDMA asks CMS to rectify this oversight by adding an exclusion for the rebates paid on SPAP sales to the long list of other exclusions from RCP AMP. The same recommendation applies with respect to 5i AMP.

The Tests Used to Identify 5i Products Not Generally Dispensed by RCPs Require Further Consideration

The two-step test outlined in the Proposed Rule for identifying 5i products gives us pause. As we read the Proposed Rule, it appears the 5i AMP methodology is only applicable to drugs that have certain FDA-assigned routes of administration, *i.e.,* products that actually are injected, infused, inhaled, instilled or implanted. Moreover, the proposal's RCP AMP methodology appears to apply only to drugs sold directly to RCPs or other entities that provide pharmacy services to the general public and to wholesalers or other manufacturers when those products can be traced to RCPs under a presumed exclusion approach. As a result, we fail to understand how, under the Proposed Rule, manufacturers should calculate and report AMPs for unit-dose products that are distributed directly or through wholesalers exclusively to hospitals, long-term care providers and other institutional facilities. It would seem such products would not qualify for either the RCP or 5i AMP methodology.

We have been told that many manufacturers have been using the 5i AMP methodology to calculate AMPs for such "forgotten" covered outpatient drugs since October 1, 2010, based on their understanding that it was Congress' intent to provide a calculation pathway for all drugs subject to the Medicaid Drug Rebate Program when it passed the Health Care and Education Reconciliation Act of 2010 amendment to ACA §2503. CMS seems not to have picked up on this intent since the Proposed Rule would again leave the

[25] *See* 42 CFR §447.504(g)(15) and 504(h)(23) (2007) (now withdrawn).

manufacturers of such products in a legal bind. They would hold a Medicaid Drug Rebate Agreement obligating them to report AMP on these covered outpatient drugs but they would be faced with a regulation that provides no methodology for doing so.

The Proposed Rule adopts a 90/10 test for determining whether drugs identified as 5i products should be subject to the 5i AMP or the RCP AMP methodology. The preamble to the Proposed Rule suggests CMS based this test on the approach dictated by the Department of Veterans Affairs for purposes of determining whether manufacturers should use direct or indirect sales to calculate non-federal average manufacturer price (non-FAMP) and set a brand product's Federal Ceiling Price (FCP) under the Veterans Health Care Act (VHCA).[26] The 90/10 test detailed in the Proposed Rule is to be applied monthly. In contrast, for VHCA purposes, the 90/10 tests is effectively applied annually and FSS pricing to the government does not change based on the test except at the beginning of each calendar year. Further, the instructions for calculating the additional discount that must be considered when a product's FCP is being set for the next calendar year also includes a way of effectively rebasing the prior year's third quarter non-FAMP used in that calculation to ensure that all VHCA pricing calculations involve only "apples-to-apples" comparisons. Manufacturers would not appear to have this luxury under the Proposed Rule since the Medicaid Drug Rebate Program only contemplates a product having one baseline AMP. We will leave it to the brand manufacturers who are more expert in AMP calculations and the impact of the additional rebate on their rebate liability to address this concern in their comments, but we suspect that they see it as an enormous problem that will skew their rebate liability and their 340B pricing obligations unfairly.

We wish to focus our comments about the 90/10 test applicable to 5i products on the skewing and variability problems we see evolving because of the requirement for manufacturers to calculate the AMP of such drugs in different ways depending on the customer mix for a product during any given month. Regardless of whether CMS uses a 90/10 test, a 75/25 test or a 51/49 test to identify 5i products "not generally dispensed through a retail community pharmacy,"[27] there always will be some 5i product(s) that will "flip-flop" between methodologies. Further, for multiple source 5i products within a given FUL grouping, there always will be situations where one manufacturer reports an RCP AMP and another reports a 5i AMP. That means that the quarterly AMP for any given 5i product could involve the weighting together of RCP and 5i AMPs. Similarly, the FUL for any given grouping of 5i products could be determined based on weighted AMPs calculated using both RCP and 5i AMPs.

The skewing of rebate liability, 340B pricing obligations and FUL caps when such mismatched 5i weightings are required seems inevitable to us given the way ACA §2503 is currently drafted. Moreover, the weighting together of flip-flopping, mismatched AMPs for 5i products will adversely increase period-to-period FUL volatility. The tightness of the 90/10 test will merely exacerbate these problems. So too will the confusion that we understand exists between manufacturers about whether the 90/10 test only looks to sales through RCPs or also has to include sales through specialty pharmacies, home infusion pharmacies and home health agencies. CMS should resolve this confusion which we suspect stems from the short-hand way in which some manufacturers are now describing RCPs, by clarifying in the preamble that the 90/10 test looks only to direct and indirect sales to independent, chain, grocery store and mass merchant pharmacies and does not consider sales to other entities deemed to offer pharmacy services to the general public. Unfortunately, we do not have a recommendation for resolving the problems that stem from the RCP AMP/5i AMP dichotomy created by the statute, but we strongly encourage CMS to forego setting FULs for 5i products until it can work with Congress to devise a more workable solution to Medicaid pharmacy reimbursement for 5i products and forgotten products that are neither 5i nor generally dispensed through RCPs than that now in place as a result of the jury-rigged amendment to ACA §2503(a)(2)(B)(i)(IV).

Revisions to the Definition of Bundled Sales Are Unnecessary and Likely Counter-Productive

The revised definition of a bundled sale in the Proposed Rule would unduly complicate the aggregation and allocation of discounts associated with wholesaler purchases of multiple products for inclusion in the portfolio of products offered to pharmacies under generic sourcing programs. We fail to understand what CMS hopes to achieve as a result of this change and the preamble to the Proposed Rule is silent on this point. We are concerned the proposed procedures would require our vendors to keep two sets of books – one for financial reporting proposes in which product-specific sales are recorded at the contracted discounted price assigned to each product reduced by the allocated amount of any overarching performance-driven volume discount and a second shadow set of books for government price reporting purposes that reflects the reallocated product-specific prices that flow from sales made under different contracts that nominally use identical product pricing. We are worried about the economic waste associated with having to renegotiate large numbers of contracts if our vendors conclude they cannot manage the manual processes that the Proposed Rule's bundled sales aggregation and allocation requirements are likely to require within the already tight 30-day timelines for monthly AMP reporting. We suspect the penalties for late AMP filing in the Proposed Rule to increase manufacturer demands for such renegotiations. We therefore urge CMS to forego changing the bundled sales definition.

[26] 77 *Fed. Reg.* at 5335.
[27] ACA §2503(a)(2)(B)(i)(IV).

The Proposed Definition of Wholesaler Is Adequate As Drafted

The Proposed Rule defines a wholesaler as an entity "engaged in wholesale distribution of prescription drugs to retail community pharmacies, including but not limited to manufacturers, repackers, distributors, own-label distributor, private-label distributors, jobbers, brokers, warehouses (including manufacturer's and distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions." CMS has specifically asked for input on further data sources or definitions that it could apply to how to provide more clarity around this definition.[28] CMS reported considering, but rejecting, the requirement that manufacturers look to licensure as a wholesaler as another element of the definition. We applaud this decision, not because wholesaler licensure is not required by ACA, but because all states do not require wholesale distributors to be licensed. Moreover, states vary in whether manufacturers are licensed as such or as wholesale distributors.

HDMA is comfortable that the definition of wholesaler in the Proposed Rule is sufficient to convey to manufacturers which merchant middlemen sales are to be considered for inclusion in AMP, assuming, if the presumed exclusion provision in the Proposed Rule is finalized, that tracing information shows such sales flow through to RCPs or to entities included in the 5i AMP calculation, if applicable. Since we are of the view that further definition is neither necessary nor likely to prove helpful, we are not prepared to provide any suggestions for clarifying the definition.

[28] 77 *Fed. Reg.* at 5326.