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AmerisourceBergen®

DEC 21 2007

December 21, 2007

VIA ELECTRONIC and HAND DELIVERY

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-2238-FC
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on CMS-2238-FC: Medicaid Program; Prescription Drugs; Final Rule

Dear Mr. Weems:

AmerisourceBergen Corporation respectfully submits the following comments welcomed by CMS pertaining to 42 CFR 447.504 "Determination of AMP" and 42 CFR 447.514(c) "Upper Limits for Multiple Source Drugs; Ensuring a Drug is for Sale Nationally" as published in the *Federal Register* on July 17, 2007 (the "Final Rule").

A. OVERVIEW OF AMERISOURCEBERGEN

AmerisourceBergen is one of the nation's largest pharmaceutical services companies. Servicing both pharmaceutical manufacturers and healthcare providers in the pharmaceutical supply channel, we provide drug distribution and related services designed to reduce costs and improve patient outcomes. AmerisourceBergen's service solutions range from pharmacy automation and pharmaceutical packaging to pharmacy services for skilled nursing and assisted living facilities, reimbursement and pharmaceutical consulting services and physician education. Through our Good Neighbor Pharmacy Provider Network, we represent approximately 5,000 community pharmacies in dealing with national third party payors. As a result of these relationships we are keenly aware of the business challenges faced by community pharmacy owners in the retail marketplace and some of our responses in this communication represent their interests as well as ours.

An integral aspect of AmerisourceBergen's business is the important role it plays in the distribution of specialty pharmaceuticals through AmerisourceBergen Specialty Group ("ABSG"). This specialty drug distribution component of AmerisourceBergen is responsible for safely and efficiently ensuring the handling and delivery of critically needed complex pharmaceuticals and providing other necessary services to manufacturers and healthcare providers.

AmerisourceBergen has been an industry leader in working to implement policies and procedures to ensure the safe delivery of pharmaceuticals by promoting a variety of innovative initiatives, including the development of a national pedigree. We are committed to finding new ways to efficiently deliver pharmaceutical products to our customers; to enhance the safety of the pharmaceutical supply chain; and ultimately to improve the quality of care received by patients who need the products that we distribute. Due to the comprehensive nature of our pharmaceutical distribution and pharmacy service business, AmerisourceBergen believes we are uniquely situated to provide Comments on the Final Rule, and we offer these comments for your consideration and look forward to the opportunity to provide additional input as this rulemaking proceeds.

B. SECTION 504: DETERMINATION OF AMP

1) Bona Fide Service Fees

AmerisourceBergen supports CMS position that bona fide services fees should not be taken into account for the purposes of determining Average Manufacturer Price (AMP). CMS' exclusion of bona fide service fees from the AMP calculation in the Final Rule accurately reflects the role of such services in the wholesale pharmaceutical distribution industry, as well as treats these services in the same manner as bona fide service fees under the Average Sales Price (ASP) calculation for Medicare Part B drugs.

AmerisourceBergen agrees with CMS' decision set forth in the Final Rule to use the same definition of bona fide service fees for calculating AMP and determining Best Price that was established as part of the implementing regulations related to the calculation of ASP, resulting in a consistent definition that will help ensure manufacturers are able to efficiently calculate both AMP and ASP because they can use parallel methodologies and consistent definitions to account for fees paid to wholesale distributors.

Similarly, AmerisourceBergen also supports and agrees with CMS' decision to adopt and incorporate into the preamble to the Final Rule the commentary explanations applicable to the definition of bona fide service fees when manufacturers are calculating ASP into the commentary explanations of when they are determining AMP and Best Price, and CMS' express reference to the discussion of bona fide service fees in the preamble to the 2007 Physician Fee Schedule Final Rule as included in the preamble for this Final Rule.

AmerisourceBergen does, however, urge CMS to further clarify its guidance related to certain fees related to the calculation of AMP. These provisions intermix fees, discounts and other concessions offered to purchasers of drug products with payments made to non-purchasing

third parties like PBMs and GPOs that do not purchase or take possession of drugs. In the preamble to the Final Rule, CMS indicated that it does not believe administrative services not associated with the "efficient distribution of drugs" would qualify as bona fide service fees. CMS indicated in the 2007 PFS Final Rule 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."[1] CMS' narrow view of how these fees should be treated is particularly problematic with regard to GPOs because they are in no way involved in the payment for drugs. This guidance from CMS would thus imply that all concessions to non-purchasers should be deducted when AMP is calculated. Therefore, we urge CMS to limit the provision clarifying AMP to only those price reductions and other payments that flow directly to purchasers, and expressly exclude any payments that flow to third parties not involved in the purchase transaction.

The provision further confuses the issue of the proper handling of bona fide service fees and appears to create unnecessary distinctions between administrative fees, service fees and distribution fees. In most instances, bona fide service fees paid to wholesalers and distributors include compensation for distribution services which are defined and bargained between the involved parties. 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 consistent with CMS' preamble guidance published with the 2007 PFS Rule.

Using the CMS narrow approach, excluded from the definition of bona fide service fees would be the administration of manufacturer chargebacks. Chargebacks are the process by which wholesalers efficiently pass negotiated price discounts from manufacturers to pharmacies and other healthcare providers. The wholesaler sells these drugs to the purchaser at the negotiated discounted price which is lower than the price the wholesaler paid and then works with the manufacturer to recover the cost between the price the wholesaler acquired the drug from the manufacturer and the discounted price at which it was sold to the purchaser. Although administratively burdensome, doing so allows purchasers to purchase at their lower prices immediately and is an efficient way for manufacturers to administer their contracts with hundreds or thousands of customers.

AmerisourceBergen urges CMS to include chargebacks and similar services related to contract administration in what it constitutes as bona fide services. The chargeback system enables purchasers to enjoy both convenience in product ordering as well as savings in inventory costs (as well as product discounts) they wouldn't otherwise realize if forced to either buy their products directly from the manufacturer, or pay full price and submit, wait for and eventually collect rebates from the manufacturer.

While further clarity is welcomed, rather than adopting a rigid list of what constitutes a bona fide service fee in the wholesaler service fee context, AmerisourceBergen requests CMS adopt a flexible approach in order to encapsulate all the various service fee models used in the distribution chain, such as the administration of chargebacks discussed herein. As such, we

[1] 71 *Fed. Reg.* at 69668.

recommend that CMS clarify 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.

2) Definition of Wholesaler

AmerisourceBergen is concerned that the Final Rule continues to encapsulate several entities as a "wholesaler" for the purposes of calculating AMP that do not, in reality, function as a wholesaler. These include physicians, pharmacy chains, pharmacies, and PBMs. We request that this definition be revised so that it is consistent with the provisions of the Food Drug and Cosmetic Act incorporating the Prescription Drug Marketing Act (PDMA)[2] and with the definitions of "wholesale distributor,"[3] "wholesale distribution,"[4] and "distribute"[5] in the FDA regulations that govern prescription drug marketing. Although we believe these definitions are quite broad, they adequately and appropriately limit wholesalers to entities engaged in selling, offering to sell, delivering, or offering to deliver drugs to persons other than a consumer or patient. Doing so stretches the meaning of "wholesale" beyond recognition and will likely result in unintended adverse consequences.

We do, however, agree that warehousing pharmacy chains and warehousing mass merchant and supermarket pharmacy operations should be treated as wholesalers for purposes of calculating AMP and Best Price. They function virtually identical to traditional wholesalers and specialty distributors: they buy drugs directly from manufacturers and/or other wholesalers; consolidate orders for products from a variety of sources; and distribute the drugs to pharmacies within their chain, which resell the drugs at retail to consumers who present a prescription. Also, warehousing chains, warehousing mass merchants and supermarkets are licensed as wholesalers under State laws implementing the requirements of the PDMA.

Although we agree that the above entities should be treated as wholesalers under the Rule, we object to identifying other entities, including mail-order pharmacies operated by PBMs, as wholesalers. In addition to reasons outlined elsewhere in these comments, these entities are quite different from wholesalers because they have a limited product inventory, routinely only sell drugs to a limited group of subscribed consumers and patients and rarely function as or are licensed as wholesalers under applicable State laws.

We are particularly troubled by the inclusion of PBMs in the definition of wholesaler. Although many PBMs operate mail-order pharmacies, they typically function merely as an ancillary to the PBM's primary business operation. As discussed above, we do not believe these types of entities should be classified as wholesalers.

We urge CMS to align that definition with the definitions of wholesale distributor, wholesale distribution, and distribute in the FDA regulations implementing the PDMA in order to bring uniformity to these well-recognized terms throughout the industry.

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[2] P.L. 100-293.
[3] 21 CFR § 203.2(dd).
[4] 21 CFR § 203.2(cc).
[5] 21CFR § 203.2(h).

3) Retail Pharmacy Class of Trade

AmerisourceBergen agrees with CMS that in order to qualify as a member of the retail pharmacy class of trade, an entity must provide public access. For that reason, we disagree with the approach CMS outlined in the preamble to the Final Rule including certain entities listed in 42 CFR § 447.504(e) as part of the retail pharmacy class of trade. Specifically, mail-order pharmacies, PBMs, and hospital inpatient pharmacies should be excluded from the definition of retail class of trade. In addition to these entities, AmerisourceBergen also believes that CMS should clarify that sales of drugs to physicians for administration in their offices should not be included in the retail pharmacy class of trade for the purpose of calculating AMP.

We object to the inclusion of PBMs in the retail pharmacy class of trade because PBMs contract with retail pharmacies to offer pharmacy services at prearranged prices to enrollees in those health plans the PBMs represent. They negotiate insurance payment terms, which is significantly different from arranging for the purchases of drugs that pharmacies make from their manufacturer and wholesaler vendors. PBMs do not affect the net prices manufacturers are paid by wholesalers and retail pharmacies for drugs dispensed to the general public. Therefore, under the controlling statutory definition of AMP, the contract terms between manufacturers and PBMs, and any related rebate payments provided to PBMs, should not be factored into the determination of AMP.

Another distinguishing characteristic of mail order pharmacies from retail pharmacies is that, similar to Long-Term Care facilities ("LTC"), they are treated as a wholly distinct class of trade by manufacturers; as such, they are able to avail themselves of special pricing typically not made available to retail pharmacies. Similar to CMS's rationale in its decision to exclude sales to LTC facilities AmerisourceBergen urges CMS to exclude sales to other entities that do not satisfy the threshold public access criterion from manufacturers' AMP calculation, including sales to mail-order pharmacies. 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[6]. These mail-order pharmacies are not open to the general public and access is limited to individuals enrolled in an employer or other organization's health plan through 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.

Likewise, physician sales similarly should be excluded from the calculation of AMP based on CMS treatment of other entities (such as certain HMOs, MCOs, and PBMs) that, similar to physicians, take possession or ownership of the drugs they purchase, and because any price concessions they receive are not available to wholesalers. In the preamble to the Final Rule, CMS indicated that HMOs that do not purchase or take ownership of drugs would be included in the calculation of AMP, as these HMOs would be operating akin to another retailer. However, physicians do not function as retailers by virtue of taking ownership of such drugs, as well as their eligibility to receive the price concessions outlined above that those in the retail

[6] *Fed. Reg. 72 page 39173*

chain cannot. Therefore, we urge CMS to reconsider its determination on physician sales and specifically list all such sales as excluded from AMP.

4) Hospital Outpatient Sales

CMS outlined its view in the Final Rule that any direct or indirect sales made to hospitals where the drug is used in the outpatient pharmacy is to be considered part of the retail pharmacy class and thus included in the calculation of ASP. AmerisourceBergen agrees with CMS approach that sales that are made between manufacturers & hospital outpatient pharmacies that legitimately function akin to a retail pharmacy should indeed be considered when calculating AMP. However, the reality is that many hospitals do not contract for sales of outpatient pharmacy products separately from inpatient sales. For those hospitals that do not have separate arrangements with manufacturers specifically tied to outpatient drugs, any sales data included in the calculation of AMP will also include drugs that may be have been purchased for inpatient use, which would operate under a different class of trade than that of the outpatient pharmacy and retail pharmacy. Therefore, we urge CMS to expressly exclude from its calculation of AMP sales from all hospitals that do not have separate arrangements for outpatient and inpatient sales, as the sales data provided may not accurately reflect the price paid for hospital outpatient drugs.

5) AMPs and FULs Set at 11-Digit NDC Level

AmerisourceBergen is concerned with the Final Rule's instruction to have manufacturers only report AMP at the 9-digit level and encourage CMS to have manufacturers report AMP data at the 11-digit NDC level. CMS has articulated the transparency and other advantages this would bring. As stated in comments submitted on the Proposed Rule, we are concerned with the utilization of the 9-digit AMPs in all cases because this methodology would exclude calculating unique FULs for certain package sizes which must be purchased and dispensed by pharmacies.

In order to address this concern, we urge CMS to modify the Rule to require manufacturers to calculate and report AMPs at the 11-digit NDC level. The utilization of 11-digit level NDC's would permit FULs to be established based on the purchased package sizes, which are typically unit-of-use measured products as prescribed by physicians.

Restricting all AMP reporting and FUL setting to the 9-digit NDC may discourage innovation in packaging, much of which is designed to promote patient safety and pharmaceutical product efficacy. This special packaging can assist patients in taking their medications properly and consistently with treatment regimens. Healthcare outcomes have been shown to be improved with innovative packaging use and overall treatment cost reduced. While obviously not the intent of the Final Rule, CMS' insistence on the 9-digit NDC has the distinct possibility of patient compliance being eschewed in favor of reimbursement recognition.

C. SECTION 514(C): AMP AND OUTLIER METHODOLOGY

AmerisourceBergen applauds CMS's recognition of the need to eliminate outlier AMPs from the determination of FUL. Eliminating outliers that may be due to the sale of product from manufacturer's exiting a product category or that may be dumping product that is short-dated or

otherwise distressed avoids setting an artificially low FUL based upon manufacturer prices that do not reflect true market conditions (comparable to CMS' decision to disregard AMPs for NDC's that have been terminated). To ensure that reimbursement is adequate to permit retail pharmacies to buy from reputable suppliers with sufficient supply to meet retail pharmacy demands, we encourage CMS to adopt a market share-based criteria (i.e. weighted average) AMP to set FUL's. However, if CMS decides it will not take that approach, we propose that the outlier test should somehow incorporate market share as a fundamental criteria in defining outliers. Low AMP's would be measured on both price and market share criteria to identify outliers that do not represent available market prices.

The Congressional intent behind the provisions establishing the new FUL calculations and outlier methodology under the Deficit Reduction Act of 2005 was to develop a benchmark price that would be representative of the prices in the retail marketplace. As such, the current outlier methodology must be expanded to ensure that the lowest AMP used to set the FUL is representative of the marketplace. The currently defined outlier methodology is far too susceptible to activity at the low end of the market. We predict that products with minimal market presence that are not representative of the broader market will not be classified as outliers using the 40% threshold and therefore will have a disproportionate impact on the retail marketplace. We therefore recommend that the outlier methodology be expanded to include market share criteria in one form or another.

Specifically, we recommend examining AMPs on a cumulative market share basis starting with the lowest reported AMP, then the next highest and so on, rejecting individual AMPs until a material and cumulative market share (e.g. 50%) is reached. This approach will allow CMS to focus directly on whether a low-priced product is only available on a limited basis (rather than the indirect price-based test CMS proposed). This will ensure that the drug representing the lowest AMP is broadly available and representative of the marketplace. For example, if five manufacturers reported monthly AMPs of $1.85, $3.50, $4.50, $5.00, and $5.50 with corresponding sales volumes of 100 units, 400 units, 6000 units, 3500 units, and 500 units, the first two would be classified as outliers as they represent less than a 5% market share. The FUL would be set based on the $4.50 price as it is the lowest price for a product that is broadly available. Such low priced AMPs often do not accurately reflect actual market conditions because products priced at such levels are in limited supply and are not available for sale nationally. Alternatively, CMS could calculate the average-weighted AMP and use it as the benchmark for defining outliers. Rather than comparing the lowest AMP to the next lowest AMP it could be compared to the weighted-average. Low AMP's could be iteratively discarded until the first low AMP meets the established threshold.

In the proposed Rule, CMS welcomed suggestions on what percentage levels should be considered among outliers in order to determine AMP. CMS decided to incorporate into the Final Rule a threshold of 40 percent from the next highest AMP, instead of the 30 percent level included in the Proposed Rule. This still would not accurately reflect the price that a drug may be sold at nationally, since the outlier threshold is still based on the lowest AMP price, irrespective of the availability and/or commercial usage of this AMP price, and thus we ask CMS to reconsider its adoption. Rather than using a potentially artificially-deflated number such as a lowest AMP price, which for the reasons above accordingly will skew the outlier,

AmerisourceBergen would like to see CMS calculate FULs using the market share of the therapeutically equivalent products available in the market, instead of the AMP of the least costly product.

* * * * *

In closing AmerisourceBergen appreciates the opportunity to provide you its comments on these important provisions contained within the Final Rule. We are available at your convenience to address any concerns related to these Comments, the Final Rule, or the pharmaceutical supply chain.

Sincerely,

Rita E. Norton

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AstraZeneca

2007 DEC 28 PM 3:58

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8012

Re: CMS-2238-FC; Comments on the Medicaid Program; Prescription Drugs; Final Rule

Dear Acting Administrator Weems:

AstraZeneca (encompassing AstraZeneca Pharmaceuticals LP and AstraZeneca LP) ("AstraZeneca") is pleased to submit the following comments on the Centers for Medicare & Medicaid Services ("CMS") final rule entitled "Medicaid Program; Prescription Drugs," published on July 17, 2007 (the "Final Rule").

AstraZeneca is a leading global healthcare company dedicated to the research and development of new medicines in therapeutic areas including cardiovascular, gastrointestinal, oncology, respiratory, and neuroscience. AstraZeneca is committed to the discovery of drugs that will allow patients to lead longer, healthier and more productive lives. We conduct and support scientifically robust research that improves the delivery of effective, high-quality care to patients.

AstraZeneca applauds CMS's efforts to issue guidance in the Final Rule concerning many of the Medicaid provisions contained within the Deficit Reduction Act of 2005 ("DRA"). We also appreciate CMS's willingness to consider recommendations from stakeholders, articulated in the proposed rule, and make changes as the agency deems necessary. Despite these efforts, many questions about the changes implemented in the Final Rule remain unanswered. Below we set forth our comments on areas where we believe the Final Rule continues to be ambiguous or where additional agency guidance would be helpful. In brief, AstraZeneca's comments are as follows:

- CMS should take a consistent approach relative to Medicaid rebate and other pricing calculations.
- The posting of AMP data should be delayed until areas of ambiguity are resolved.
- What constitutes a bundled arrangement should be more clearly defined through the issuance of additional guidance and specific examples.
- CMS should provide additional guidance regarding what it considers as constituting a customary prompt pay discount.

- CMS should issue specific guidance that non-mail order PBM rebates are included in best price only where the express language of a contract provides for such rebates to adjust prices or costs at the retail or provider level.

- CMS should clarify procedural issues concerning restatements of base date AMPs.

- Manufacturers should be directed to apply the average sales price ("ASP") smoothing methodology to smooth price concessions in monthly AMP calculations.

- CMS should allow manufacturers to submit or reference their reasonable assumptions underlying the calculation when submitting their certification.

I. General Comments

As CMS continues to further refine the Medicaid rebate calculation requirements applicable to manufacturers, AstraZeneca requests that CMS make every effort to take a consistent approach relative to AMP and best price calculations and, where appropriate, ASP. Having different and conflicting calculation requirements pertaining to AMP, best price and ASP creates confusion and increases the likelihood that a manufacturer may make unintended errors. We applaud CMS for being cognizant of this issue when it sought guidance in the CY 2008 Physician Fee Schedule Proposed Rule concerning applying the same standards to the treatment of bundled arrangements in ASP as under the Medicaid rebate program. We now urge CMS to follow through on this concept as it continues to issue guidance on the Final Rule.

We further recommend that CMS consider delaying the public posting of AMPs to avoid confusion and adverse effects on access to patient care. We are aware of recent litigation concerning the promulgation of the Final Rule.[1] Further, as evidenced by the number of comments contained herein and CMS's issuance of responses to Qs and As, there remains uncertainty about fundamental aspects of the AMP calculation. In addition, most recently, the OIG expressed concerns about unit of measure inconsistencies that could have reimbursement and rebate implications.[2] CMS should have more experience with the new pricing data before it makes AMP public. In other contexts (e.g., delaying the implementation of a specific methodology pertaining to the treatment of bundled sales arrangements in the CY 2008 Physician Fee Schedule Final Rule), CMS has shown a willingness to delay an action where significant questions and uncertainty exists in the industry. We believe that delay is similarly appropriate here.

II. Specific Comments

A. Definitions – Section 447.502

1. Bundled Arrangements

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[1] Nat'l Assn. of Chain Drug Stores; Nat'l Community Pharmacists Assn. v. US Dept. of Health and Human Services; Sec'y Michael O. Leavitt; Ctrs. for Medicare and Medicaid Services; Acting Admin. Kerry Weems 11/7/2007 1-07-cv-02017 RCL.

[2] See Unit of Measure Inconsistencies in the Medicaid Prescription Drug Program, November 2007, OEI-05-07-00050.

CMS's definition of bundled arrangements and responses to public comments in the Final Rule create significant ambiguity and, under certain interpretations, could have far-reaching and unintended implications for manufacturers. Comprehensive guidance from CMS is necessary to ensure that manufacturers consistently and properly follow CMS's guidance. It is imperative that CMS include specific examples to illustrate different types of contractual offerings that CMS believes constitute bundled arrangements and how price concessions should be allocated among the specific items in the offerings.

First, detailed guidance is needed concerning multiple product, but non-contingent, discount offerings in a single contract. These should not constitute bundled arrangements. By way of example, many manufacturers have a single contract with customers that contains master terms and conditions governing the general agreements of the parties (e.g., term, indemnification). That contract then has multiple schedules with respect to the agreed to pricing for various products, and the pricing is determined independently for each product. The customer is not required to agree to or maintain any particular schedule or product to maintain the overall contract. For example, Schedule A might provide a 5% discount on Product A if it is listed on a formulary (without regard to product strength or package size), Schedule B might provide a discount of 10% on Product B if it is listed on a formulary (without regard to product strength or package size). If a customer elects not to list Product A on the formulary, or to terminate Schedule A, that has no effect on Schedule B or Product B, and vice versa. Similarly, GPO bids and wholesaler price lists often contain multiple products in a single contract with non-contingent prices for various products listed on a single schedule or multiple schedules. In short, the multiple product single contract format is a mere matter of convenience, and does not reflect any contingencies that cross products. CMS should issue guidance that multiple product contract formats with independent pricing for each product, such as the ones described, do not constitute bundled arrangements because the discounts in each of the schedules are not contingent on the purchase of products under the other schedules.

Second, CMS should clarify that, in a contract with contingent and non-contingent discounts, only the contingent discounts should be included in the bundled calculation. For example, assume a basic contract structure that includes a 5% discount on Product A and a 10% discount on Product B. The contract also has an "overlay" feature where, if the customer agrees to list both Products A and B on its formulary and meets a minimum market share for both products, the customer will receive an additional 2% discount on both products. Under the Final Rule, the 2% overlay would be allocated across the products as part of a bundle calculation. We ask CMS to confirm that its discussion of "contingent and non-contingent discounts" was not meant to mean that the 5% and 10% discounts also would be allocated across Products A and B such that the products have a new, single uniform discount percentage.

Third, we request that CMS reconsider its position that a multiple product arrangement with only a formulary requirement constitutes a bundle. There is no purchase requirement associated with such a provision, nor does it require specific performance. Further, inclusion on a formulary does not necessarily correlate to increased product utilization. For these reasons, CMS should reconsider its position that discounts contingent on formulary status constitute bundled arrangements.

Fourth, CMS should clarify that contingent discounts applicable only to the same drug (i.e., NDC-9) should be treated as a volume discount and not as a bundled sale. The

new definition of bundled sale covers an arrangement where a price concession is conditioned on the purchase of the same drug.[3] Such arrangements are more properly characterized as volume discounts, as CMS indicates may be the case in the preamble to the Final Rule.[4] CMS should revise the bundled sale definition to remove the reference to "same drug."

B. Definition of Customary Prompt Pay Discounts – Section 447.504(c)

CMS should provide further guidance concerning the definition of customary prompt pay discounts. In the Final Rule, CMS construes the definition narrowly to exclude certain discounts that are not routinely offered to all customers.[5] Such an interpretation excludes different types of customary prompt pay discounts that may be offered to certain market segments for a specific purpose. For example, when a new product is introduced, it may be necessary to offer an extended payment period during which a customer is eligible to receive a prompt pay discount because of delays in the distribution chain or to encourage stocking of a product. We request that CMS reconsider its definition to ensure that it has not taken an unduly restrictive position with regard to these commonplace types of activities. Manufacturers should be permitted to apply reasonable assumptions in identifying customary prompt pay discounts rather than CMS requiring adherence to a narrowly tailored requirement. We believe such latitude is necessary to promote marketplace efficiency.

C. Determination of BP – Section 447.505

1. Treatment of Non-Mail Order PBM Rebates

CMS should clarify that non-mail order PBM rebates are considered to adjust prices at the retail or provider level, and are thereby included in best price, only where this is the express contractual intent of the parties. Although the treatment of PBM rebates in best price calculations is included in the section of the regulations entitled "Prices excluded from best price," the regulatory language of the Final Rule suggests that certain non-mail order PBM rebates should be included in best price. Section 447.505(d)(13) provides that the following are excluded from best price:

> "PBM rebates, discounts, or other price concessions except their mail order pharmacy's purchases or where such rebates, discounts, or other price concessions are designed to adjust prices at the retail or provider level."

Based on this language, PBM rebates that are "designed to adjust prices" at the retail or provider level are not excluded from best price. Section 447.505(b) defines "provider" as "a hospital, HMO, including an MCO or entity that treats or provides coverage or services to individuals for illnesses or injuries or provides services or items in the provision of health care." Under this language, PBM rebates that are designed to adjust HMO or MCO prices would not be excluded from best price. Because PBMs routinely work on behalf of HMOs or MCOs, rebates to PBMs arguably could affect the price an HMO or MCO pays for product. Following this reasoning would result in most PBM rebates being included in best price where they involve HMOs or MCOs. However, such a result seems to be contrary to CMS's intent to exclude PBM rebates in most cases.

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[3] 72 Fed. Reg. 39420 (Jul 17, 2007).
[4] Id. at 39158.
[5] Id. at 39166.

To address this issue, CMS should clarify that non-mail order PBM rebates are generally excluded from best price, as the language of the regulations seems to imply. The only cases when non-mail order PBM rebates should be included in best price is where the express language of a contract directs that such PBM rebates adjust prices at the retail or provider level.

D. Requirements for Manufacturers – Section 447.510

1. Base Date AMP Restatements

Section 447.510(c) permits a manufacturer to report a revised base date AMP to CMS within the first four full calendar quarters following the publication of the Final Rule. However, neither the regulation nor the text of the Final Rule addresses the process for making such changes. We request that CMS issue guidance permitting manufacturers to input restated base AMPs into the DDR System either manually or via an upload on a date certain determined by CMS. We further recommend that CMS indicate when the upload file format will be available (i.e., when the DDR System is available) and clarify for manufacturers that there will be a new field in the DDR System where manufacturers will enter the restated base AMP data.

2. Price Concession Smoothing

CMS should direct manufacturers to apply the ASP smoothing methodology to smooth price concessions in monthly AMP calculations. Section 447.510(d)(2) of the Final Rule provides that "In calculating monthly AMP, a manufacturer must estimate the impact of its lagged price concessions using a 12-month rolling average to estimate the value of those discounts." CMS has not specified what precise methodology should be used. Consistency in the smoothing calculation applied by manufacturers is necessary to achieve consistency in the calculation of AMP. This was one of the purposes that Congress sought to achieve through the enactment of the DRA. Accordingly, CMS should provide additional guidance concerning the applicable smoothing methodology. Manufacturers are familiar with the ASP smoothing methodology, having used it to smooth lagged price concessions on Part B drugs for the past several years. CMS should therefore direct manufacturers to use this methodology in the context of the monthly AMP calculation.

CMS should allow (but not require) manufacturers to apply the price concession smoothing methodology for monthly AMP reporting using historical data from prior to October 1, 2007 that is reformatted to comply with the requirements of the Final Rule. This is necessary to be consistent with the requirements of Section 447.502(d)(2), which provides that "monthly AMP should be calculated based on the best data available to the manufacturer at the time of submission." However, CMS should not require manufacturers to restate or refile pre-October 1, 2007 AMPs in those cases where manufacturers elect to reformat data for price concession smoothing purposes.

In clarifying its guidance on price concession smoothing, CMS should direct manufacturers to include price concessions from bundled sale arrangements that are realized after the sale of the drug in their 12-month rolling average methodology for purposes of calculating AMP (where post Oct. 1, 2007 data constitutes the 12 months of data). We believe this approach is consistent with CMS requirements for the treatment of "lagged price concessions" in 42 C.F.R. § 447.502 and would avoid having manufacturers reallocate bundled discounts across time periods or restate AMP.

3. Certification of Pricing Reports

In connection with the submission of the required certification, manufacturers should be permitted to include or reference their reasonable assumptions underlying the calculations. AstraZeneca is aware of instances where CMS has rejected such letters, despite guidance to the contrary from Jim Stansel, CMS Deputy General Counsel, in a discussion with PhRMA. We believe that, especially during this critical time of transition to new Medicaid rebate program requirements affecting AMP and best price, CMS should facilitate the submission of, or reference to, reasonable assumptions and should use this information to identify areas where further guidance may be needed.

* * * *

Again, AstraZeneca appreciates the opportunity to share our views on the Final Rule. We look forward to working together with CMS to refine and clarify Medicaid rebate program requirements. Please do not hesitate to contact Sandy Leonard at (202) 350-5525, or Sandra.Leonard@astrazeneca.com if you have any questions or need further information about these comments.

Sincerely,

Diana Bronstein

Diana Bronstein
Director, Government Operations

Sandy Leonard

Sandy Leonard
Director, Government Reimbursement

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Johnson & Johnson

JAN - 9 2007

OFFICE OF
GENERAL COUNSEL

1350 EYE ST., N.W., SUITE 1210
WASHINGTON, DC 20005

By E-Mail and Hand Delivery

December 21, 2007

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8012

Re: Suspending Monthly AMP Calculations Until Resolution of the NACDS/NCPA Litigation

Dear Administrator Weems:

On behalf of the Johnson and Johnson operating companies ("J&J"), I am requesting that the Centers for Medicare and Medicaid Services ("CMS") suspend the monthly Average Manufacturer Price ("AMP") reporting requirement imposed on pharmaceutical manufacturers in light of the recent injunction issued by the United States District Court for the District of Columbia. J&J is the world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services, for the consumer, pharmaceutical and medical devices and diagnostics markets. We are concerned that imposing a continuing obligation on pharmaceutical manufacturers is meaningless and unnecessary. Monthly reports were required to calculate AMPs for possible use as a reimbursement metric. Given the recent injunction, there is no point in requiring monthly reports when, so long as the injunction is in effect, there can be no reimbursement-related use of the monthly reports.

As you know, the National Association of Chain Drug Stores ("NACDS") and the National Association of Community Pharmacists ("NCPA") sought a preliminary injunction against CMS to prevent Medicaid pharmacy reimbursement reductions from being implemented ("NACDS/NCPA litigation"). On December 19, 2007, Judge Royce Lamberth of the United States District Court for the District of Columbia signed an order

enjoining CMS from "[u]ndertaking any and all action to implement the AMP Rule to the extent such action affects Medicaid reimbursement rates for retail pharmacies under the Medicaid program."[1] Plainly, the submission of monthly AMPs is an action that was intended for purposes of setting retail pharmacy reimbursement rates.

J&J strongly believes that suspension of AMP reporting is the appropriate action for CMS to take in light of the injunction. The rationale underlying CMS' monthly AMP report submission requirement was to facilitate CMS' establishment of accurate Medicaid reimbursement rates for pharmacies. Under the Deficit Reduction Act of 2005, Congress stated "[b]eginning July 1, 2006, the Secretary shall provide on a monthly basis to States . . . the most recently reported [AMP] for single source drugs and multiple source drugs . . . ." [2] When promulgating the regulations, CMS acknowledged that there were two possible interpretations of this statutory language, but CMS' interpretation required manufacturers to submit monthly AMPs, in addition to their quarterly AMP submissions, so that CMS could calculate and disseminate the federal upper limit ("FUL") on a monthly, rather than quarterly basis.[3] Moreover, CMS repeatedly explained throughout the Preamble that it intended to use manufacturers' monthly AMPs to be the basis in calculating the FULs,[4] which CMS would provide to the States so States could set their reimbursement rates for retail pharmacies.[5] The injunction effectively prevents CMS from changing, or acting to attempt to influence a change in those pharmacy rates. Pursuant to injunction therefore, CMS should cease requiring pharmaceutical manufacturers to submit monthly AMP calculations, pending the completion of the NACDS/NCPA litigation, as the submission of the monthly AMPs is an action in furtherance of setting pharmacy reimbursement rates.

From a practical perspective, CMS' continuation of the monthly AMP reporting requirement would result in unnecessary administrative activity and costs that manufacturers must incur without any benefit. Additionally, the continued uncertainty of the requirements for how AMP should be calculated, as illustrated by Judge Lambert's order, the revised FAQs on CMS' website, and the fact that AMPs must be certified, underscore the need for this suspension while these issues are clarified. We believe it is arbitrary and capricious to impose this burden when there is no governmental purpose, and certainly no purpose reflected in the Medicare Modernization Act that is furthered by the burden, as long as the injunction is pending.

---

[1] *National Association of Chain Drug Stores v. Leavitt,* No. 1:07cv02017 (D.D.C. Dec. 19, 2007).

[2] 109 Pub. L. No. 171; 120 Stat. 4 (2005).

[3] Medicaid Program; Prescription Drugs; Final Rule, 72 Fed. Reg. 39142, 39153 (Jul. 17, 2007).

[4] 72 Fed. Reg. at 39207.

[5] *Id.* at 39213.

We urge CMS to consider suspending the monthly AMP reporting obligation for pharmaceutical manufacturers. We appreciate your time and consideration of this very important issue.

Best regards,

Stephanie Gilson
Assistant General Counsel

cc: James C. Stansel, HHS Office of General Counsel
Larry Reed, Centers for Medicare and Medicaid Services

PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

Howard A. McLure
President
Caremark Pharmacy Services
CVS Caremark

Mark Merritt
President & CEO

January 2, 2008

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

FILE CODE: CMS-2238-FC

Dear Mr. Weems,

On behalf of America's pharmacy benefit managers (PBMs), the Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit additional comments on the Final Rule (CMS-2238-FC) implementing provisions of the Deficit Reduction Act of 2005 (DRA). Our specific comments pertain to provisions of the Act relating to prescription drug reimbursement.

PCMA appreciates CMS recognizing in the Average Manufacturer Price (AMP) Final Rule published on July 17, 2007, issues of particular concern to the PBM industry. Specifically, we're pleased that CMS chose to recognize that PBM's negotiated rebates, discounts, and price concessions should not be included in the definition of "retail class of trade."

However, PCMA remains concerned with some of CMS's interpretations and rulemaking in the Final Rule, particularly as it relates to the inclusion of mail service pharmacy and specialty pharmacy in the definition of the "retail class of trade."

PCMA recommends the following:

1. CMS should exclude mail service pharmacy in the definition of "retail class of trade."

As we stated in our previous comments on the NPRM, mail service pharmacy is a separate and distinct business from retail pharmacy, with different overhead, inventory, equipment and personnel needs that distinguish its cost structure and function.

CMS bases its decision to include mail service pharmacy in the definition of the retail class of trade primarily on its belief that, like retail pharmacies, mail service pharmacies dispense drugs to the "general public." Again, we would argue this is not an accurate

reflection of how mail service pharmacies operate. Mail service pharmacies do not dispense drugs to the general public in the manner a retail pharmacy does. You cannot walk into a mail service pharmacy the same way you could a retail pharmacy to fill a prescription, regardless of health coverage. Nor can you get a prescription filled through a mail service pharmacy without being a member of a health plan providing that benefit through that particular pharmacy. Emphasizing this difference, many states Board of Pharmacies recognize mail service pharmacies as different from retail pharmacies. Furthermore, CMS exempts long-term care (LTC) pharmacies because they are deemed not to dispense drugs to the general public. Analogous to LTC pharmacies, mail pharmacies limit their services to defined groups of individuals (residents in the case of LTC pharmacies and plan members in the case of mail pharmacies.)

In response to these arguments, the final rule cites GAO and OIG references to definitions of the retail class of trade as including those entities that dispense to the general public. This is circular reasoning—CMS is justifying its view that mail order pharmacies dispense to the general public by referencing OIG and GAO reports defining retail class of trade as including those entities that dispense drugs to the general public. But neither GAO nor the OIG actually make such assertions in the reports referenced. In fact, OIG has historically held the opposite position regarding mail service pharmacy's inclusion in the retail class of trade. What's more, none of CMS, GAO or the OIG defines what is meant by the term "general public." PCMA believes a reasonable interpretation of an entity that dispenses drugs to the general public would necessarily exclude an entity where access is only achieved through purchasing membership to a particular health plan.

In addition, as AMP will serve as a benchmark for Medicaid FULs, it is appropriate to note that Medicaid beneficiaries can go to almost any retail pharmacy and get a prescription filled. However, mail service pharmacy is virtually non-existent in the Medicaid program and a Medicaid beneficiary could not fill a prescription through a mail order pharmacy unless that Medicaid program had a contract with such pharmacy. Thus, it is not appropriate to incorporate mail service in the definition of retail class of trade.

2. CMS should exclude specialty pharmacy from the definition of "retail class of trade."

The rationale provided in the preamble to the Final Rule, at page 39176, Federal Register, Vol 72, No. 136, for including sales to specialty pharmacies in the calculation of AMP appears to be "that the drugs supplied through specialty pharmacies are within the regular retail marketplace." This is an untrue statement. Similar to LTC pharmacy, which CMS exempts from the retail class definition, specialty pharmacy serves a very small patient population with chronic, rare and/or life-threatening conditions. Specialty pharmacies generally do not have store front operations where a patient could walk in a fill a prescription like in retail pharmacy but instead provide home delivery of patient therapies.

PCMA believes that establishing the standard of "dispenses drugs to the general public" as the determinant of whether a sale is included in the retail class of trade ignores critically important cost, infrastructure and functional differences that distinguish retail pharmacy from specialty pharmacy. For example, retail pharmacies need to be centrally located, need to carry a large and varied inventory of drugs and don't typically store injectable biologics on premises. Specialty pharmacies, on the other hand, maintain a small volume of very high dollar medications that often have special refrigeration and storage needs. These differences alone have a direct impact of the cost of drugs dispensed, and PCMA believes it is inappropriate to lump them together for the purposes of calculating AMP.

Beyond the infrastructure and inventory differences, specialty pharmacy provides hands on clinical services not available at retail pharmacy. In fact, "specialty pharmacy" is somewhat of a misnomer because it implies simple drug dispensing when, in fact, specialty pharmacy provides patients with conditions like hemophilia, rheumatoid arthritis, multiple sclerosis and cancer not only their medications, but also the tools to care for themselves at home when clinically appropriate. This includes sending health professionals to patient homes to educate patients and their caregivers on self-injecting medicines, proper storage and disposal of medicines and supplies, and how to manage side effects. Patient support is provided 24/7 via home visits or telephone consultation with health professionals. We believe drugs distributed and care management provided by specialty pharmacy in no way compare to the transactional nature of drugs dispensed through retail pharmacy and therefore their sales should be excluded from the definition of retail class of trade.

For example, specialty biologics like Flolan and Ventavis both treat pulmonary hypertension. These drugs have limited distribution through specialty pharmacies and are not sold in retail pharmacies. Flolan requires refrigeration and a pump for administration while Ventavis requires a special inhalation device for administration. Both products require significant patient education and monitoring by health professionals, services that specialty pharmacies are uniquely capable of providing.

3. CMS should recognize the impact a broadly defined AMP will have on cost-shifting to the commercial market and pharmacy access.

As we noted in our comments on the NPRM, PCMA is concerned that if AMP is inclusive of price concessions that retail pharmacy does not receive, such as mail service pricing, AMP-based reimbursement to pharmacies will not cover their costs and pharmacies will look to make up the difference by shifting those costs to other payers. While reforms to Medicaid payments for drugs are warranted, reimbursements that are significantly below drug acquisition cost are problematic, not just for retailers filling Medicaid prescriptions but for commercial payers as well.

Furthermore, retail pharmacies, particularly independent pharmacies in rural areas, may have a difficult time purchasing drugs at or below the AMP. In areas where Medicaid sales are a substantial part of a pharmacy's business, this will threaten the very survival

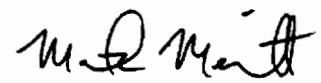
of these pharmacies. PBMs rely on chain and independent pharmacies alike to provide access to prescriptions for their government and commercial clients and would not want to see that access put in jeopardy.

4. CMS should remove the exceptions from the Best Price exclusion for PBM rebates.

PCMA believes that the Best Price exclusion for PBM rebates covers retrospective PBM rebates on both retail and mail utilization. These rebates are tied to formulary, benefit design and other contractual obligations and are not passed on to the retail or mail pharmacy. As a result, PCMA feels that it is critical for CMS to remove the exceptions (mail order pharmacy purchases and other price adjustments) from the Best Price exclusion for PBM rebates. Such regulatory action is reasonably necessary to clear up the confusion and uncertainty that currently exists in rebate negotiations between manufacturers and PBMs concerning the scope of the exceptions to the new Best Price exclusion for PBM rebates. PCMA also believes that the exceptions are not necessary because Sections 447.505(c) and (e) clearly indicate that Best Price would include any price concessions which reduce the price available from the manufacturer.

On behalf of PCMA, I appreciate the opportunity to make additional comments on the AMP Final Rule (CMS-2238-FC). PCMA looks forward to working with the Administration to ensure fair and balanced implementation of the DRA with particular attention paid to the broader impact this rule may have on the drug distribution channel. Please don't hesitate to contact us if you have any questions about our comments.

Sincerely,



Mark Merritt
President and Chief Executive Officer

17

PRASCO

January 2, 2008

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Attention: CMS–2238–FC

Dear Sir/Madam:

Prasco, LLC appreciates the opportunity to offer comments on the final rules regarding DRA implementation published on December 22, 2006 (71 FR 77174 *et seq.*).

Prasco is a privately held generic pharmaceutical company that has become a leader in the authorized generic drug industry. Prasco is not owned, wholly or in part, by any brand-name drug company. Prasco is an independent organization that specializes in offering a broad range of authorized generic drug products from several brand manufacturers. Prasco markets authorized generic drug products during and after the 180-day exclusivity period. Prasco also markets authorized generic products when there is no exclusivity period.

Prasco submits the following comments on the published rules:

Prasco believes that authorized generics provide competition and savings to all purchasers of pharmaceuticals, especially the Federal Government. Authorized generics help to lower the prices of pharmaceuticals for all consumers and that the recent CMS rule threatens the ability of certain authorized generics to compete in the marketplace. We do not believe that CMS intended to limit the availability of authorized generics as an option for consumers of health care.

Authorized generics have been around since the first NDA's and their occurrence has increased exponentially over the past 4 years. From 2003 to July 31, 2007, at least 108 authorized generics have been launched by both brand subsidiaries and generic companies. We hereby present information regarding authorized generics introductions and competition. (Attachment 1a-1f) The main conclusion to be drawn from the corresponding attachment is that despite rumors to the contrary, authorized generics stay

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in the market to compete and are not introduced as a mechanism to injure generic substitution. In fact, we are not aware of any instances of authorized generics pulled from the market after competing with the ANDA during 180-day exclusivity period. Authorized generics support and are reliant upon a robust generics industry, which since 2001 has been performing better every year with authorized generics in the marketplace. ANDA filings and Paragraph IV ANDA filings are up since 2001 and the generic share of the pharmaceutical market continues to increase. (Attachment 2a-2c)

Regulatory and Legal entities such as the FDA, the Federal Courts and the FTC have supported the conclusion that authorized generics are good for competition and lower prices for consumers. The FTC is taking a step further by undertaking a study on the long-term affects of authorized generics. While the impact of authorized generics continues to be reviewed, all studies to date have demonstrated that authorized generics increase competition and reduce prices for health care consumers.

Prasco recognizes CMS did not publish this rule with the intent to limit authorized generics competitive effect in the marketplace and thus make the ongoing FTC study irrelevant. However, the manner in which the rule is constructed runs counter to the consensus regarding authorized generics.

First, it is clear from the rule and the accompanying Questions and Answers posted on the CMS website that a secondary manufacturer selling authorized generics may operate as a wholesaler, and any units sold to such a wholesaler are included in the primary manufacturer's AMP calculation. (See Questions and Answers dated September 28, 2007, "...to the extent that a Secondary Manufacturer is not a wholesaler...") It is also clear that CMS defines a wholesaler as an entity that does not repackage or relabel the product it sells. There has been some confusion regarding what constitutes a "relabeling" and/or "repackaging" for an authorized generic. Since all authorized generics have a NDC number, label and package different from the brand product, the CMS rule and the subsequent Questions and Answers posting on its website can only be interpreted as meaning a relabeling or repackaging of the authorized generic. Otherwise, a secondary manufacturer could never be a wholesaler. It would be helpful if CMS clarified that a secondary manufacturer is a wholesaler so long as the secondary manufacturer does not relabel or repackage the authorized generic product it receives from the primary manufacturer.

Second, while it is appropriate that sales of authorized generics to a wholesaler are counted in the brand manufacturer's AMP, there are many instances in which an authorized generic is not sold to a wholesaler and there is no public policy justification for excluding those sales from the primary manufacturer's AMP. Certainly the Congress in the Deficit Reduction Act did not suggest this dichotomy.

Should a secondary manufacturer not be able to operate as a wholesaler, as defined in the regulations, then those respective authorized generic units would not be included in the primary manufacturer's AMP calculation. As a result, the primary manufacturer's rebate calculation is unbalanced and inconsistent. If the authorized generic units must be included in the brand best price (authorized generic transfer price equals the brand best price), but are not included in the primary manufacturer's AMP, then as generic prices

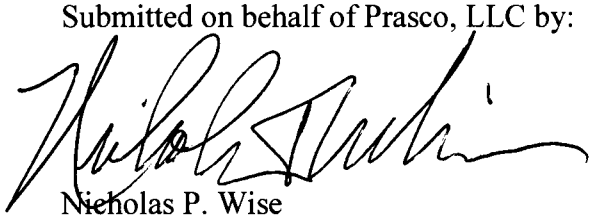
decrease, the government net cost can fall to less than zero because the pharmacy reimbursement for the brand at the FUL could be equal to or less than the increasing Medicaid rebate. This would result in the brand company either giving Medicaid the brand product for free or paying Medicaid to take its product. (Attachment 3)

Obviously, this is an unsustainable model preventing brand companies from entering into authorized generic agreements in which the secondary manufacturer is not a wholesaler. This will undoubtedly decrease competition in the generic market and prices for pharmaceuticals will rise. Again, there is nothing in the Deficit Reduction Act to suggest that the Congress intended to reduce competition in the generic market.

Prasco believes a straightforward solution to this problem is to provide for consistent treatment of authorized generics in the brand best price and the brand AMP calculations. If the authorized generic transfer price is included in the brand best price, then the transfer price of those authorized generic units should also be included in the brand AMP. Under this scenario, the government net cost for the brand will continue to decrease as the price of the authorized generic continues to decrease. (Attachment 4) In fact, often the government net cost will be lower than if the government were purchasing the brand product or an ANDA generic product. Including authorized generics units in the brand AMP will result in the least cost to the government. The incentive to market the authorized generic will continue and the competition from the authorized generics will drive down prices for Medicaid and consumers.

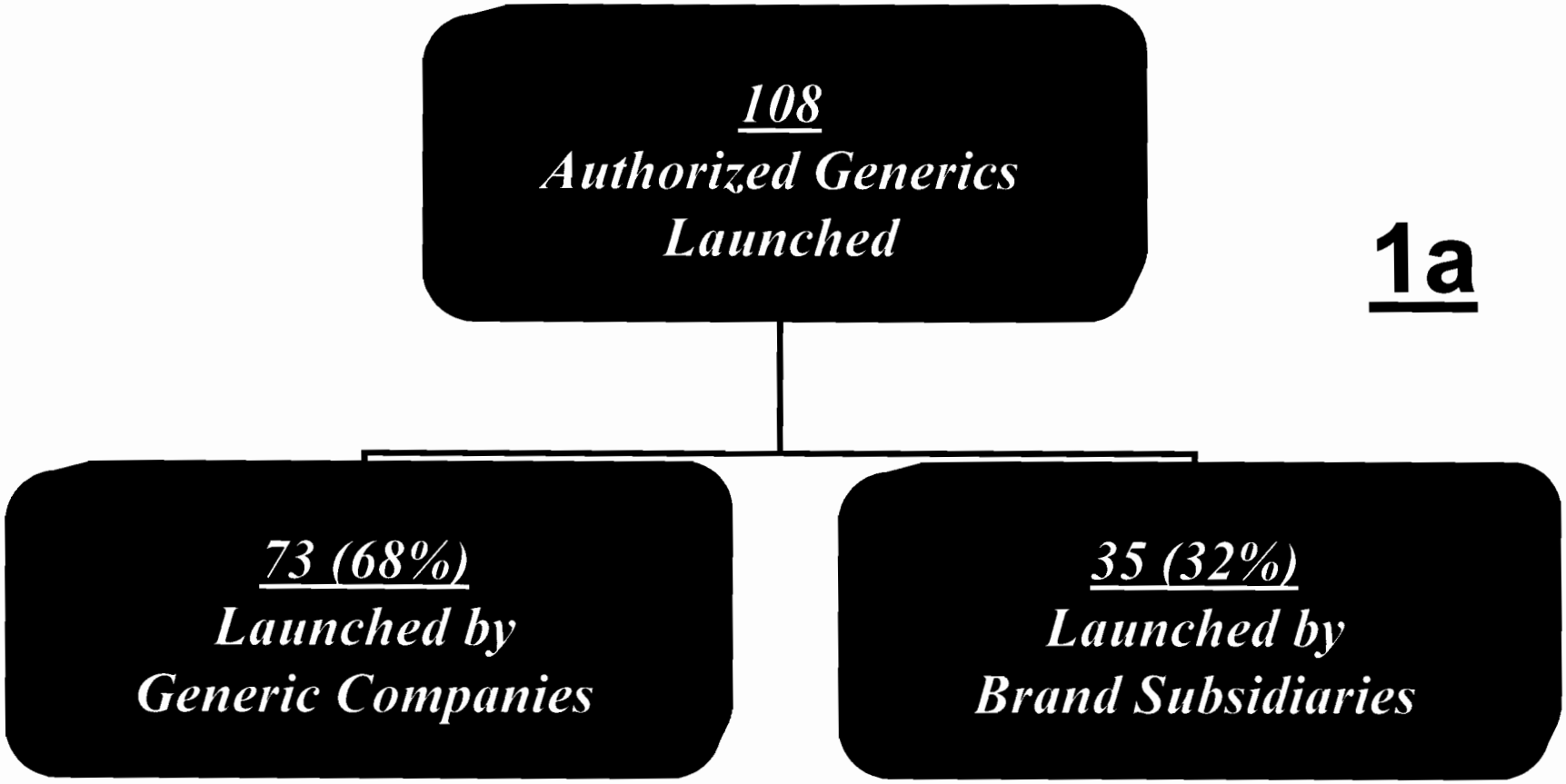
If you have any questions about the above comments, please contact Nicholas Wise at 202- 737-1960.

Submitted on behalf of Prasco, LLC by:



Nicholas P. Wise
Senior Vice President
Government Affairs

Companies Launching Authorized Generics



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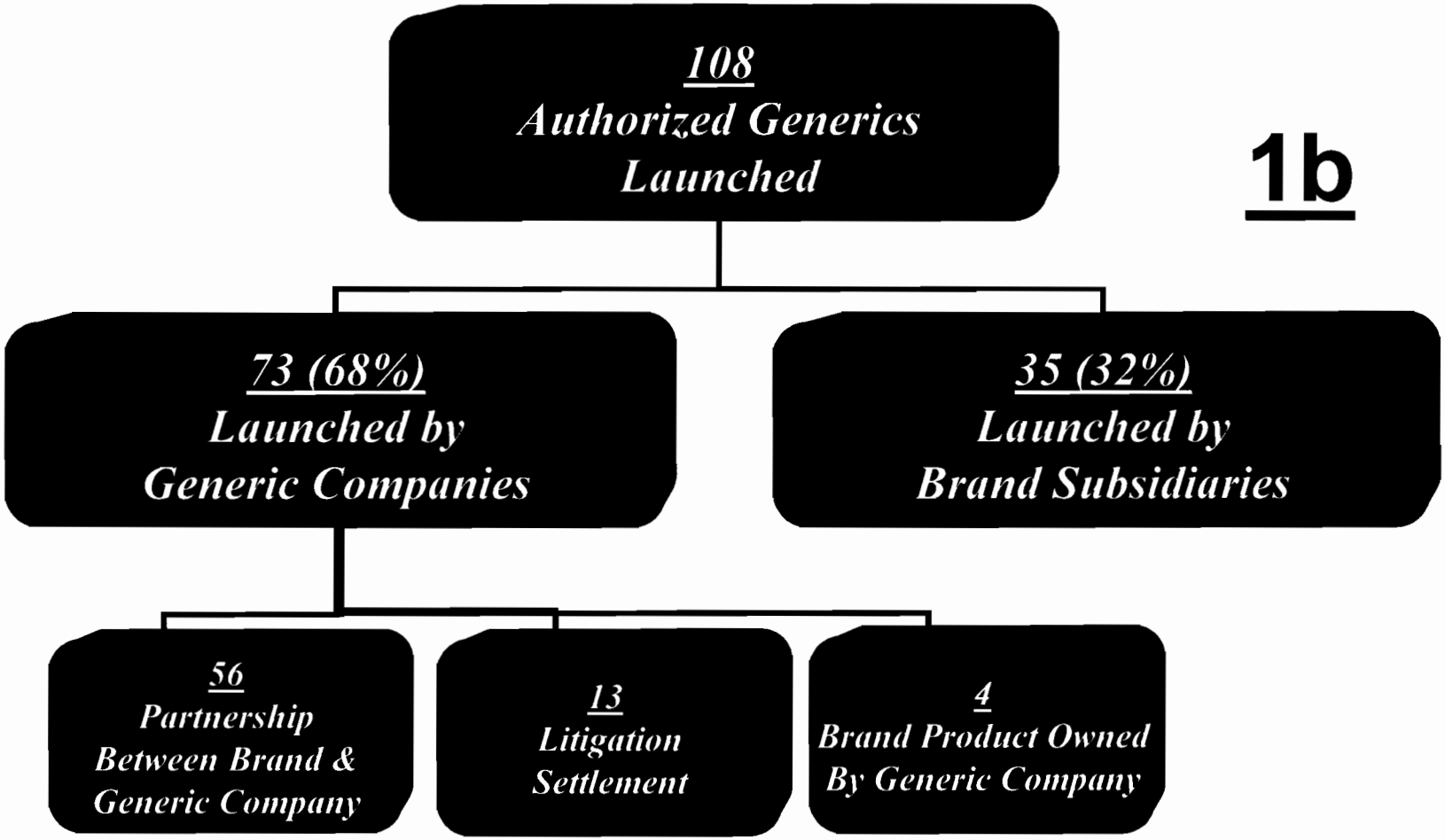
Classifying Authorized Generic Agreements



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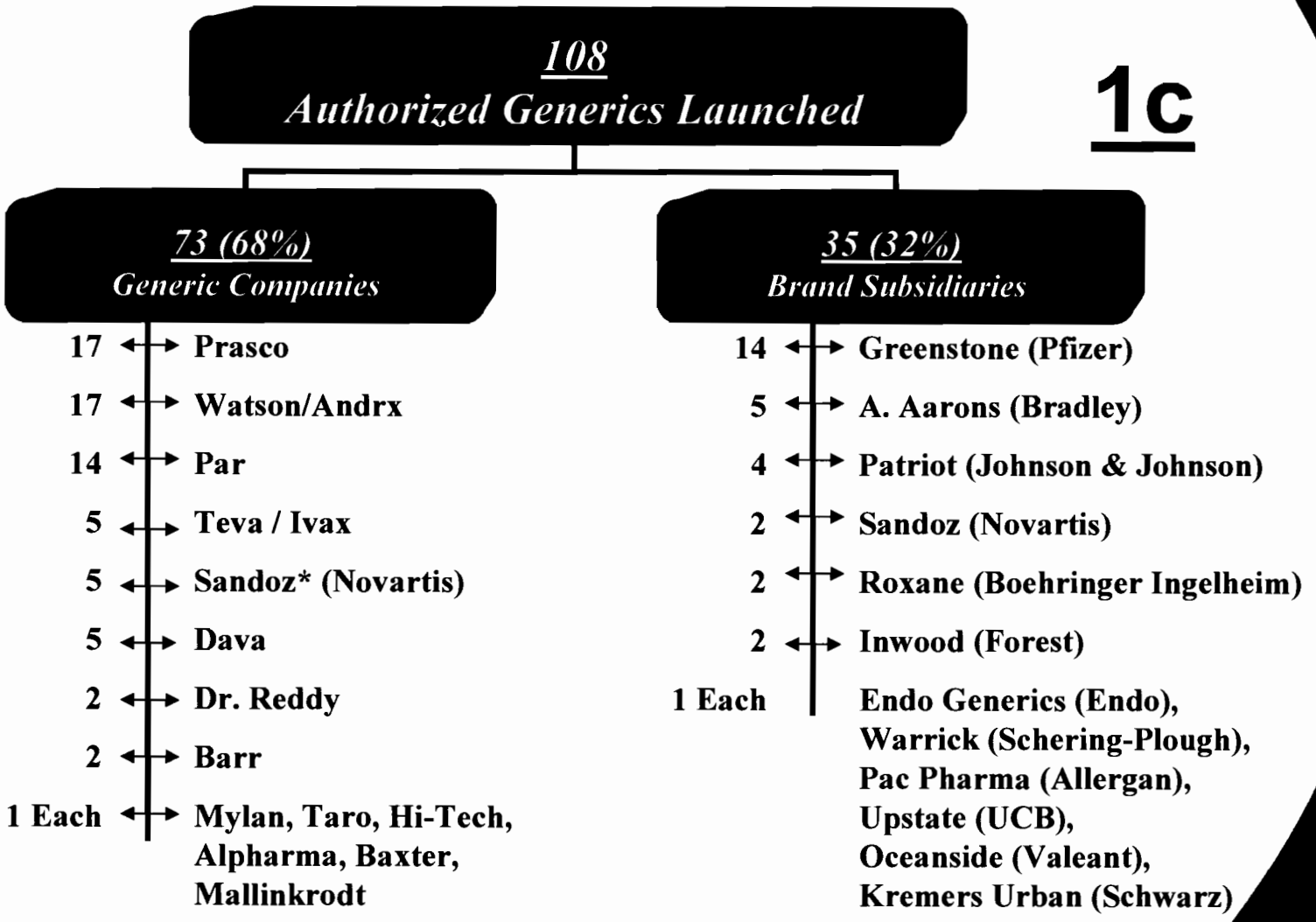
Companies Launching Authorized Generics



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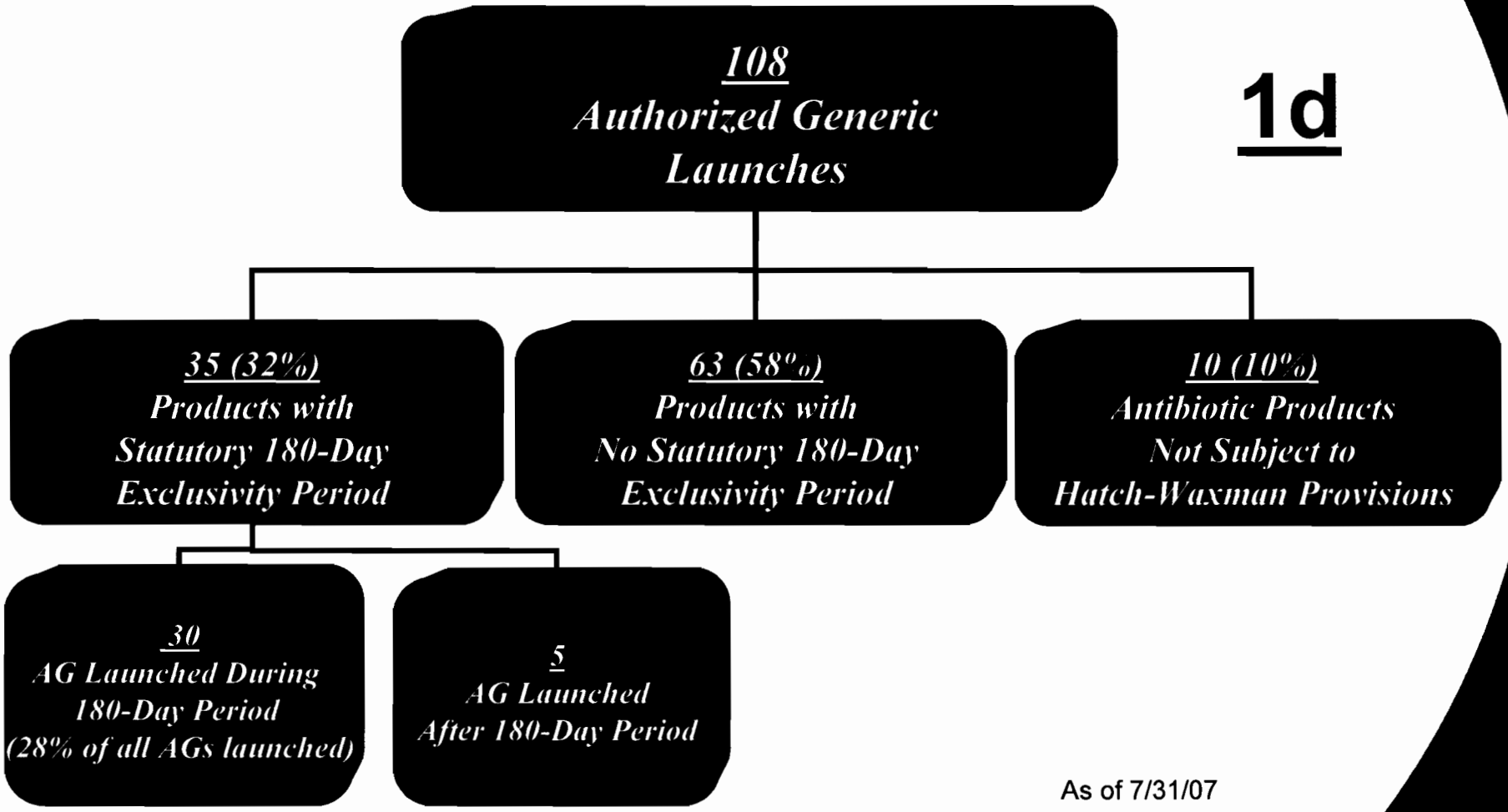
** At present, only two of Sandoz's Authorized Generics are Novartis products*

Authorized Generics and Statutory 180-Day Exclusivity



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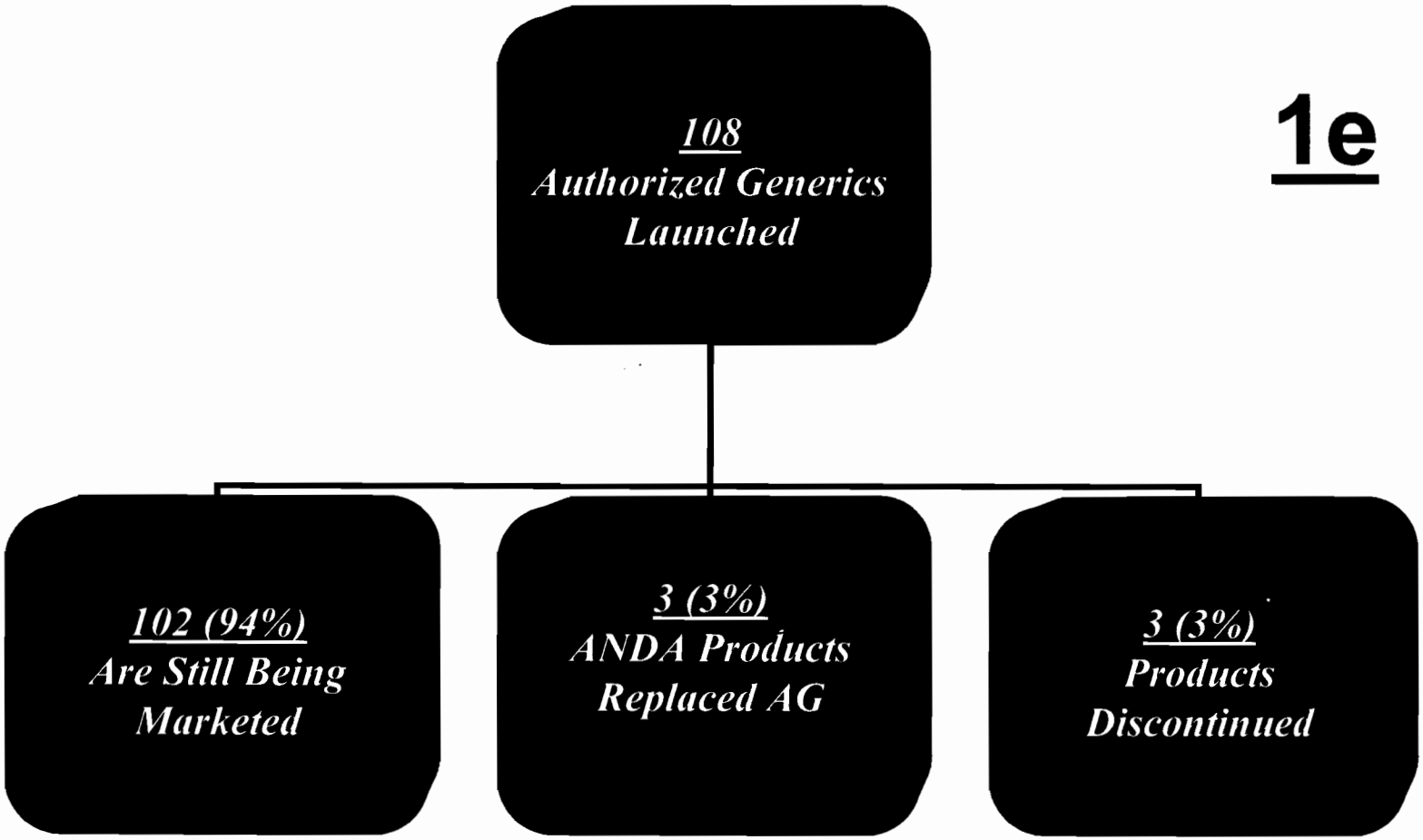
Authorized Generics Still Being Marketed

1e



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Authorized Generics & Statutory 180-Day Exclusivity

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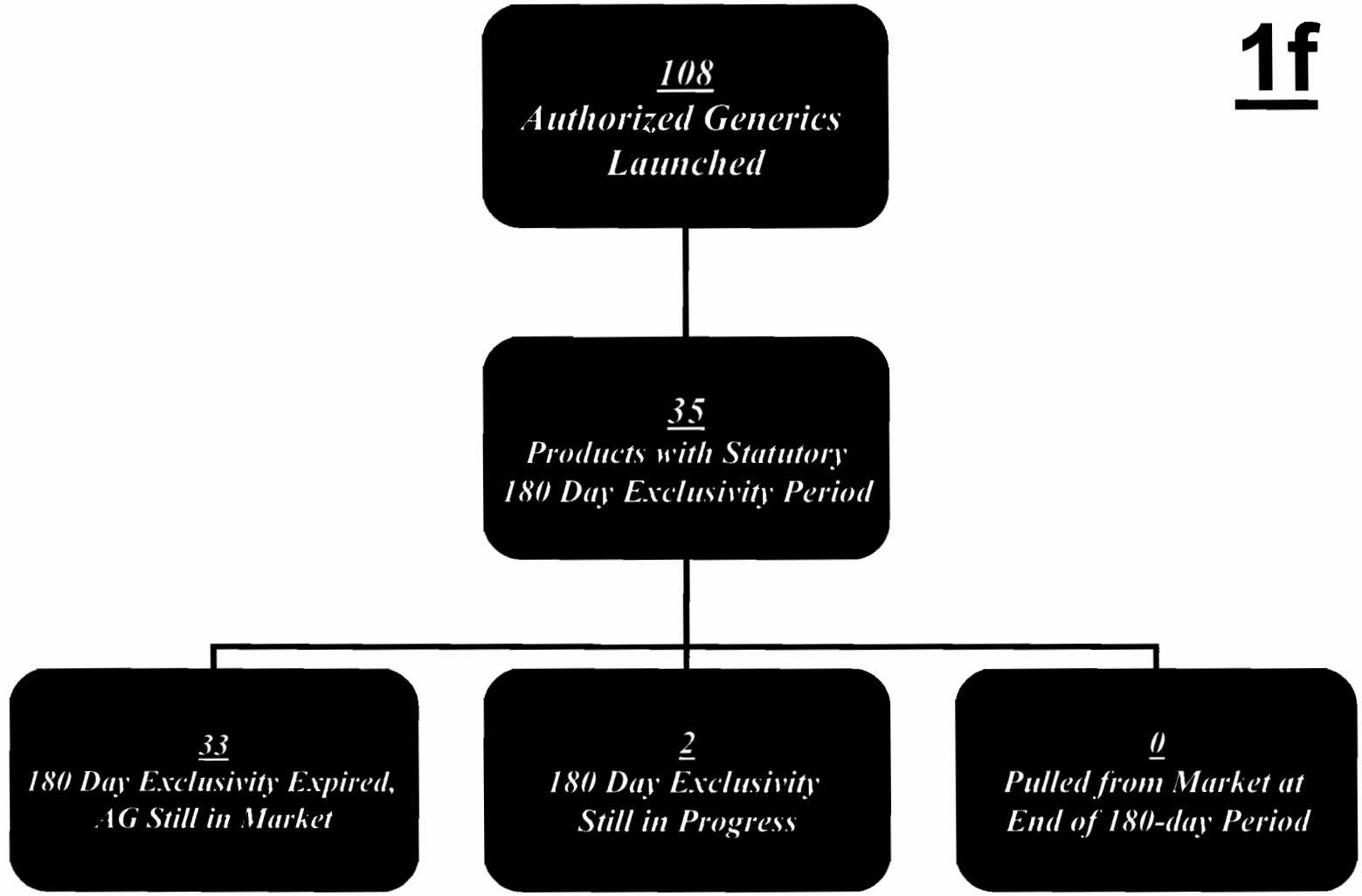

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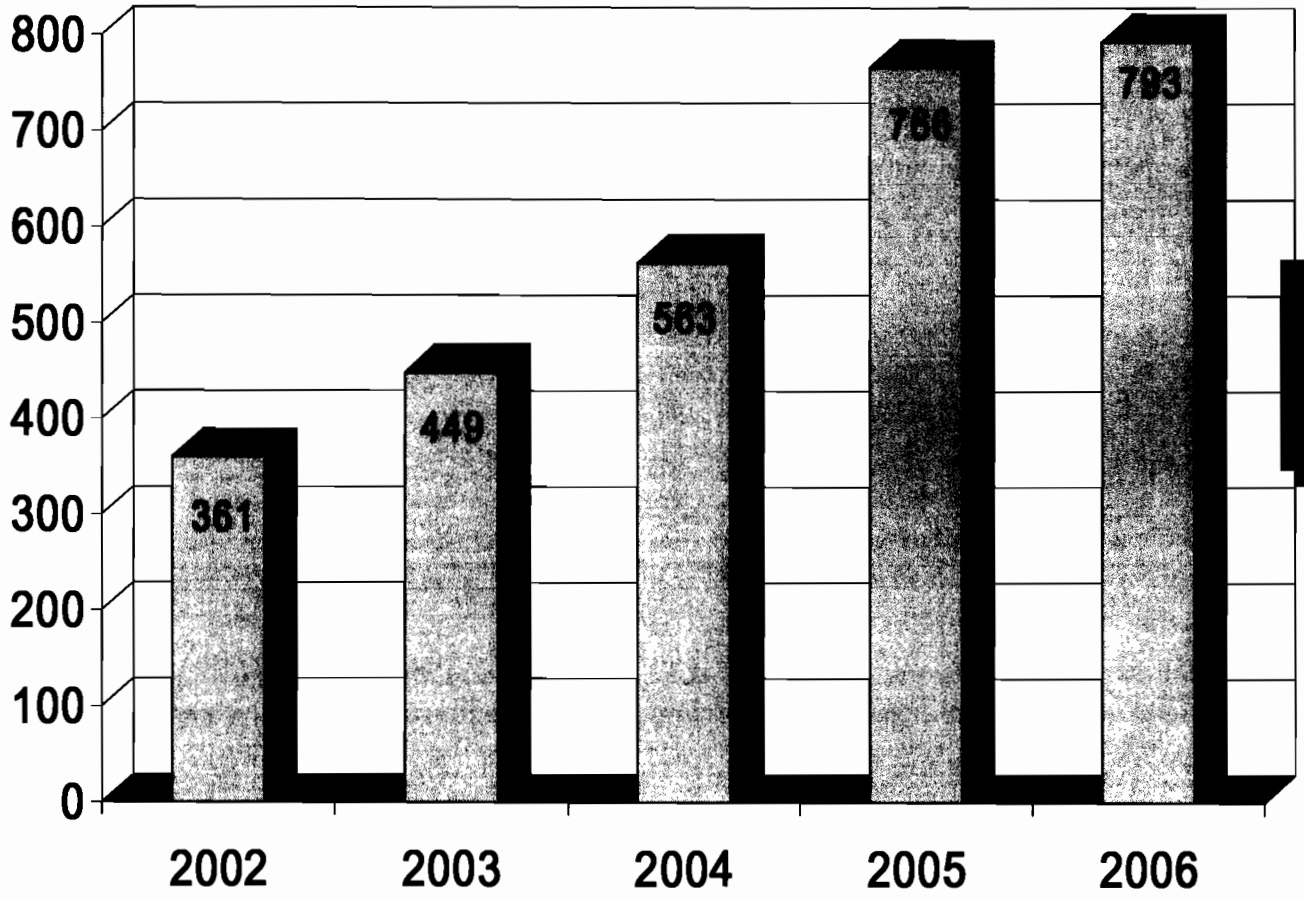
Reality



2a

ANDA Applications Directly Correlate with Brand Patent Cycle

Number of ANDAs Received by the Office of Generic Drugs

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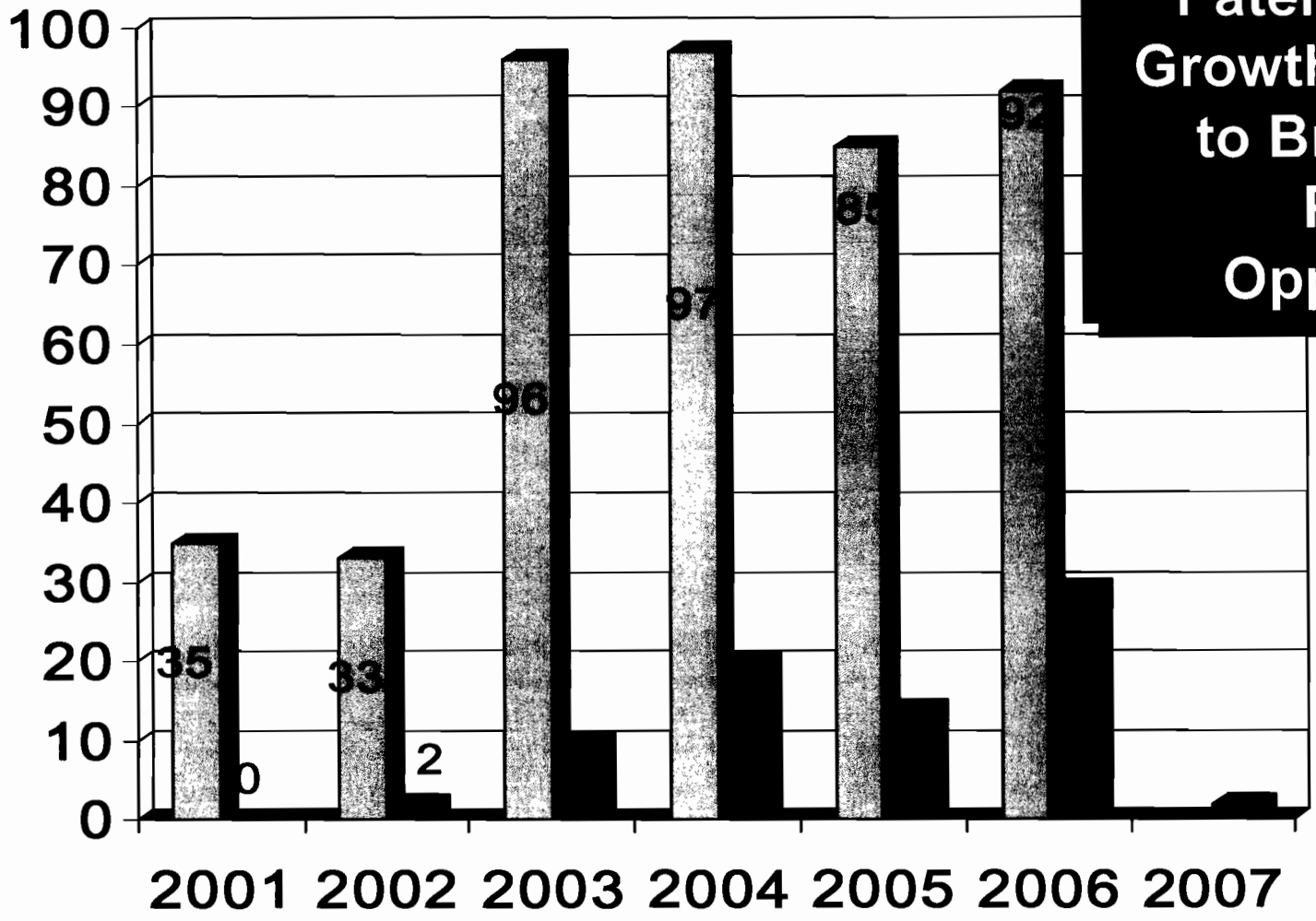
Reality

Paragraph IV Patent Challenge Growth Comparable to Brand Patent Pipeline Opportunities

2b



Source: Paragraphfou
Lynch 2005 Generic
Perspectives; CDI
Certifications 1/

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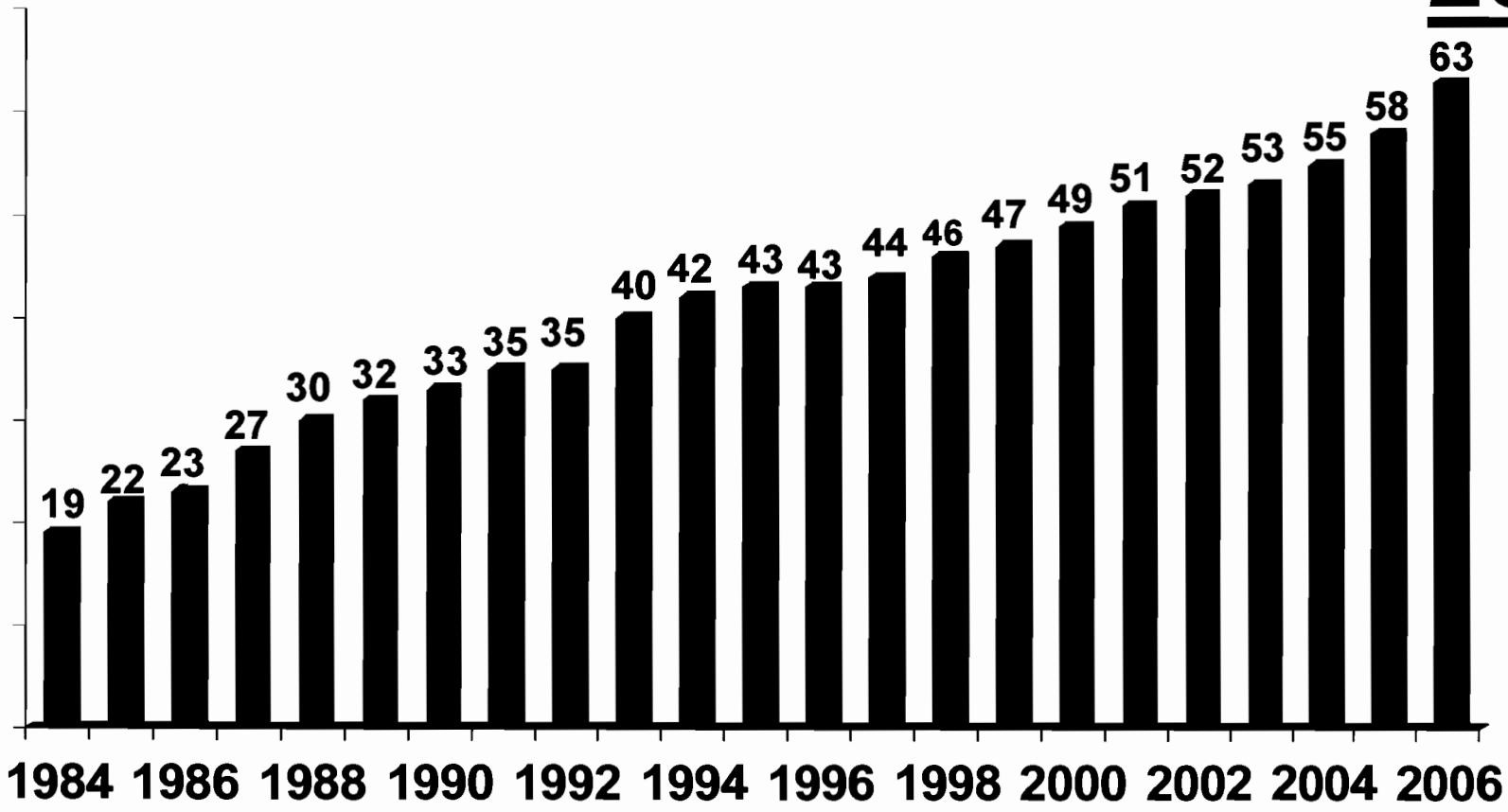
Generics Industry Growth

Generics' Share of U.S. Prescription Drug Market
1984 - 2006

2c



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Scion Companies

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Impact of CMS Rule

3

[illegible]					
Pharmacy Reimbursement [2]	**$150**	**$100**	**$75**	**$50**	**$25**
Medicaid Rebate [3]	**($50)**	**($67)**	**($75)**	**($83)**	**($91)**
Government Net Cost	**$100**	**$33**	**($0)**	**($33)**	**($66)**
[illegible]					
Medicaid Rebate (11% of AMP)	**($7)**	**($4)**	**($3)**	**($2)**	**($1)**
Government Net Cost	**$143**	**$96**	**$72**	**$48**	**$24**

NOTES: 1. Transfer Price = Manufacturing cost + Share of distributable profits; 2. Pharmacy reimbursement = 250% of Generic AMP = Federal Upper Limit; 3. Medicaid rebate = Difference between AMP and BP = Brand AMP – Transfer Price for AG

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Impact of CMS Rule 4

Government Cost when Brand Dispensed to Medicaid Patient & AG Present					
Pharmacy Reimbursement [2]	**$150**	**$100**	**$75**	**$50**	**$25**
Medicaid Rebate [3]	**($50)**	**($67)**	**($75)**	**($83)**	**($91)**
Government Net Cost	**$100**	**$33**	**($0)**	**($33)**	**($66)**
Government Cost for ANDA Dispensed to Medicaid Patient					
Medicaid Rebate (11% of AMP)	**($7)**	**($4)**	**($3)**	**($2)**	**($1)**
Government Net Cost	**$143**	**$96**	**$72**	**$48**	**$24**
Government Cost when Brand Dispensed to Medicaid Patient & AMP Includes AG					
Medicaid Rebate (AG in AMP)	**($15)**	**($13)**	**($12)**	**($11)**	**($10)**
Government Net Cost	**$135**	**$87**	**$63**	**$39**	**$15**

NOTES: 1. Transfer Price = Manufacturing cost + Share of distributable profits; 2. Pharmacy reimbursement = 250% of Generic AMP = Federal Upper Limit; 3. Medicaid rebate = Difference between AMP and BP = Brand AMP – Transfer Price for AG

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NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

WWW.NCPANET.ORG

January 2, 2008

Comments of the National Community Pharmacists Association

THREE COPIES HAND DELIVERED TO CMS WASHINGTON, DC OFFICE
(G. Hubert H. Humphrey Building, Room 445, 200 Independence Avenue, SW., Washington, DC 20201)

Re: 42 CFR Part 447
[CMS-2238-FC]
RIN 0938-A020
Medicaid Program; Prescription Drugs implementing the Medicaid Prescription Drug provisions of the Deficit Reduction Act of 2005 (DRA)

The National Community Pharmacists Association (NCPA)[1] submits the following response to CMS' request for comments to the Average Manufacturer Price (AMP) and Federal Upper Limit (FUL) outlier sections of CMS-2238-FC (CMS' final AMP rule). An unaltered final rule will be in violation of the DRA and other AMP and Medicaid drug reimbursement statutes. Additionally, an unaltered final rule will result in significant negative economic impact upon independent pharmacy because CMS abdicated its responsibility for conducting a complete Regulatory Flexibility Act (RFA) analysis in either the proposed or final rule. In addition to our response to the CMS requested comments, NCPA includes an appendix that updates the RFA analysis in our CMS-2238-P comments submitted on February 20, 2007.

The following comments are written without regard to CR-05-151, *NACDS and NCPA v. US Dept. of Health and Human Services, et al*, in the U.S. District Court for the District of Columbia and does not alter the position of the plaintiffs in that litigation.

I. AMP Must Be Revised So That it Accurately Reflects, with Respect to a Covered Outpatient Drug of a Manufacturer for a Rebate Period, the Average Price Paid to the Manufacturer for the Drug in the United States by Wholesalers for Drugs Distributed to the Retail Pharmacy Class of Trade[2]

(under II. Provisions of the Proposed Regulations – *Definition of Retail Pharmacy Class of Trade and Determination of AMP – at Federal Register Vol. 72. No. 136, July 17, 2007 beginning at p. 39146 and Section 447.504 Determination of AMP, beginning at p. 39241) ("Federal Register, final rule").*

[1] NCPA represents the nation's independent pharmacists, including the owners of more than 23,000 pharmacies, with 75,000 pharmacists, over 300,000 employees and millions of patients who rely on us for their prescription care.

[2] 42 U.S.C. Sec. 1396r-8(k) (1).

The DRA assigned CMS the task of making AMP serve two distinct purposes; 1) as a baseline for pharmacy reimbursement and 2) as an index for manufacturer rebates paid to states. CMS has the statutory authority, flexibility and opportunity under the DRA to properly define AMP, the retail class of trade and the outlier requirement in conformity with the DRA and other federal statutes regarding AMP and Medicaid pharmacy reimbursements. CMS also has the opportunity to accomplish savings through both increasing rebates and raising generic drug utilization rates by setting an accurate baseline for reimbursement limits.[3]

CMS now claims that it is balancing the interests of manufacturers and retail pharmacies while also ensuring the well being of retail pharmacists and the patients they serve. CMS did not, however, use its authority under the DRA to make policy choices that would balance the impact of the DRA. NCPA has consistently disagreed with CMS' assertion that its definition of AMP will have a minimal impact on independent pharmacy's ability to participate in the Medicaid program. CMS still has the opportunity to appropriately exercise its authority under the DRA to create definitions that reflect what actually happens in drug sales and reimbursements.

A. Correct definition of AMP

NCPA requests that CMS revise its definition of AMP, 44 CFR Sec. 447.504(a) to accomplish the Congressionally-mandated task of creating an appropriate AMP, as follows:

AMP means, with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA)) for a calendar month, the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade. AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include retail pharmacy[4] sales only (chain and independent) and only adjustments that reduce the actual price paid by retail pharmacy. Prices extended to mail-order are excluded from the calculation of AMP.

CMS' final AMP rule violates the DRA by failing the requisite four-part test for determining whether a price may be included in AMP. Those requirements are that first, only prices paid to drug manufacturers may be included -- and not payments by a manufacturer to a third party, or payments by a manufacturer for separate services. Sales and rebates to PBMs, rebates and discounts "associated with" sales and low income patient programs should have been excluded under this first prong of the test.

[3] NCPA supports CMS' decision to exclude prices to nursing home facilities and PBMs from AMP -- a policy choice that even manufacturers urged CMS to make.

[4] Independent pharmacies are those that are not publicly traded. They can include franchise stores, but they are almost exclusively locally-owned and are not publicly traded corporations. For these comments, "retail pharmacy" refers to independent and chain (publicly traded) pharmacies. "Retail pharmacy class of trade" is defined later in these comments as the industry does, to include other forms of "brick and mortar" pharmacies.

Second, those prices must be paid by drug wholesalers, which industry practice defines as middlemen between manufacturers and providers who are licensed by States as wholesalers and do not dispense drugs to consumers. In contrast, CMS' final AMP rule considers patients, physicians, hospitals, retail pharmacies and virtually "any entity that purchases drugs from a manufacturer to be a "wholesaler" *See* CMS' final AMP rule at Sec. 447.504(f). This new definition runs counter to federal and state laws and regulations, and CMS' own policies.

Third, it is commonly understood in the industry that a retail pharmacy is an entity that is licensed (by a state) as a retail pharmacy, has a licensed pharmacist to dispense medications, and serves the general public. A specialty pharmacy, dialysis center, home infusion provider, mental health center, or mail order pharmacy or other provider only serves a subset of the public not the general public and thus fails to meet this part of the four-part test.

Fourth, a price paid for a drug may be included in AMP only if the drug is a "covered outpatient drug" *See* 42 U.S.C. Sec. 1396r-8(k)(1)(A). The Social Security Act defines "covered outpatient drug", and specifically excludes drugs provided to patients in connection with "physician services" or "outpatient hospital services" or "renal dialysis" 42 U.S.C. Sec. 1396r-8(k)(3). CMS' final AMP rule improperly includes in its AMP calculations sales of drugs to physicians, outpatient hospital pharmacies and clinics and sales to dialysis centers – these are sales of drugs that will ordinarily be provided to patients incident to physicians' services or outpatient hospital services or renal dialysis. CMS's final AMP rule also includes sales to surgical centers, ambulatory care centers and mental health clinics *See id.* at Sec. 447.504(g)(8), even though these drugs are ordinarily provided "incident to" physician's services.

In sum, CMS included in its calculations of AMP prices that are not paid to manufacturers by wholesalers for drugs distributed to retail pharmacies. The following are examples of sales that CMS' AMP rule improperly includes in calculations of AMP as the purchasers and entities or drugs at issue are one or more of the following: 1) not wholesalers; 2) not retail pharmacies; 3) the drugs will not be distributed to the retail pharmacy class of trade; or 4) not part of the "price paid to the manufacturer" for drugs:

CMS must exclude the following sales/fees/rebates that it includes in its final rule in the referenced sections:

- Direct sales to patients *(patients are neither wholesalers nor retail pharmacies, Sec. 447.504(g)(7)))*
- Sales to physicians *(physicians are neither wholesalers nor retail pharmacies, Sec. 447.504(g)(13))*
- Sales to medical outpatient facilities, i.e. sales to dialysis centers, surgical centers, mental health facilities, ambulatory care facilities and physician clinics. *(are not sales to wholesalers, nor are they sales of drugs distributed to the retail pharmacy class of trade, Sec. 447.504(g)(8))*
- Sales to retail pharmacies *(are not generally licensed as wholesalers, Sec. 447.504(g)(5))*

- Sales to other manufacturers *(are not normally licensed as wholesalers and the drugs they buy are not necessarily distributed to retail pharmacies, Sec. 447.504(g)(2))*
- Specialty pharmacy sales *(are neither wholesalers nor retail pharmacies, Sec. 447.504(g)(11))*
- Sales at nominal price to any entity *(entity almost certainly not a wholesaler and drugs will almost certainly not be distributed to the retail pharmacy class of trade, Sec. 447.504(g)(4))*
- Sales to home health care providers *(are not sales to wholesaler, not distributed to retail pharmacy class of trade, Sec. 447.504(g)(12))*
- Sales to home infusion providers *(are not wholesalers, Sec. 447.504(g)(10))*
- Sales to hospital pharmacies, clinics or affiliated entities *(these entities are neither wholesalers nor are they retail pharmacies, Sec. 447.504(g)(3))*
- Sales and rebates to PBMs *(are not part of the "price paid to the manufacturer" for drugs and PBMs are not wholesalers, Sec. 447.504(g)(6))*
- GPO Fees *(are not prices paid to manufacturers; these fees are paid by manufacturers, often to non-purchasers, and GPOs are not normally wholesalers, Sec. 447.504(i))*
- Rebates and discounts "associated with" sales *(are not "prices paid to the manufacturers and are not linked to sales to wholesalers, Sec. 447.504(g)(14))*
- Sales reimbursed by third parties *(might not be sales to wholesalers, Sec. 447.504(g)(15))*
- Low income patient programs *(do not involve prices paid to manufacturers, Sec. 447.504(h)(9), (12), (16), (17))*
- Sales to mail order pharmacies *(are not normally wholesalers nor are they part of the retail pharmacy class of trade, Sec. 447.504(g)(9))*

B. Retail Pharmacy Class of Trade should be defined as only retail pharmacies. The definition should not include Pharmacy Benefit Manager (PBM) mail-order operations, which dispense almost no Medicaid prescriptions.

NCPA repeats its request that CMS change its proposed definition of retail pharmacy class of trade, *42 CFR Sec. 447.504(e) at Federal Register, final rule at p. 39241* as follows:

(e) Retail pharmacy class of trade means any independent pharmacy, independent pharmacy franchise, independent chains, independent compounding pharmacy, traditional chain pharmacy – including each traditional chain pharmacy location, mass merchant pharmacy and supermarket pharmacy.

This definition currently encompasses over 58,000 retail pharmacy locations.

In order then to be included in the definition of retail pharmacy class of trade, the prices must be prices available to retail pharmacy and the prescriptions must be "publicly accessible."

Under this definition, sales to mail-order facilities would not be included in AMP. Mail-order facilities are wholly owned and operated almost exclusively by PBMs, and as such they do not meet the above mentioned criteria. Mail-order facilities are extended special prices and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.

Mail-order pharmacies are operated as closed model systems that are not available to the general public, and are excluded from the retail pharmacy class of trade under Medicare Part D. Because a majority of Medicaid beneficiaries are children, there is more of a need for rapid relief medications, e.g., antibiotics and pain medicine, so the mail-order pharmacy model has not been found to be an efficient one and therefore has not been adopted by the majority of state Medicaid programs. Since mail-order pharmacies seldom service these beneficiaries, they should not be included in the definition of retail pharmacy class of trade.

Moreover, including these sales and rebates would create a benchmark that would be of little use to state Medicaid directors to set reimbursement rates for retail pharmacies. Including mail-order in the definition of AMP would thus inappropriately drive down AMPs. CMS should not include such sales, which have little relevance to Medicaid.

Finally, NCPA finds the following three flaws with CMS' rationale for its treatment of mail-order facilities in the final rule:

1) CMS has not explained why mail-order is included in the Medicaid retail class of trade, but is specifically excluded from the Medicare Part D retail class of trade;

2) CMS' cite to GAO report is misleading – the GAO has in fact opposed CMS' position on mail-order; and

3) Unlike technical issues left to the Secretary, CMS had clear notice of Congressional intent as both the House and Senate versions of the DRA excluded mail-order from the definition of AMP.

C. CMS Ignores the State Availability Requirement

Implicit in formulating an accurate measurement of AMP is that the definition of multiple source drug (generic drug) must be accurate. CMS, however, chose a definition of multiple source drug that runs counter to existing federal statutes and conflicts with previous CMS/HHS decisions and also is in opposition to specifically stated Congressional intent to avoid "unreasonably low" upper payment limits. *See* 136 Cong.Rec. S15658 (1990).

In 1972, Congress established a system for setting upper limits on Medicaid reimbursement for multiple source drugs that required the upper limits to be based on charges for drug products that were "widely and consistently available in a locality." *See* Social Security Act Amendments of 1972, Pub. L. 92-603, Sec. 224, 86 Stat. 1395 (Oct. 30, 1972). HHS regulations included this requirement. *See* 45 C.F.R. Sec. 19.5, published at 40 Fed. Reg. 32302 (July 31, 1975).

Finally, proposed FUL regulations defined "multiple source drug" as drug products that are "sold or marketed in the State during a rebate period," *See* Fed. Reg. 48442, 48483 (Sept. 19,

1995) and limited AMP calculations to prices paid to manufacturers for the drug "in the State" by wholesalers. *Id.* at 48487.

The DRA did not alter this State availability requirement. Nonetheless, CMS' rule discards the statutory requirement that the drug must be "sold or marketed in the State" and replaces it with language that the drug must be "sold or marketed in the United States. . . ." *See* CMS' final AMP rule Sec. 447.502.

This is an important distinction because analogous to CMS including in its definition of AMP drug products that are not available to retail pharmacies but are available through other medical providers, (e.g. physicians, hospitals, clinics), CMS' impermissible change in the State availability test will also result in inappropriately low FULs based upon prices for drugs that are not available to retail pharmacies in certain areas.

There are often situations when regional maufacturers, wholesalers and distributors sell drugs in parts, but not every state in the United States. These products may have low AMPs that are used to calculate FULs, even though pharmacies in other states cannot purchase those products at those low prices. Including AMPs of multiple source drugs that are sold anywhere in the country thus improperly lowers the reimbursements for those regionally-only available drugs.

II. NCPA Advocates that CMS Increase the Outlier requirement to 80%
(under II. Provisions of the Proposed Regulations – *Upper Limits for Multiple Source Drugs,* *Federal Register, final rule at 39154 – 39156, Outlier AMPs at 39216 - 39217 and Sec. 447.514 at 39244)*

CMS proposes to set the outlier limit at 40% - a modest increase from the 30% it announced in the proposed rule. CMS incorrectly reasons that this standard will "further safeguard to ensure" that "a very low AMP is not used by us [CMS] to set a FUL that is lower than the AMP for other therapeutically and pharmaceutically equivalent multiple source drugs." *Federal Register, Proposed rule at p. 77187.*

The newly proposed requirement means that FUL could be calculated using an AMP that is a mere 40 percent of the second lowest AMP for that drug – so an AMP as low as $4 could be used to calculate the FUL where the next lowest AMP was up to $10.

CMS fails to address the issue of generic drug availability Smaller generic manufacturers seeking to capture additional market share are willing to enter the market with a steeply discounted price in an effort to force pharmacies to buy their product. **The problem is manufacturing capacity**. Smaller generic manufacturers do not have the product inventories to serve more than just a small percentage of the Medicaid population.

In many cases there simply will not be enough supply for all pharmacists – particularly independent pharmacists. Independent pharmacists do not have access to the lowest AMP attached to a generic drug newly entering the market from a particular manufacturer. Independent

pharmacists will be unable to buy generics at that lowest AMP, no matter how diligently they try to buy drugs cheaply. There will always be buyers that will not be able to catch up to the best price of the generic drug seller. AMPs do and will vary dramatically among manufacturers and among what buyers can obtain.

CMS' use of a low outlier requirement, in the face of such an inability to meet the lowest price, is an undesirable manipulation of market forces. To allow the lowest generic AMP to set the benchmark for low rebates to states and as the benchmark for a low FUL when that generic is as low as 60% below the next lowest AMP would serve to permanently keep many independent pharmacies from providing patient access to Medicaid drugs.

CMS repeatedly asserts that the final rule will lead to adequate compensation for pharmacists. It has presented the outlier provision as a positive part of this overall rebate and reimbursement metric. For example, at two recent International Institute for Research conferences, CMS presented hypothetical AMPs for an unnamed representative class of drugs[5]:

AMP #1	$15.00
AMP #2	$10.00
AMP #3	$3.90

Using these numbers, CMS stated that the FUL would be sufficient at $25.00 (2.5 * $10.00). What CMS failed to point out is that if the second lowest AMP for the representative drug was a mere 10 cents higher ($4.00, as opposed to $3.90), the maximum FUL would yield a reimbursement of only $10.00:

But if AMP #3A	$4.00	**FUL would be $10.00** (2.5 * lowest AMP as it is 40% or more of 2nd lowest AMP)

Many independent pharmacists will not be able to provide Medicaid medications to their patients if CMS retains the 40% outlier provision in the final rule. Here are similar numbers for a class of drugs whose second lowest AMP was $15 and $20, respectfully:

2nd lowest AMP at $15.00

AMP #1	$22.50	
AMP #2	$15.00	
AMP #3	$5.90	**FUL would be $37.50** (2.5 * AMP #2)
But if AMP #3A	$6.00	**FUL would be $15.00** (2.5 * lowest AMP as it is 40% or more of 2nd lowest AMP)

[5] Deidra Duzor, CMS presentation July 26, 2007 in Baltimore, MD and September 25, 2007 in Chicago.

2nd lowest AMP at $20.00

AMP #1	$30.00	
AMP #2	$20.00	
AMP #3	$7.90	**FUL would be $50.00** (2.5 * AMP #2)
But if AMP #3A	$8.00	**FUL would be $20.00** (2.5 * lowest AMP as it is 40% or more of 2nd lowest AMP)

This simple mathematical illustration proves the 40% outlier policy to be grossly inadequate to ensure adequate pharmacy reimbursement. NCPA believes that an 80% outlier is a necessary step to keep from making acquisition of generic drugs under Medicaid unworkable for independent pharmacists.

Excluding from the calculation of the FUL those generic AMP prices that are 40% to 80% of the next lowest AMP will capture a much larger group of AMPs. The logical exclusion of AMPs that are less than 80% of the next lowest AMP will significantly move AMP to a much more realistic market based measure of the average manufacturers price for Medicaid generics.

Based on the findings of the GAO and OIG, independent pharmacies that have a high level of Medicaid beneficiaries will simply be unable continue servicing them at a financial loss. If CMS goes forward with this approach many pharmacies with a high percentage of Medicaid business will even be forced out of business.

III. Conclusion

For all the reasons outlined and to maintain patient access to independent pharmacy, NCPA requests that CMS:

- Adjust the definitions of AMP and retail pharmacy class of trade so that AMP is, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the maufacturer for the drug in the United States by wholesalers for drugs distributed only to the retail pharmacy class of trade, as the DRA requires and as such is consistent with our proposed revisions.

- Increase the outlier requirement to 80% so that the FUL allows for adequate pharmacy reimbursement consistent with market availability

We appreciate the opportunity to submit these comments on behalf of our membership.

January 2, 2008

APPENDIX to Comments of the National Community Pharmacists Association

THREE COPIES HAND DELIVERED TO CMS WASHINGTON, DC OFFICE
(G. Hubert H. Humphrey Building, Room 445, 200 Independence Avenue, SW., Washington, DC 20201)

Re: 42 CFR Part 447
[CMS-2238-FC]
RIN 0938-A020
Medicaid Program; Prescription Drugs implementing the Medicaid Prescription Drug provisions of the Deficit Reduction Act of 2005 (DRA)

Under a Regulatory Flexibility Act ("RFA") analysis, CMS is clearly setting an unrealistic threshold for Outlier Prices in the FUL calculation. The FUL Outlier should be changed to 80%.

(II. Provisions of the Proposed Regulations – *Upper Limits for Multiple Source Drugs, Section 447.514 at p. 39244 and discussed at pgs. 39154 – 39157 and pgs. 39216 - 39127)*

CMS' definition of AMP, including the definition of retail pharmacy class of trade, combined with the 40% outlier provision, will have a significant negative impact upon independent pharmacists and will impact patient access to Medicaid drugs. Our RFA analysis shows that the definition of AMP and the outlier requirement must be substantially adjusted.

I. Regulatory Flexibility Act

Cuts to pharmacy are much greater than CMS' characterization of a "1% loss of drug revenues"

(II. Regulatory Impact Analysis – B.3. Effects on Retail Pharmacies at p. 39233)

CMS misleadingly, and erroneously, claims that the effect of implementation of the rule will be less than "1 percent" of prescription drug revenues. CMS wrote in the proposed rule that:

> First, almost all of these stores sell goods other than prescription drugs, and overall sales average more than twice as much as prescription drug sales. Second, pharmacies have the ability to mitigate the effects of the proposed rule by changing purchasing practices. . . . Pharmacies will often be able to switch their purchasing to the lowest cost drugs and mitigate the effect of the sales loss by lowering costs. *CMS-2238-P, Federal Register, Vol.71, No. 246, December 22, 2006, pgs. 77192 – 77193 ("Federal Register, Proposed rule") (emphasis added).* CMS repeats the last assertion in *Federal Register, Final rule at p. 39233.*

CMS' assertions are simply wrong. NCPA offers the following rebuttal:

First some 92% of independent pharmacy revenues are from prescription drug sales. The negative effect of CMS-2238-FC will be tremendous on independent pharmacies, which are disproportionately located in rural and urban areas. This negative impact will not be abated by the small portion of non-pharmaceutical sales that occur at these pharmacies.

Second, in claiming only a 1 percent loss of revenues, CMS looks at gross revenue sales figures for all of pharmacy (chain and independent), and fails to look at the percentage of Medicaid business per pharmacy. Based on analysis of 2006 data, Medicaid comprises 15% of the average independent pharmacies' business—approximately double the Medicaid business of a typical chain location. For over 10% of independent pharmacies, Medicaid represents 50% or more of their business. If Medicaid reimbursements will be significantly below acquisition costs, as government oversight organizations have projected, then many independent pharmacies will have to suspend their participation in the Medicaid program or close their doors, thus restricting patient access, increasing health care costs, and deteriorating beneficiary/patient health.

Because of these qualitative differences between independent pharmacies and chain pharmacies, and because of the newly estimated negative impact of the final rule upon independent pharmacies, *infra,* NCPA repeats its request for an exemption from the new definition of AMP for either: 1) small business as defined by the Small Business Administration (SBA) definition based on gross dollar of business - $6.5 million or less annual; or 2) pharmacies that have a 10% or higher volume of Medicaid business.

A. The OIG and the GAO have stated that FUL will be insufficient

The DRA sets the new FUL at a maximum of 250% of the lowest AMP for therapeutically equivalent and nationally available generics. This 250% ceiling is a best-case scenario as states will be unlikely to set reimbursement at the FUL (many states currently reimburse below the FUL). The OIG recently reported that even with the 250% multiplier, the FUL would still fall below pharmacy acquisition cost for 19 of the 25 high-expenditure generic drugs studied. For 5 of the other 6 drugs in the study, the pharmacy would only cover the cost of the drug, but would still realize a loss once the cost-to-dispense (pharmacy operational costs) is considered.

Retail pharmacy cost-to-dispense averages $10.50 nationwide according to a comprehensive 2007 study by the international accounting firm Grant Thornton. The dispensing fee paid under state Medicaid programs is far lower at an average range of $3.00 - $5.00. When these numbers are applied to the findings of the OIG study, only 1 of the top 25 high-expenditure Medicaid drugs would post a meager profit under the new FUL.

These findings confirm those of a December 2006 GAO study (released January 2007) which found that the new FUL would fall below acquisition cost for 59 of the 77 generics profiled. The AMP-based FUL was 65% below acquisition cost for the 27 high-expenditure drugs studied,

15% below acquisition for the 27 most-frequently prescribed generics, and an average of 36% below pharmacy acquisition cost across the entire sample.

B. On average, independent pharmacists stand to lose nearly 80% of total net profits under the new AMP – patient access will decline

CMS did not undertake a substantive RFA analysis in either its proposed or final rules. CMS dismissed the findings of the OIG and GAO. CMS then claimed a lack of evidence to substantiate the significant economic impact of the final rule. CMS then went on to state ". . . we [CMS] have retained our prior conclusion that this proposed rule is likely to have "significant impact" on some pharmacies." *Federal Register, Final Rule at 39233.*

CMS is not technically required to conduct an RFA analysis if it does not find evidence of a significant economic impact, however NCPA believes the intent of the RFA was violated when CMS dismissed the evidence offered by the OIG and GAO. NCPA does not understand how CMS can say that if finds no evidence of a significant economic impact in light of these data and analyses. In addition to a comprehensive review of the OIG and GAO studies, CMS should also consider the following NCPA analyses based on newly acquired 2006 data.

Based on recently acquired 2006 data, NCPA estimates that implementation of the AMP-based FUL will lead to a 79% reduction in net profits of the average independent pharmacy. This estimate: 1) assumes that sales from other drugs and products at the pharmacies stays constant, and 2) uses the GAO's projection of pharmacists being reimbursed for the average Medicaid drug under CMS' new AMP-based FUL at 36% below the acquisition cost – even if that reimbursement is at the maximum FUL of 250% of AMP. Due to the changes that CMS has made to its definition of AMP, reimbursements could even be lower.

Using those assumptions, NCPA estimates that the average total revenues from Medicaid will reach $104,326 in the first year that AMP is implemented. Projected average total Medicaid expenses of $180,222 will therefore exceed the average total revenues by $75,896. The total net profit of the average independent pharmacy in 2006 was $96,030. The projected $75,896 reduction in net revenue, to $20,134, equals a 79% drop from 2006 net revenue.

In addition, while the average amount of Medicaid business for an independent pharmacy is 15%, for some ten percent (10%) of independent pharmacies, over half of their business is from Medicaid, with the majority of those prescriptions being filled as generics. These high Medicaid volume business independent pharmacies and their patients will be greatly negatively impacted by the final rule.

The total revenue from generic Medicaid prescriptions is low relative to the total median independent pharmacy business because generic drugs are significantly cheaper than brand name

drugs.[1] Because net profits per prescription are much lower for generic drugs than they are for brand name drugs, implementation of the final rule will affect independent pharmacists to a much greater degree than might be assumed based on gross revenue calculations. Simply put, a relatively small cut in federal Medicaid expenditures on generic drugs will cause significant profit losses for some independent pharmacies. Because they will lose money on most Medicaid generic prescriptions, many will have to discontinue dispensing Medicaid prescriptions and some will have to shut their doors.

1. National Average

Table 1 (assuming an average $4.50 state dispensing fee)

Projected independent pharmacy revenue losses under new CMS AMP – assuming GAO's projection of reimbursement at 36% below acquisition cost
Except as noted, data expressed as projected revenues for the average independent pharmacy with $3,612,000 in annual sales (2006 average)

	Dollar Value at 15% Medicaid business	Dollar Value at 30% Medicaid business	Dollar Value at 50% Medicaid business
New Generic Medicaid Revenues			
Drug Product Reimbursement	$82,060	$164,119	$273,532
Dispensing Fee Revenue	$22,266	$44,532	$74,221
Total Revenues	$105,326	$208,652	$347,753
Expenses			
Cost of Goods Sold	$128,218	$256,437	$427,394
Cost to Dispense	$52,004	$104,008	$173,347
Total Expenses	$180,222	$360,445	$600,741
Net Loss	**(-$75,896)**	**(-151,793)**	**(-$252,988)**
Average Independent Pharmacy Total Net Profit (2006)	$96,030	$96,030	$96,030

[1] Based on CMS data from January to June 2006, the average prices paid for a generic and brand name drug under Medicaid are $21.92 and $155.98, respectively. NACDS' *The Chain Pharmacy Industry Profile 2007* at page 69 lists the average price for all generic drugs as $32.23 and the average price for all brand name drugs as $111.02. The $32.23 value was used in calculating the figures found in Table 1, *infra*.

Total Projected Net Profit/Loss of average independent pharmacy under new CMS AMP	$20,134 **(Drop of 79% from 2006)**	**(-55,763) (Drop of 158% from 2006)**	**(-$156,958) (Drop of 263% from 2006)**

2. Even an example independent pharmacy that does a modest volume of Medicaid business would be hurt by CMS' AMP and would likely stop servicing Medicaid beneficiaries

An NCPA member whose pharmacy's Medicaid sales total only 2.08% of its total drug revenues and whose net profit margin is almost identical to the national independent average net profit margin provided us with data regarding its Medicaid business that shows that even independents with a small volume of Medicaid business will be hurt by CMS' AMP rule and will have financial incentive to stop servicing Medicaid beneficiaries.

In the last year, the sample independent shows a 2.743% net profit margin of which $2,614.61 was generated from its Medicaid generic drug sales. Under the GAO projection of reimbursements at 64% of costs, and including dispensing fees, the independent pharmacy calculated that it would incur a $20,410 loss of Medicaid generic drug sales revenue if it were to continue servicing Medicaid beneficiaries under CMS' new AMP.

If the sample independent were to terminate its Medicaid contract, however, the calculated net loss would only be $13,069. This calculation also takes into consideration losing ancillary prescriptions filled by family members or care givers that are not covered by Medicaid. The sample independent is thus trying to accurately project -- and not minimize -- the anticipated loss from dropping out of the Medicaid program.

This sample independent calculates, as many others will, that terminating their Medicaid contract will be less harmful than continuing to serve Medicaid patients under CMS' AMP. A few independent pharmacies with a small volume of Medicaid business may decide to absorb the losses as a courtesy to needy Medicaid beneficiaries. Those independent pharmacists with a larger volume of Medicaid business will not have that option and will either drop out of the Medicaid program or be forced out of business.

Table 2 shows the sample independent's projected losses for continuing or discontinuing service in the Medicaid program based on the current and hypothetical levels of Medicaid business:

Table 2 (assuming a $4.00 dispensing fee)

Percentage of business as Medicaid business	Net loss if sample independent pharmacist remains in Medicaid program	Net loss if sample independent pharmacist terminates Medicaid contract
2.08%	(-$20,410)	(-$13,069)
15%	(-$146,181)	(-$93,944)
30%	(-$292,129)	(-$187,794)
50%	(-$486,875)	(-$313,022)

3. CMS's criticisms of the GAO and OIG reports are unfounded and its reference to state power to address reimbursements is not realistic

CMS has disputed the findings of both the OIG and GAO reports; however, the methodologies used by each agency are congruent with provisions contained in the rule. CMS failed to refute any of the reports specific findings, instead using sweeping generalizations to dismiss two independent government agency reports as flawed and irrelevant. The HHS Secretary also offered wholesale rejection of the GAO study during testimony before the House Committee on Energy & Commerce without providing any specific refutation of the study's findings.

CMS suggests states should examine dispensing fees as well as estimated pharmacy acquisition cost to ensure that pharmacy costs are sufficiently covered. CMS even included a cost-to-dispense definition similar to the definition within Medicare Part D for state's consideration. CMS did not, however, provide any guidance or incentive for states to ensure pharmacy operational and acquisition costs are covered.

While CMS incorrectly claims that the new FUL will sufficiently cover acquisition costs, CMS makes it clear that states are free to pay pharmacies more than what the federal government will give to the states. CMS acknowledges that the states need to make up the difference between this new metric and what pharmacists have received in the past from state Medicaid programs. Where are the states supposed to find this new funding? This amounts to another unfunded mandate being handed to the states.

Last year the Louisiana Legislature passed a measure which would have increased dispensing fees to $10 for brand name prescriptions and to $15 for generic medicines, which would cover pharmacy's operating costs and encourage generic utilization. In July of this year, CMS rejected the Louisiana plan. This does not bode well for states hoping to preserve patient access by covering pharmacy's cost to dispense. CMS' approach of leaving the problem to the states to solve, when it apparently will not approve plans that will substantively address the problems in the new AMP, is one other reason CMS must adjust its definitions and the outlier requirement.

II. Conclusion

Not only must CMS significantly adjust its final AMP rule to correspond with federal statutory requirements regarding AMP and Medicaid pharmacy reimbursements (see NCPA's comments), but it must also conduct a meaningful RFA analysis of the impact of its final rule on retail pharmacies, particularly upon independent pharmacies and those that currently service a high volume of Medicaid beneficiaries. A review of NCPA's RFA analysis should prompt CMS to act appropriately to safeguard community retail pharmacies and their patients.

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January 2, 2008

Mr. Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–2238–FC
Mail Stop 314G
200 Independence Avenue, S.W.
Washington, D.C. 20001

Re: Comments on the DRA Final Rule [Provisions in the DRA Final Rule Regarding Average Manufacturer Price (AMP) and Federal Upper Limit (FUL) Outlier] – CMS 2238-FC

Dear Acting Administrator Weems:

On behalf of a client, we submit the following comments to the final rule with comment period that implements the provisions of the Deficit Reduction Act of 2005 ("DRA")[1] relating to prescription drugs under the Medicaid Program (the "Final Rule").[2] We appreciate the continued guidance of the Centers for Medicare and Medicaid Services ("CMS" or the "Agency") relating to the Medicaid program. The Medicaid program can only be administered effectively where CMS provides clear, consistent, and specific guidance. Accordingly, on behalf of our client, we appreciate this opportunity to provide comments, and CMS' willingness to consider them. We are very grateful for CMS' hard work in issuing the Final Rule, and we understand how challenging that task must have been.

In the Final Rule, CMS requested public comments relating to the definition and determination of Average Manufacturer Price ("AMP") under § 447.502 and § 447.504 to assist the Agency in its full consideration of this issue and related

[1] Deficit Reduction Act of 2005, Pub. L. No. 109-171 (2005).
[2] Dep't of Health and Human Servs., Ctrs. for Medicare and Medicaid Servs., Medicaid Program; Prescription Drugs; Final Rule ("Final Rule"), 72 Fed. Reg. 39,142 (Jul. 17, 2007).

policies. We respectfully request that the Agency revise the Final Rule's definition of AMP to not only include sales in the retail class of trade, but also to include the corresponding discounts, rebates and other price concessions associated with those sales. The Agency's initial definition of AMP and inclusion of certain sales to third party payors as discussed in the proposed rule relating to prescription drugs (the "Proposed Rule")[3] were consistent with previous legislation and guidance. Unfortunately, we believe that, with the Final Rule, CMS has set forth a Final Rule that is not consistent with the statutory framework or the historical guidance. Indeed, after careful review, we are concerned that the Final Rule is not consistent with the Medicaid Rebate Agreement,[4] the Omnibus Reconciliation Act of 1990 ("OBRA 90"),[5] or the DRA.

The Final Rule's definition of AMP represents essentially a fundamental change in policy regarding the purpose and nature of AMP and its well-established definition. This is particularly apparent with respect to the treatment of price concessions and sales included in AMP.

Historically, AMP has been recognized as an average that reflected the mean net price for a drug dispensed in the retail class of trade. Established by OBRA 90, AMP was statutorily defined as "the average price paid to the manufacturer"[6] for transactions relating to the retail class of trade. Shortly following OBRA 90, the Medicaid Rebate Agreement, both a binding regulation and a binding agreement between and among the United States, the States, and manufacturers, similarly defined AMP by referring to the key term "Net Price."[7] Because of the statutory and the MRA definitions of AMP, direct and indirect price concessions that otherwise are within the definition of AMP must be included in the calculation of AMP.

In the Proposed Rule, consistent with the previous legislation and guidance above, CMS defined AMP as:

> AMP shall be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation.[8]

This definition properly included discounts, rebates and other price concessions associated with the retail class of trade, which CMS correctly recognized to include

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[3] Dep't of Health and Human Servs., Ctrs. for Medicare and Medicaid Servs., Medicaid Program; Prescription Drugs, Proposed Rule ("Proposed Rule"), 42 Fed. Reg. 77,174 (Dec. 22, 2006).
[4] Medicaid Rebate Agreement, *available at* http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf (Dec. 21, 2007).
[5] OBRA, Pub.L. 101-508 (Nov. 5, 1990).
[6] 42 U.S.C. § 1396r-8(k)(1) (2007).
[7] *Supra* n. 5.
[8] Proposed Rule, 71 Fed. Reg. at 77,196.

pharmacy benefit managers ("PBMs"), Medicare Part D and state pharmaceutical assistance programs. This is wholly consistent with the Medicaid Rebate Agreement, which, in stressing the "Net Price" nature of AMP, required that indirect price concessions be included in AMP.

In the Proposed Rule and in keeping with the MRA, CMS correctly acknowledged 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."[9] Citing the MRA, CMS explicitly stated that AMP must include "cash discounts and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid."[10] Significantly, the MRA, which was issued after notice and comment, has the force and effect of a regulation and is the contractually binding statement of policy under which manufacturers participate in the Medicaid rebate program. As a matter of basic interpretation, the plain language of the MRA must be given effect. Accordingly, the exclusion of Medicaid rebates from the plain language reference to "all ... price concessions" in the MRA must mean, quite simply, that "all other price concessions" must be taken as reductions to AMP.[11]

This conclusion is entirely consistent with the Agency's statement in the Proposed Rule that AMP should "provide a reflection of market transactions."[12] The references to "market transactions" and the "net price" nature of AMP are an explicit acknowledgment that AMP includes all price concessions, whether direct or indirect, and no matter who the recipient may be of the concession, so long as the drug relates to the retail class of trade. Manufacturers have relied upon this binding language in deciding to participate in the Medicaid rebate program.

In the Final Rule, however, CMS appears to abandon the correct and MRA and statutorily mandated position set out in the Proposed Rule. Instead, the Final Rule seeks to reinterpret the average "manufacturer price" into the average "acquisition cost" for a retailer, which is inconsistent even with the term AMP itself. Although the Final Rule includes in AMP some price concessions that are not paid to a traditional wholesaler or retail pharmacy, as it should, it excludes numerous price transactions that subsequently help to establish the "Net Price" of drugs, in direct contravention to the Proposed Rule, the statute and the MRA. In order for AMP to be an accurate reflection of the "Average Manufacturer Price" (the manufacturer's Net Price), AMP must include "all ... price

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[9] *Id.* at 77,179.

[10] *Id.* at 77,177.

[11] *DeMarco Durzo Dev. Co. v. United States*, 69 Fed. Cl. 262, 272 (Ct. Cl. 2005) ("[T]he United States Court of Appeals for the Federal Circuit consistently has held that . . . government contract interpretation begins with the plain language thereof.") (citing *Scott Timber Co. v. United States*, 333 F.3d 1358, 1366 (Fed. Cir. 2003)); *U.S. v. Westlands Water Dist.*, 134 F. Supp.2d 1111 (E.D. Cal., 2001). Furthermore, the doctrine of *expressio unius est exclusio alterius* provides that when a contract affirmatively designates certain things, omissions are the equivalent of exclusions. *See R. L. Coolsaet Constr. Co. v. Local 150, Int'l Union of Operating Eng'rs*, 177 F.3d 648, 659 (7th Cir. 1999) (citing *Plumbers & Steamfitters Local 150 v. Vertex Const. Co.*, 932 F.2d 1443, 1449 (11th Cir. 1991); *Asbestos Settlement Trust v. City of New York* (*In re Celotex Corp.*), 487 F.3d 1320, 1334 (11th Cir. 2007) (observing that the doctrine "would dictate the same result [a court would] reach by interpreting the contract's plain language").

[12] *Id.*

concessions," except as explicitly precluded by statute and the MRA. Any other definition would ultimately lead to a price that arbitrarily is determined and that does not reflect the "Net Price" explicitly required under the MRA. AMP must capture as many transactions and concessions as possible that occur in the marketplace and relate to drugs dispensed in the retail class of trade in order for the metric to reflect the net drug price.

CMS seems to attempt to justify the exclusion of PBM and other third party payor concessions by stating that the Final Rule itself excepts PBM and other third party concessions from inclusion in AMP. However, CMS' rationale for excluding certain third party payor price concessions misses the mark. Despite CMS' suggestion to the contrary, the MRA and its explicit requirement that AMP be a "Net Price" excepting only Medicaid rebates cannot be changed by a subsequent regulatory pronouncement, because the MRA is binding on all of the parties to it. The MRA only permits one section of the Medicaid statute to be changed automatically by subsequent regulatory changes. No other provision of the MRA is permitted to be varied by subsequent regulation. CMS could, of course, prospectively amend the MRA to reflect regulatory changes that CMS wishes to make binding on a participating manufacturer, notwithstanding the fact that those changes are not consistent with the MRA as it currently exists, but CMS has not taken that step. As noted above, a basic precept of construction is that an explicit reference to one circumstance or item necessarily excludes all other circumstances or items.

As the Agency is aware, under the Administrative Procedures Act,[13] a regulation may be found to be arbitrary and capricious if it is inconsistent with statute, the regulation is internally inconsistent, or the regulation attempts to affect a change in policy without supplying a "reasoned analysis" for the change in policy.[14] All of these issues are present here. The Final Rule is internally inconsistent because it simultaneously includes and excludes price concessions that should be included for AMP to be the net price that it is intended to be. The Final Rule is also inconsistent with the statute because it attempts to redefine the statutory "Average Manufacturer Price" term into something fundamentally different – a purchaser's average acquisition cost. Finally, the Final Rule departs from previous guidance regarding the definition of AMP without providing a reasoned analysis or revising the MRA.

In sum, consistent with the principles articulated in the Proposed Rule, the MRA, and the statute, we urge CMS to modify the Final Rule by including all rebates, discounts, and other price concessions provided to PBMs and third party payors, where those concessions relate to drugs dispensed in the retail class of trade. The Final Rule defines AMP to include all the sales to the retail class of trade but excludes the vast majority of associated discounts, rebates and other price concessions provided by the manufacturer. If CMS believes that the sales to which PBM and third party payor concessions relate fit within the retail class of trade definition, as it clearly does, then the associated discounts, rebates and other price concessions must also be included in the calculation of AMP. CMS' decision to exclude certain third party payor price concessions cannot be defended.

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[13] *See* Administrative Procedures Act ("APA"), 5 U.S.C. § 550 *et seq.* (2007).

[14] APA at § 706(a)(2). *See also Motor Veh. Mfrs. Ass'n v. State Farm Ins.*, 463 U.S. 29, 41-42 (1983); *Huntington Hosp. v. Thompson*, 319 F.3d 74, 80 (2d Cir. 2003).

We appreciate the opportunity to provide these additional comments to CMS regarding the Final Rule. We look forward to further discussions with CMS on these and other important issues related to the Medicaid program. We appreciate CMS' commitment to the Medicaid program and its many efforts on behalf of that program. Please do not hesitate to contact me with any questions that you might have.

Sincerely,

William A. Sarraille