GPhA
Generic Pharmaceutical Association

June 5, 2015

By Electronic Mail

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
Andy.Slavitt@cms.hhs.gov

Re: Medicaid Program; Covered Outpatient Drugs; Proposed Rule [CMS—2345—P]

Dear Acting Administrator Slavitt:

On behalf of the Generic Pharmaceutical Association (GPhA), I am writing to follow up concerning the April 2, 2012 comments (the "Comments") that GPhA submitted in response to the *Medicaid Program; Covered Outpatient Drugs; Proposed Rule* (the "Proposed Rule").[1] Our understanding is that the Proposed Rule soon may be finalized. For the reasons stated in our Comments, GPhA has substantial concerns about the Proposed Rule and respectfully believes that certain provisions of the Proposed Rule, if adopted, would have unintended adverse consequences and would be contrary to law, including the Administrative Procedure Act (APA).[2] GPhA, however, values its constructive relationship with CMS and wishes to avoid litigation concerning the Proposed Rule if at all possible.

Below, we provide additional information about the concerns that GPhA raised in its Comments. Once you have had an opportunity to review this information, we would like to schedule a meeting with you to discuss GPhA's concerns. Our hope is that, by doing so, we can work cooperatively to address GPhA's concerns before the Proposed Rule is finalized.

1. "Build-Up" Approach to AMP Calculation

In its Comments, GPhA objected to CMS's proposed abandonment of the long-established "presumed inclusion" approach to Average Manufacturer Price (AMP) calculations in favor of a "build-up" approach. Perhaps most significantly, GPhA objected to the build-up

---

1 77 *Fed. Reg.* 5318 (Feb. 2, 2012).

2 5 U.S.C. § 500, *et seq.*

approach because it would require manufacturers to calculate AMP based on data that is not available to them.

Presumed inclusion has been the established method of AMP calculation for decades, and for good reason: it is the only workable methodology by which manufacturers can calculate average manufacturer price, which the controlling statute defines to include "the average price paid to the manufacturer . . . by wholesalers for drugs distributed to retail community pharmacies."[3] When drug manufacturers sell drugs to wholesalers, the manufacturers have only limited information about what the wholesalers then do with the drugs. Some of that limited information comes through chargeback data, and some comes from rebate data. Years ago, CMS constructed the presumed inclusion approach to account for these realities. In particular, it allowed manufacturers to presume that drugs sold to wholesalers ultimately went to retail community pharmacies unless chargeback or rebate data indicated otherwise.

Contrary to this pragmatic approach, the Proposed Rule would require manufacturers to determine that a particular product sold to a wholesaler in fact went to a retail community pharmacy before counting that sale in AMP. It would be costly for manufacturers to undertake the investigation necessary to make this type of determination. Moreover, because wholesalers often view their distribution information as proprietary, in many cases manufacturers could not obtain information about the ultimate destination of their products. The end result would be that, under a build-up methodology, manufacturers would have to perform AMP calculations using less-than-complete data. This would reduce the reliability of AMP data and render it more volatile.

2. Definitions of Innovator Multiple Source Drug and Single Source Drug

In its Comments, GPhA also objected to CMS's attempt to redefine the statutory terms "single source drug" and "innovator multiple source drug." Under the Medicaid Drug Rebate Statute, a drug qualifies as a single source drug or an innovator multiple source drug only if it was approved under an "original new drug application" (original NDA); otherwise, a drug is a "noninnovator multiple source drug."[4] Noninnovator multiple source drugs are subject to a formula that yields lower rebates than the formula governing single source drugs and innovators. The Proposed Rule would define the term "original NDA," which is undefined in the statute, to mean *any* NDA.[5] Consistent with this definition, the Proposed Rule also would alter the regulatory definitions of single source drug and innovator multiple source drugs, replacing the term "original NDA" in each definition with "NDA."[6]

In defining the term "original NDA" to include any NDA, the Proposed Rule would read the word "original" out of the Rebate Statute. This would violate a basic principle of statutory

---

3 42 U.S.C. § 1396r-8(k)(1)(A).

4 *Id.* § 1396r-8(k)(7)(A).

5 Proposed 42 C.F.R. § 447.502.

6 *Id.*

interpretation—namely, that statutes should be interpreted so as to give meaning to all of their terms.

The proposed definition also would contravene congressional intent. CMS recognized as much in 1995, when it proposed a rule that would have defined "original NDA" to mean "an FDA-approved drug or biological application that received one or more forms of patent protection, patent extension under [the Hatch-Waxman Act], or marketing exclusivity rights granted by the FDA."[7] As CMS explained, that interpretation was the only one that accorded with "the intent of Congress"—in particular, its decision to subject single source and innovator multiple source drugs to higher rebates.[8]

Moreover, reading the word "original" out of the statute would have harmful, and perhaps unintended, effects. It would result in treating many drugs as innovator multiple source drugs—and thus subjecting them to the higher rebate formula—even though they never received market exclusivity or patent protection and have been treated as noninnovator multiple source drugs for decades. This consequence of the Proposed Rule would be unfair, given that many of the drugs that the rule would treat as innovators are priced and reimbursed like generic drugs.

The proposed definition of "original NDA" also would create significant administrative difficulties for CMS and for manufacturers, who for the first time would have to treat as innovators drugs that for decades had been reported as noninnovator drugs. For example, because the rebate formula for innovator drugs takes price increases relative to inflation into account, manufacturers would have to determine their "base AMP" for any newly-reclassified innovators. This may be quite difficult—if not impossible—for manufacturers of older drugs, particularly for manufacturers who have not manufactured a drug throughout its lifespan.

Finally, treating older generic drugs as innovators almost certainly would increase drug costs. This is because "Best Price" is a component of the rebate formula for innovator drugs, but not for noninnovator drugs. A manufacturer that may have been quick to give discounts before may become reluctant to do so if the effect would be to increase its liability for Medicaid rebates. Moreover, some generic manufactures have never had occasion to develop methodologies or administrative procedures for calculating Best Prices.

3. Expansion of Rebate Program to U.S. Territories

GPhA also urges CMS to avoid expanding the definition of the term "States" for purposes of the Medicaid Drug Rebate Program (MDRP) to include the U.S. Territories (*i.e.*, Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and America Samoa).[9] For decades, the term "States" has been defined to mean the fifty States and Washington, D.C. Broadening the term to include the Territories could have materially adverse effects on the provision of cost-effective, generic drugs in the healthcare system.

---

7 60 Fed. Reg. 48442, 48483 (Sept. 19, 1995).

8 *Id.*

9 *See* Proposed 42 C.F.R. § 447.502.

In addition to increasing the volume of rebates for which manufacturers would be responsible, manufacturers would be required to include transactions in the Territories in their calculations—including AMP and Best Price—from which rebates are determined. But the Territories are subject to unique local laws, including single-payer systems and price controls not applicable to the fifty U.S. States, and they have different pricing structures and distribution arrangements. Expansion of the MDRP to the Territories thus has the potential to decrease Best Price for many drugs, substantially increasing manufacturers' total rebate liability. In so doing, the Proposed Rule would give manufacturers an incentive to rethink their provision of drugs to the Territories and the terms on which they provide such drugs.

Additionally, expanding the MDRP to the Territories could impose significant operational burdens on manufacturers, including requiring alterations to existing data collection systems and disrupting contracts and pricing structures currently in place. This, too, could result in higher prices and less supply of cost-affordable drugs. For years, the government and manufacturers have understood the term "States" to mean only the fifty States and Washington, D.C. There is no reason for a different—and likely harmful—change to that understanding now.

4. <u>Implementation of AMP-Based Federal Upper Limits</u>

GPhA also objected in its Comments to the Proposed Rule's changes in the formula for calculating Federal Upper Limits (FULs) on the amount the Federal Government reimburses the States for their Medicaid drug costs. FULs cap the amount that the Federal Government will reimburse the States for their expenditures on multiple source drugs (both innovator and noninnovator). Thus, if a state Medicaid program reimburses pharmacies for multiple source drugs at rates exceeding the FULs, the Federal Government will not reimburse the state for those excess amounts. Although FULs were historically calculated based on a drug's wholesale acquisition cost (WAC) or average wholesale price (AWP), the 2010 Patient Protection and Affordable Care Act (ACA) mandated that CMS begin using average manufacturer price (AMP) instead. In particular, it provides that, for any multiple source drug, CMS must calculate a FUL of no less than 175% of the weighted average of the most recent monthly AMP for pharmaceutically equivalent and therapeutically equivalent drugs.[10]

The Proposed Rule would impermissibly expand the class of drugs that are subject to FULs. Under the ACA, a multiple source drug is subject to a FUL only if there are at least two other pharmaceutically and therapeutically equivalent drugs available "on a nationwide basis." *Id.* § 1396r-8(e)(5). But rather than determine whether a particular drug is actually available in every state, the Proposed Rule would simply presume that if a drug "has at least one other FDA-approved, pharmaceutically and therapeutically equivalent drug," then "the drug is generally sold or marketed on a nationwide basis."[11] This not only would conflict with the statute, but also

---

10 *See* 42 U.S.C. § 1396r-8(e)(5).

11 *See* 77 Fed. Reg. at 5347.

would have the undesirable effect of limiting reimbursement for drugs based on prices of other drugs that are not even available in the relevant geographical area.

The Proposed Rule also would arbitrarily cap FULs at 175% of AMP. Although the Affordable Care Act permits CMS to calculate FULs of more than 175% of AMP, the Proposed Rule would not go above 175%. That level is insufficient to incentivize the use of generic drugs. Limiting FULs to 175% of AMP would so reduce pharmacists' Medicaid reimbursements that they would demand pricing concessions from manufacturers to avoid taking losses. Those concessions, in turn, would cause AMPs to decrease, driving FULs even lower. This vicious cycle would reduce often-thin margins on generic drugs, thus discouraging generic drug production and utilization.

Finally, the Proposed Rule does not contain an adequate smoothing process to eliminate month-to-month variability in FULs.[12] Monthly fluctuations in FULs will create significant administrative burdens for manufacturers and all other participants in the supply channel.

5. 5i Product Determination Rule

CMS should reject the Proposed Rule's determination of when so-called "5i drugs" are dispensed through a retail community pharmacy. The proposal would result in overly burdensome and unnecessary expenses for drug manufacturers, thereby making healthcare more expensive.

As originally enacted, the ACA defined AMP only by reference to sales to Retail Community Pharmacies (RCPs), or wholesalers that resell to RCPs. Post-enactment, CMS and Congress recognized that whole categories of drugs are not dispensed through RCPs and therefore would have no sales to support the AMP calculation. To address these non-RCP drugs, Congress amended the Medicaid statute to create an alternative AMP formula for 5i drugs, *i.e.*, "an inhalation, infusion, instilled, implanted, or injectable drug" that is "not generally dispensed through a retail community pharmacy."[13] This alternative "5i AMP" formula is much broader and includes sales and discounts to most commercial entities.

The Proposed Rule would find that a product is "not generally dispensed through a retail community pharmacy"—and is thus subject to the broader AMP formula—if 90 percent or more of a manufacturer's sales for the drug were to an entity other than a retail community pharmacy or wholesaler for distribution to retail community pharmacies.[14] The Proposed Rule further provides that a manufacturer must determine a 5i drug's status on a monthly and quarterly basis.[15]

---

12 *See id. at* 5349-50.

13 *See* 42 U.S.C. § 1396r-8(k)(1)(B)(i)(IV).

14 Proposed 42 C.F.R. § 447.507(b)(1).

15 *Id.* § 447.507(b)(2).

There are at least two fundamental problems with this proposal. First, the 90 percent threshold is far too high. It would result in the inadvertent exclusion of certain drugs from the alternative AMP formula. Second, because calculations would be required on a monthly and quarterly basis, a 90 percent threshold would cause fluctuation on a month-to-month and quarter-to-quarter basis for drugs that only meet the threshold in certain months or quarters. This volatility would make rebates less predictable and would result in burdensome operational costs for manufacturers. As we noted in our Comments, analyses performed by GPhA members found that a 75 percent threshold would significantly minimize fluctuation and promote stability. We therefore urge CMS to adopt a 75 percent threshold, rather than the 90 percent level that has been proposed.

* * *

For all of the reasons stated in its Comments and above, GPhA has serious concerns about the Proposed Rule. We ask that CMS consider and address each of these concerns before finalizing the Proposed Rule. As noted above, we also would welcome the opportunity to discuss these issues with you in the hope that we can avoid more formal proceedings. Please let us know if there is a time when you would be available to meet with us to discuss this matter. Thank you for your consideration.

Sincerely,

Ralph G. Neas
President and CEO
Generic Pharmaceutical Association

cc. William B. Schultz, Esq.
General Counsel
United States Department of Health and Human Services

GPhA
GENERIC PHARMACEUTICAL ASSOCIATION

April 2, 2012

VIA ELECTRONIC SUBMISSION (www.regulations.gov)

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS—2345—P
Mail Stop C4—26—05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments to the Medicaid Program; Covered Outpatient Drugs Proposed Rule [CMS—2345—P]

Dear Acting Administrator Tavenner:

The Generic Pharmaceutical Association (GPhA) is pleased to submit these comments on the *Medicaid Program; Covered Outpatient Drugs Proposed Rule* (the "Proposed Rule" or "Rule").[1] GPhA shares the commitment of the Centers for Medicare and Medicaid Services (CMS) to compliance with the Medicaid Drug Rebate Program. We appreciate the opportunity to provide comments on CMS's proposals related to implementation of the Affordable Care Act (ACA) and otherwise.

GPhA is an association representing the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Together, the members of GPhA manufacture the vast majority of all generic pharmaceuticals dispensed in the United States. GPhA members manufacture products that are used in nearly three billion prescriptions every year.

As an initial matter, and overarching comment, we want to emphasize that certain aspects of the Proposed Rule would inadvertently impact generic drugs by increasing costs that would, ultimately, increase the overall cost of health care. The generic industry works hard to keep pharmaceutical expenses as low as possible, reducing costs for the government and for individuals. Changes to the Medicaid Drug Rebate Program and average manufacturer price (AMP) methodology that increase the cost of compliance will inevitably lead to higher drug prices, both for beneficiaries and for the Medicaid program. We ask CMS to carefully consider the costs associated with the proposed policy changes as the agency finalizes the Rule since increased costs will

[1] 77 *Fed. Reg.* 5318 (Feb. 2, 2012).

negatively impact manufacturers, and, ultimately, the health care system as a whole. Our specific comments are provided below.

1. Presumed Inclusion (§ 447.504(b))

In a complete reversal of policy, CMS proposes that manufacturers report AMP based upon their *actual* sales to retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies, rather than adopting a "presumed inclusion" approach. Although not explicit, it appears that sales to wholesalers should only be included where there is evidence or documentation reflecting that the wholesaler subsequently sold the drug to a retail community pharmacy. This policy represents a major shift in how manufacturers determine whether a sale should be included in the AMP calculation that will be very difficult to operationalize and, ultimately, will impose significant additional costs on manufacturers.

a. Manufacturers Have Inadequate Access to Verifiable Information on Where Products are Ultimately Sold

GPhA strongly supports using a "presumed inclusion" policy due to lack of manufacturer (or otherwise verifiable) data on "actual sales." CMS's proposal of an "actual sales" policy represents a complete reversal of the current approach and is ill-advised in light of the distribution data actually received by manufacturers.

Generic pharmaceutical manufacturers often distribute their products directly to wholesalers who, in turn, distribute to a variety of entities, including hospitals, pharmacies, and clinics. While manufacturers are aware of the location of their drug product after the first sale, they frequently have incomplete knowledge of where their products end up after that first purchaser resells or redistributes it. In fact, some generic products are distributed exclusively through arrangements where little or no data is available to definitively document whether drugs sold to wholesalers were ultimately distributed to retail community pharmacies. It would be difficult, if not impossible, to obtain the distribution data from wholesalers as, often, that data is viewed as proprietary. Even if manufacturers could obtain the data, there may be no way to verify the accuracy of the information provided. In addition to sales to wholesalers, manufacturers may also have difficulty verifying whether sales to chain pharmacies should be included, given that most chain pharmacies have mail order divisions, and mail order sales are to be excluded. Generic manufacturers lack data on a meaningful percentage of their sales and, thus, for that reason (as well as those discussed below), CMS should adopt a presumed inclusion policy.

b. Under an "Actual Sales" Policy, AMP Would be Calculated Using a Small Number of Sales and May Fluctuate Based on Differences in Manufacturer Access to Data

We are particularly concerned that the "actual sales" approach could lead to the exclusion of a significant number of unverifiable sales which, ultimately, could skew the reporting. The AMP data reported will be much more complete and consistent if CMS continues to recognize the presumptive inclusion approach.

Further, the subset of sales that a manufacturer would be able to document as actually distributed to retail community pharmacies would vary based on each manufacturer's access to data. AMPs across products and manufacturers would vary due to contract terms, even where discount structures and pricing were similar. This would contribute to greater variability in AMP for reasons that would not exist under a "presumed inclusion" approach.

Under the actual sales approach, where a manufacturer does not have documentation regarding an actual sale, the sale would not be included in the AMP calculation. CMS acknowledges that, "*in contravention of the statute*, those sales would not be included in the AMP calculation since the manufacturer does not have adequate documentation."[2] While neither the proposed "actual sales" policy nor a "presumed inclusion" policy may perfectly capture the sales contemplated in the statutory definition, "presumed inclusion" is the preferred approach and will lead to the most accurate AMP. The proposed policy will lead to the inappropriate exclusion of a large number of sales that should be included pursuant to the statute and an unnecessarily high degree of variability in the data reported by manufacturers.

c. Certifying AMP Based on "Actual Sales" Would Require Manufacturers to Rely on Outside Data

AMP has always been based on a manufacturer's own data, but the proposed "actual sales" policy would require manufacturers to rely on outside data that the manufacturer did not create and cannot verify, e.g. 867 or IMS data. Ultimately, this policy would require manufacturers to certify the accuracy of information based on outside sources of data. Because it is the manufacturers that are required to certify the accuracy of data reported, CMS policy must recognize the limits on what data manufacturers can actually access and verify. A manufacturer should not be required to certify data it cannot verify.

d. Additional Comments

In addition to these significant operational concerns, we are also more broadly concerned about the potential far-reaching effects of CMS's proposal. A decline in AMPs (due to an "actual sales" policy) could trigger a shift to AMP from average sales price (ASP) for purposes of drug reimbursement under Medicare Part B. Under policy finalized in the FY 2012 Physician Fee Schedule, CMS plans to substitute 103 percent of AMP for 106 percent of ASP where an applicable percentage threshold (5 percent) has been satisfied for the two consecutive quarters immediately prior to the current pricing quarter, or for three of the previous four quarters immediately prior to the current pricing quarter.[3] ASP is more likely to exceed AMP by the relevant percentage if it is depressed due to the proposed shift to requiring inclusion only of "actual sales." A growing disparity between AMP and ASP would trigger more frequent substitution away from ASP+6 in the Part B context. There is an inherent misalignment associated with using AMP, which is based on retail sales, as the basis for drug reimbursement in the Part B setting (where most customer types are specifically excluded from AMP as non-retail). The Office of Inspector General (OIG) has

---

[2] *Id.* at 5330 (emphasis added).
[3] 78 Fed. Reg. 73026, 73291 - 73294 (Nov. 28, 2011).

carefully monitored drugs for which ASP exceeds AMP by more than 5 percent,[4] and, in general, CMS has sought to align AMP and ASP. CMS's current AMP proposals would have the opposite effect.

For these reasons, we urge CMS to adopt the presumed inclusion approach.

2. Definitions of Innovator Multiple Source Drug and Single Source Drug (§ 447.502)

GPhA strongly disagrees with CMS's proposal to treat any drug approved under a new drug application (NDA) submitted under Federal Food Drug and Cosmetic Act (FFDCA) section 505 as an "innovator drug" for rebate calculation purposes. Although CMS characterizes this proposal as a "clarification," it will have a significant impact on drugs approved under duplicate or paper NDAs prior to the 1984 enactment of the Hatch-Waxman Act which created the abbreviated new drug application (ANDA). Under this proposal, all drugs marketed under pre-1984 NDAs (between 1962 and 1984), including those that never benefited from patent protection or other forms of exclusivity, will be categorized as either "single source" or "innovator multiple source" and, consequently, be subject to rebate payments at the much higher branded rate. For all purposes, including Medicaid rebate liability, the affected drugs have previously been treated as generic. Changing the drug classification of these drugs will result in higher health care costs and, potentially, reduced access to generic medicines.

Significantly, generic manufacturers have relied on CMS guidance provided in 1995 indicating that the agency viewed the statutory term, "original NDA," to mean an "application that received one or more forms of patent protection, patent extension . . . , or marketing exclusivity rights granted by the FDA."[5] In 1995, CMS acknowledged that the rationale for using the term "original NDA" is that "innovators with market protection are required to pay larger rebates than noninnovators that produce generic drugs with no market protection."[6, 7] Deviating from this interpretation would mean subjecting products that never profited from the benefits of patent protection, exclusivity, or higher reimbursement, to the higher rebate costs that were intended for innovator products.

In the 1995 guidance, CMS went on to state that it would define a "noninnovator multiple source drug" as a multiple source drug that was marketed under an *abbreviated* NDA, including

---

[4] *E.g.* Memorandum Report: Comparison of Second-Quarter 2011 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2011, OEI-03-12-00020 (Jan. 3, 2011), *at:* http://oig.hhs.gov/oei/reports/oei-03-12-00020.pdf.

[5] *Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate Agreements With Manufacturers, Proposed rule*, 60 Fed. Reg. 48442, 48453, (Sept. 19, 1995) at: http://www.gpo.gov/fdsys/pkg/FR-1995-09-19/pdf/95-22860.pdf.

[6] *Id.*

[7] CMS has also stated that "[a]n innovator multiple source drug first must be a sole source drug," which is not the case for products approved using an NDA other than an "original" NDA. *Medicare Program; Hospital Outpatient Prospective Payment System; Payment Reform for Calendar Year 2004, Interim final rule with comment period,* 69 Fed. Reg. 820, 822 (Jan. 6, 2004), at: http://www.gpo.gov/fdsys/pkg/FR-2004-01-06/pdf/03-32322.pdf.

those products approved under a *paper NDA* pursuant to FDA's former "Paper NDA" policy (54 FR 28873), or an application under *section 505(b)(2)* of the FFDCA.[8]

Although the definition of "original NDA" proposed in 1995 was never finalized, it nonetheless appears to be the only and, arguably, the most specific guidance that CMS previously provided regarding this issue. Accordingly, manufacturers have relied on this previously proposed definition to determine the drug category for each of their covered outpatient drugs which has resulted in treatment of pre-1984 NDAs as generic for price reporting purposes.

Manufacturers' reliance on the 1995 guidance from CMS is further supported by the FDA which subsequently transferred to the Office of Generic Drugs those drugs that had been approved under NDAs prior to 1984. Additionally, in a 1989 proposed rule, the FDA specifically referred to NDAs approved prior to enactment of the Hatch-Waxman Act for "duplicate" drug products.[9]

Contrary to its earlier guidance, in the Proposed Rule, CMS states that it considers an "original NDA" to be "equivalent to an NDA filed by the manufacturer for approval under section 505 of the FFDCA for purposes of approval by the FDA for safety and effectiveness." CMS also proposes to "use the term 'NDA' when addressing such application types for brand name drugs and not use the term 'original NDA' when referring to such drugs."

CMS indicates that the terms "NDA" and "original NDA" are equivalent "*when addressing such application types for brand name drugs*" (emphasis added). The proposed regulatory text to be added to the definitions of "innovator multiple source drug" and "single source drug" provides that "*[f]or purposes of the MDR program*, an original NDA is equivalent to an NDA filed by the manufacturer for approval under section 505 of the FFDCA for purposes of approval by the FDA for safety and effectiveness" (emphasis added). Although not discussed or explained in the preamble, CMS is also proposing to replace the term, "original NDA" with "NDA" in the regulatory definition of "noninnovator multiple source drug." Thus, the proposal to consider any NDA to be an "original NDA" would apply throughout the Proposed Rule, including in the context of generic, non-innovator products.

This proposal disregards the statutory language which specifically refers to "original NDA" when describing those drugs subject to rebate calculation at the branded rate. Furthermore, the proposed text fails to recognize that duplicate and paper NDAs, although filed under 505(b), were not filed for "purposes of approval by the FDA for safety and effectiveness" because safety and effectiveness were established by the Drug Efficacy Study Implementation (DESI) notice (used for drugs marketed prior to 1962) or the approval of the NDA referenced by the paper NDA, in that clinical trial data are not included in either type of filing.

Because these products have been on the market for decades, competition among the multiple equivalent products results in relatively low pricing – the intended effect of the Hatch-Waxman Act. Consequently, price competition also results in very low margins for the generic manufacturers. The implications for treatment of a drug as a brand name product are extensive,

---

[8] 60 Fed. Reg. at 48452 (September 19, 1995) (emphasis added).
[9] 54 Fed. Reg. 28,872, 28,873 (July 10, 1989).

including requirements that a manufacturer calculate best price and absorb additional rebate liability. CMS would need to provide significant additional guidance regarding how manufacturers would manage this change in a drug's status. For example, it is unclear whether the change would apply retroactively and whether and how manufacturers would be required to rebase AMP for affected products. In most cases, there may be no reliable way to calculate base AMP and market date data for these products,[10] and the data available (if any) may be insufficient to calculate best price. Some generic manufacturers currently do not calculate best price for any product but would be required to develop a best price methodology based on this revised definition. This amounts to a significant administrative burden and increased costs. Although CMS did not include this provision in its impact analysis, GPhA members have indicated that the impact would be significant. Ultimately, the impact will be higher health care costs for consumers and for government health care programs. Where market conditions prohibit increasing the price, some companies could elect to exit the marketplace resulting in reduced access to generic drugs.

For these reasons, GPhA recommends that CMS not finalize the proposed change, which could inappropriately result in the treatment of many generic products as brand name drugs.

3. Expansion of Rebates to U.S. Territories (§ 447.502)

CMS proposes to revise the definition of "States" to include not only the 50 States and the District of Columbia, but also the following territories: Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. CMS believes it has authority to expand rebates to the territories based on section 1101(a)(1) of the Social Security Act, which defines "state" to include the territories that CMS is proposing to include in the rebate program. We are concerned about the operational impact of this significant proposed expansion.

For decades, the term "States" has been defined to mean the 50 States and DC for purposes of the rebate program. We are not aware of any change in the statute or any other directive from Congress suggesting that CMS should reinterpret this term at this time. CMS's proposal to expand the term to include U.S. territories is a material expansion that is without a specific statutory directive. Congress gave significant consideration to the rebate program during the health care reform debate but at no point signaled that CMS should expand the program to the territories. This would impose a significant operational and financial burden on manufacturers, including requiring alterations to existing systems and collection of data not currently captured. This expansion would also disrupt contracts and pricing structures currently in place. Increased operational costs for generic manufacturers likely will impact health care costs for consumers and public and private payers. For these reasons, we strongly oppose this proposed expansion.

If CMS decides to move forward with the proposed expansion, manufacturers will need time to update their systems and contractual arrangements before extending rebates to the territories. CMS should allow at least one year after the first day of the first full quarter after the publication of the final rule before implementing this provision. CMS proposes not to apply requirements under

---

[10] For example, for a drug (including a 5i drug) that has been purchased from another manufacturer, possibly decades ago, there may be no way to calculate base AMP, as getting information from the original manufacturer would be almost impossible.

§447.511 to the territories before such time, and it is critical that manufacturers have a parallel timeframe to prepare for the expansion of the rebate program.

4. Inhalation, Infusion, Instilled, Implanted and Injectable Drugs (§ 447.507)

Statutory changes require that manufacturers include in AMP certain sales for "5i drugs" that are "not generally dispensed through retail community pharmacies." To clarify the term, "not generally dispensed," CMS proposes a "90% principle." Meaning that, if 90 percent or more of the manufacturer's sales of a 5i drug are to an entity other than a wholesaler for distribution to retail community pharmacies or retail community pharmacies that purchase drugs directly from the manufacturer, then the drug would be classified as "not generally dispensed" through a retail community pharmacy.

GPhA believes that the proposed 90% threshold is too high and could result in the inadvertent exclusion of certain drugs. Further, the proposed threshold would cause fluctuation on a month to month basis for drugs that meet the 90 percent threshold in some months but fall short in others. GPhA agrees with CMS that providing a quantitative method to determine when a drug is "not generally dispensed" provides a more definitive meaning than a more qualitative, drug-specific approach, but we recommend that CMS use a lower threshold percentage. In response to the agency's request for comments on alternative quantitative approaches, several GPhA member companies performed analyses of the proposed threshold and alternative threshold percentages. These companies, which together represent a significant share of the 5i drug market, each independently found that a 75 percent threshold would significantly minimize fluctuation and promote stability. Modeling the effects of various options showed that a 75 percent threshold would optimize stability, as products tended to consistently be either above or below this threshold. The companies' analyses showed that the proposed 90 percent threshold caused more frequent variation in whether or not products met the threshold. We therefore recommend that CMS adopt a 75 percent threshold.

Regardless of the final threshold percentage, further clarification is needed to determine how to calculate whether the threshold has been met. For instance, GPhA seeks clarity on whether the calculation would be based on units or dollars.

As an additional issue, CMS states that, because manufacturers are responsible for reporting AMP on a monthly and quarterly basis, "determination of a 5i drug's status as 'not generally dispensed' through a retail community pharmacy will need to be evaluated on a monthly and quarterly basis." Shortly after making this statement, CMS solicits comments on whether this evaluation should be on a monthly or quarterly basis. Manufacturers will need additional clarity on this issue. Operational costs will be particularly high if CMS expects manufacturers to use separate baselines for AMP in months or quarters during which drugs qualify as 5i and in periods when they do not. Maintaining separate base AMPs and calculating a product's AMP by both the regular method and the 5i method would be a significant burden for manufacturers. This is particularly true for generics, as generic manufacturers operate with very low margins. As proposed, it is unclear whether the quarterly determination or the monthly determination would ultimately decide the status of a drug. For example, drug sales in months 1 and 2 of a quarter might meet the 90% threshold, but sales in month 3 could fall short. It is unclear whether the drug should therefore be

considered to be "not generally dispensed through retail community pharmacies." A lower threshold percentage would help to minimize such issues, but some degree of fluctuation is inherent in the proposal.

GPhA recommends that CMS adopt an approach that reduces the operational burdens of calculating and reporting AMP for 5i drugs to the maximum extent possible. To reduce the administrative burden and cost of compliance, CMS should allow the "not generally dispensed" determination to be made on an annual basis, such that manufacturers could use a consistent methodology to calculate AMP for these products during the course of the year.

Finally, we note that there may be other drugs (not 5i) that are sold primarily outside of retail community pharmacies that should be captured in the regulation. For 5i drugs, CMS recognizes that AMP should include sales beyond those generally included in the AMP calculation. The same rationale applies to non-5i drugs that are primarily dispensed other than at retail community pharmacies. The special rules that allow an AMP to be calculated for 5i drugs would be beneficial for these other products as well.

5. Administrative fees, including bona fide service fees, as well as the treatment of group purchasing organizations (GPOs) (§ 447.504(c)(14))

While CMS proposes to revise the definition of "bona fide services fees" which are to be excluded from the calculation of AMP, CMS does not propose a definition for "fair market value." CMS states that, due to the "rapidly changing market in which new types of arrangements arise," it believes that "manufacturers should appropriately determine fair market value and make reasonable assumptions consistent with adequate documentation that will support their payment for these services at fair market rates sufficient that an outside party can determine the basis for the fair market value determination." The distinction between fees and discounts is critical, and clarity is needed to ensure consistency in how AMP is calculated. GPhA believes that CMS has provided insufficient guidance on how "fair market value" should be determined. In an effort to ensure consistency, manufacturers need additional clarity on the meaning of "fair market value."

We are also concerned with the criterion used to establish a "bona fide" fee requiring that no part of the fee be passed on to an entity's clients or customers. In many instances, it is difficult for manufacturers to ascertain whether these fees are, in fact, passed on.

6. Entities conducting business as retail community pharmacies or wholesalers, including but not limited to specialty pharmacies, home infusion pharmacies and home healthcare providers (§ 447.504(b)(4))

CMS proposes that manufacturers include in the determination of AMP the sales of covered outpatient drugs that are dispensed through "entities conducting business as wholesalers or retail community pharmacies," including, but not limited to, specialty pharmacies, home infusion pharmacies, and home healthcare providers.

GPhA seeks clarity on the treatment of mail order sales within the context of entities conducting business as community retail pharmacies. For instance, many specialty pharmacies

operate exclusively by mail, but mail order sales are generally excluded from AMP by statute. We request that CMS clarify how mail order sales should be treated in this situation.

Many injectables or other drugs that could fall within the 5i category are distributed exclusively or primarily through specialty mail order pharmacies. Treating specialty pharmacies as retail community pharmacies would mean that AMP for such products would be calculated using the regular method, rather than the proposed 5i method. We seek additional clarity on how the 5i methodology would be applied in this context.

7. Identification of Charitable and Not-for-Profit Pharmacies (§ 447.504(c)(11)–§ 447.504(c)(12))

CMS proposes that sales to "charitable" and "not-for-profit" pharmacies are to be excluded from AMP. CMS further defines such pharmacies as organizations described in section 501(c)(3) of the Internal Revenue Code of 1986. Manufacturers may not be able to readily and consistently identify whether pharmacies where their products are sold meet this definition. GPhA therefore requests that CMS identify or provide a resource for manufacturers to identify which pharmacies qualify as charitable and/or not-for-profit, or provide additional guidance.

8. Calculation of Monthly AMP (§ 447.510(d)(2))

GPhA appreciates that CMS's proposals regarding the AMP smoothing process are consistent with guidance previously provided in Medicaid Drug Rebate Program Release No. 83. Under the Proposed Rule, in calculating monthly AMP, a manufacturer would estimate the impact of its lagged price concessions using a 12-month rolling percentage to estimate the value of those discounts. GPhA agrees with CMS that this process will result in more stable AMP calculations on a month to month basis. We believe that the process currently in place under Release 83 is effective and appropriate. We encourage CMS to finalize its proposal and maintain this policy.

9. FULs Smoothing Process

In the Proposed Rule, CMS notes that it considered whether to implement a "smoothing process" applicable to the FUL calculation due to observed variability in the FULs from one month to the next. However, CMS decided not to propose a specific methodology to smooth the FULs. Without a FULs smoothing process, the FULs will have a certain degree of volatility, as CMS has observed. GPhA recommends that CMS institute a smoothing process to avoid the swings seen in the draft FULs.

10. Upper Limits for Multiple Source Drugs (§ 447.514)

CMS proposes to establish the upper limit reimbursement at 175 percent of the weighted average of monthly AMPs in the aggregate. GPhA believes that the multiplier should be set at a level such that pharmacy reimbursement is adequate to incentivize generic utilization, particularly given the overall cost-savings to the system that are experienced with increased usage of generic products.

CMS also proposes that, in computing the FUL, it would use the monthly AMP and the monthly utilization data submitted by the manufacturer to allow for revisions to the FUL list on a monthly basis. CMS further states that it will use monthly AMPs to calculate the FUL. Changing the reimbursement levels on a monthly basis will create a significant administrative burden for all parties within the product supply channel and will create confusion in the marketplace as parties react monthly to the volatile and unpredictable product FULs. The frequency in which CMS proposes to update the FULs to the various State Medicaid agencies should be extended to a quarterly basis or greater length of time. Monthly changes in the FULs could ultimately harm the generic industry.

11. Failure to Report AMP (Penalties) (§ 447.510)

GPhA has serious concerns about the potential implications of CMS's proposal related to penalties for untimely AMP reporting. CMS proposes that a manufacturer that fails to submit and certify monthly and quarterly AMP data by the statutory deadline will be reported to the OIG and be subject to a $10,000 *per drug per day* civil monetary penalty. While we appreciate CMS's objective to ensure timely AMP reporting, the proposal goes beyond what is authorized by the statute and could have a significant and disproportional effect on generic manufacturers.

By imposing a $10,000 per day *per drug* penalty, CMS is taking an expansive interpretation of the statutory penalty. The statute provides that, "[i]n the case of a manufacturer that . . . fails to provide information. . . on a timely basis, the amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided . . ."[11] This statutory text suggests the maximum penalty for failing to provide timely information is $10,000 per day. The proposed regulatory text nonetheless would impose a penalty of "$10,000 per day per drug."[12] By imposing the penalty on a *per drug*, per day basis, CMS would far exceed the statutory authority by allowing for a fine which could be significantly in excess of the statutory limit. This is particularly significant for generic manufacturers, which typically manufacturer a large number of different drugs. We request that CMS revise its proposed regulation to more closely track the statute.

GPhA is also concerned that the proposed regulations state that manufacturers "will" be subject to penalties in cases of untimely submission. These penalties should not be automatic, and CMS should retain the ability to waive penalties when appropriate. CMS should value accuracy of AMP over timeliness and not penalize for lateness in cases where manufacturers are making adjustments or corrections to ensure accuracy.

Additionally, while GPhA shares CMS's interest in the timely filing of AMP, we request that CMS allow a grace period of at least six months following publication of a final rule to enable manufacturers to incorporate required changes into their systems before penalties are imposed.

In the Proposed Rule, CMS also discusses adding regulatory guidance on suspension and termination for manufacturers that do not report AMP data on a timely basis or are otherwise out of compliance with rebate requirements. GPhA encourages CMS to provide additional guidance on an

[11] Social Security Act § 1927(b)(3)(C)(i).
[12] Proposed 42 C.F.R. § 447.510(a)(5).

administrative appeals process. We believe that an opportunity for appeal and reconsideration is essential before sanctions such as suspension or termination would apply.

12. Reporting Revised Monthly and Quarterly AMP, Best Price, Customary Prompt Pay Discounts, or Nominal Prices (§ 447.510(b))

CMS proposes to consider any request from a manufacturer to revise the monthly and quarterly AMP, best price, customary prompt pay discounts, or nominal prices that is outside of the 12-quarter filing deadline if it falls within one of several specified categories, including if the change is to address specific *underpayments* to States or potential liability regarding those underpayments. GPhA seeks parity on when CMS will consider a request to revise filings. Specifically, given that CMS will allow a revision in the event of an underpayment, we request that revisions be considered in the case of an overpayment.

GPhA supports CMS's contemplated policy of allowing manufacturers to make certain revisions to their pricing data on a retroactive basis without any time limits back to beginning of the program. Any time limit could pose a problem if a manufacturer discovers an error in reporting that occurred several years in the past. By not setting a time limit, CMS can avoid arbitrarily curtailing manufacturers' ability to address errors.

13. Effective Date

CMS should allow manufacturers adequate time to update their systems and operationalize the clarifications and policies articulated in the Proposed Rule. GPhA recommends that the effective date of any finalized changes should be at least six months after the publication date of any final rule. Sufficient time is needed for manufacturers to implement changes. Further, we believe that these policies should be applied on a prospective basis only.

* * *

Thank you for the opportunity to submit these comments. GPhA looks forward to working with CMS while these provisions in the Proposed Rule are being finalized. Please do not hesitate to contact us if you have any questions or concerns.

Sincerely,

Ralph G. Neas
President and CEO
Generic Pharmaceutical Association