



Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTENTION: CMS-2238-P
PO Box 8015
Baltimore, MD 21244-8015

1/15/2007

Dear Ms. Leslie V Norwalk, ESQ:

I thank you for the opportunity to comment on the proposed rule changes that will implement the provisions of the Deficit Reduction Act of 2005 (DRA).

My first comments, after reading the 150 pages are that there seems to be some problems with the assumptions that influenced the final rulings. Also, many of these rules use a flawed GAO report, "*Medicaid Drug Rebate Program – Inadequate Oversight Raises Concerns about Rebates Paid to States*" (GAO-05-102), dated February 2005 as its basis for many parts of this ruling.

In press releases, after the implementation of Medicare Part D, you personally praised the efforts of Community Pharmacy (Chain Store & Independent) for the help they provided during these troubled times. Billions of dollars have already been saved by the Federal Government, and most importantly, the "senior" consumer has much better access to its pharmaceutical needs. Now you are asking Community Pharmacy to give up another \$8.4 Billion dollars over the next 5 years. This is not the "Thank You" we expected.

This ruling only pertains to multiple source drugs (generics), which is within itself a very complicated and time sensitive part of Pharmacy. Prices change on a daily basis, some increased & others decreased due to market place availability and the number of manufacturers supplying the product. Updating pricing monthly, with a 30 day window for the manufactures to supply pricing means that pricing will always be 60 days behind the market place pricing; while invoicing to Community Pharmacy changes daily.

While everyone agrees that Average Wholesale Price (AWP) is no longer an accurate basis for pricing, all I can say at this point about Average Manufacturer's Price (AMP) is that AMP could also be an acronym for "**Ain't My Price**". The one major flaw I see in your calculation for determining Federal Upper Limit (FUL) using AMP is that distribution costs added to this price by Wholesalers & Distributors is not calculated in your formula. While your people may feel that this is a minimal mark-up (like with Brand Name Products), in reality this figure ranges at a low of 15% to a high of about 35%. With Independents, 95% of their purchases of generics are through Wholesalers & Distributors. Chain store purchases of generics through Wholesalers & Distributors are lower, but their net price after warehousing and distribution of products purchased direct from the manufacturers are very similar to the Independents invoice pricing.

Wholesalers in the United States are very important in the day-to-day operation of a pharmacy and only because of them are drugs available to the consumer in a timely manner. Maybe the authors of these rulings should spend a day at a wholesaler's distribution center and see the technology involved in this process. Without the wholesalers, distribution of product to the end user would be in chaos.

Now let's get into your specific requests for comments:

Including mail-order pricing into the pricing formula to calculate FUL's –

The fact that manufacturers have instituted different prices for different categories is discriminatory and has been in Federal Court for the past 11 years. That being said, including mail-order pricing in the formula is wrong and in its stead there should be a Retail Average Manufacturers Price (RAMP) and a Mail-Order Average Manufacturers Price (MAMP), and reimbursement to these two entities should use the RAMP price or the MAMP price. Better yet, the Federal Government should mandate a "One Price Policy" by all manufacturers to all categories, thereby lowering the price to the consumer, leveling the playing field and ending discriminatory pricing. It seems to work in Europe and Canada – but PHRMA spends millions to prevent this from occurring in the United States

Including rebates to PBM's in the calculation of AMP –

You state in your rulings that you have no way of knowing what portion of these rebates are passed onto Community Pharmacy or the consumer. Allow me to simplify this matter for you – ***NONE OF THESE DOLLARS ARE PASSED ONTO COMMUNITY PHARMACY OR THE CONSUMER*** – The present day PBM's (no longer just an administrator) is big business and their profits are astronomical and at the point where they are unconscionably increasing the costs of health care. There are multiple reports showing this that are available to you by our national organizations and the business pages of every newspaper report "settlements" made by PBM's to the States, HMO's, etc. quite often.

Effect of these new proposed rulings on the growth of dispensing of generics in the future, and to what extent PBM's act as wholesalers.

Over the past few years generic utilization has greatly increased saving the government billions of dollars. This utilization has increased from about 30% ten years ago to approximately 55% now. Decreasing reimbursement for generics will reverse this increase in utilization very quickly and more than make up the proposed \$8.4 Billion in savings. As for the PBM's acting as wholesalers, they own the Mail-Order houses, mandate the use of the mail-order by consumers using unfair business practices (co-pay differentials) and take advantage of their mail-order category to obtain discriminatory pricing which they do not pass on to consumer or the end payor. They do not actually act as a wholesaler, but use the "charge-back system" developed by the wholesalers and manufacturers to greatly increase their profits. They also spend millions of

dollars fighting “transparency” law suits throughout the country, rather than allowing any one the ability to see “the money trail”.

Allowing each State to set Professional Fees:

Many cost surveys have been published over the past few years showing that the actual costs by the Pharmacy Community to dispense a prescription are in the range of \$9.50. With each State having its own budgetary problems, these surveys have been ignored and there is no reason to think that the States will mandate a fair reimbursement. This would be an excellent opportunity for CMS to mandate a \$10.00 professional Fee for Brand products and a \$15.00 Professional Fee for generics. This would assure that generic utilization increases and access by the consumer of their prescription needs would not be seriously affected. Also at the same time, rather than instituting a complicated method of calculating AMP by manufacturers, why not use the present Wholesale Acquisition Cost (WAC) which is a much better picture of a stores acquisition cost and is already readily available and published by the pricing guides. Of course, the above mandated Professional Fees must also be included in the formula.

Including in the AMP calculation, rebates paid to SCHIP, Medicare Part D Plans, and SPAP Plans.

You are excluding rebates to Medicaid, DoD, HIS, and DVA because prices to these entities are not available to the Retail Pharmacy Trade. What makes you think that rebates offered to SCHIP, Medicare Part D Plans, and SPAP Plans are available to the Retail Pharmacy Trade? All your assumptions in this portion of the proposed rules are definitely flawed and should be revisited.

Initiation of the Definition of Fair Market Value:

In this section, you mention Medicare Part B initiating a Fair Market Value for their limited number of drugs and whether this method should be instituted in these rulings.

First, in many cases Part B drugs can not be bought by the Pharmacy Community at the prices set. Initiating this method would transform Chain Pharmacy Stores into variety stores and Independent Pharmacy would cease to exist. Access to Prescription drugs would cease to exist and hospital emergency rooms would become understaffed clinics.

Secondly, let me just say NO.

Pricing for new generic Products entering the Market-Place:

Over the past few years when a brand name product nears the end of their patent, the manufacturer works out a deal with just one generic manufacturer to have exclusive rights for a period of about 6 months. In many cases, the Brand manufacturer has an equity ownership in the generic manufacturer or the Brand Name manufacturer shares in the profits during this period through a licensing agreement. Invoice pricing is not generally decreased by more than 20 – 25% than the Branded product during this period. Therefore, an FUL price should not be

permitted until at least 2, or preferably 3 manufacturers make it available and affect market-place pricing.

Inclusion of Administration Fees or Service Fees paid to Wholesalers, PBM's or HMO's:

These fees are not available to the Retail Pharmacy Trade and should be excluded from the calculation. They are kept by the above entities and have no affect to invoice pricing to Retail Pharmacy. If you actually feel that these fees are more than nominal, then further legislation in the future should address this. It should not be even considered at this time.

Nominal Pricing:

This pricing is also not available to the Retail Pharmacy Trade and should be excluded from any calculations.

Use of pricing services in any way to determine FUL's:

We have seen over the past 3 years when most manufacturers stopped supplying AWP's to the pricing services because of multiple lawsuits that all pricing services are not the same. We have seen some able to update prices in a timely manner, while others take 60 – 90 days to update price changes. Using the "lowest price" from these pricing services would just mean that you would be using outdated information in many cases. This should be done internally in a timely manner and the "slow poke" should be excluded entirely.

Use of 9 digits NDC versus the 11 digits NDC:

Every stores inventory of a product is determined by actual usage of a product. In these times, proper control of inventory is very important to a stores bottom line. Therefore, since you agree that keeping the 11 digits NDC is no more work than keeping the 9 digits, I would suggest that the 11 digits be used to allow for the difference in the popularity of a drug in different areas of the country.

Outlier Price:

Because a manufacturer stops manufacturing a product does not mean that the pricing services remove the product. In fact, it remains for quite some time. There are many instances where many manufacturers decide to stop manufacturing a drug and the price from the remaining manufacturers increase sharply in price. Your guidelines do not consider this, and this has become a very common practice. Under your guidelines, it could take well over 90 days for you to catch up while stores would lose money filling these prescriptions.

What must be done is for your department to set up a process whereby pharmacies can fill out a form showing that a product is not available from their distributors at the price you are paying. This information can be verified quickly and pricing changed in a timely manner. We presently have a program in affect in Pennsylvania with most of the Third Party Plans, including Medicaid Programs and Part D Programs, and have had great success.

Savings Estimates developed by the Office of the Actuary in CMS:

In this section you mention the impact on just 3 types of small businesses, & they are (1) small pharmaceutical companies participating in the Medicaid Drug Rebate Program, (2) small retail pharmacies & (3) physicians and other practitioners (including small hospitals or other entities such as non-profit providers) that bill Medicaid for physician administered drugs.

It should be noted that while these proposed rules will affect all of Pharmacy, including the large Chains, no consideration is given to these small retail pharmacies that have increased their generic utilization to over 55% and whose business is much more dependent on prescription sales than the larger chains.

In the summary of this section, your people say this will only result in an overall 1% decrease.

From what I have seen and heard from others with much more information in hand, AMP pricing will decrease reimbursement by \$3.00 to \$4.00 per prescription which will decrease gross profits by approximately 15 – 20% for an industry that is seeing its profits decreasing yearly.

The loss of access by the consumer when more Independents close their doors CANNOT be picked up by the Chains or mail-order who do not offer the personal services provided by Independent Pharmacy (counseling, pick-up & delivery, house charges, third party administrative help, and the knowledge of their patient needs to name just a few).

Summary:

It seems that Pharmacy is the easiest group to attack and from which to take money back.

Federal Antitrust laws prevent us from working together so what can a “small” Independent do to fight back with any success? Medicare Part D has placed such a burden on Pharmacy that only a very few have the time to read over these 150 pages & express their concerns. I hope my comments and suggestions are considered.

Suggestions:

Include the Pharmacy Profession in your meetings and allow our National Groups to sit in and express their feelings at your meetings before a proposed ruling is sent out for just a 60 day comment period. Include managers of Chain Stores & owners of Independent Stores that “live” the day-to-day operations of a pharmacy.

Do your “Cost of filling an Rx” surveys and abide by their results. Include input from the Pharmacy Community & I am sure your results will not differ from those surveys already completed by CPA’s, Schools of Pharmacy & State Agencies.

With Gross Profits so low in this industry, a fair Federally Mandated Profession Fee must be included in your final rulings if you now expect to receive acquisition costs. Do the calculation on a drug where a 30 day supply may cost 50 cents, \$5, \$10 etc. One price does not fit in Pharmacy, never did & never will. At least a Minimum Professional Fee must be mandated that will allow stores some type of Return on Investment.

Include Wholesaler & Distributors Mark-Ups in your calculations.

Insist that your employees spend a full day in a Pharmacy before they write up the final rules.

Members of PHRMA are not affected by these rulings while their products still account for **85%** of your drug costs. Have them explain the much lower pricing they offer other countries. Have them explain why they spend more on TV advertising than they do on Research & Development.

A 5% decrease in pricing from PHRMA will save much more than \$8.4 Billion.

Finally:

It is time someone in the government gets the courage to go after the real money to be found in the huge profit margins of big PHRMA and the PBM's. Take any more from Community Pharmacy and there will be no next generation of patient and service oriented independent pharmacist/owners since they will no longer be able to make a decent living. That would indeed be a tragedy and very short sighted on CMS's part. Pharmacists are the most respected and easily accessible health care professionals. The patient medication counseling they now provide saves CMS million, if not billions of dollars annually in hospital and related expenses that do NOT occur due to the influence they have on patients taking medication correctly. These CMS proposals will put many independent pharmacy owners out of business and the positive influence they have on patient outcomes will disappear. Any savings CMS thinks it will gain will be far outweighed amid skyrocketing costs in other areas of healthcare.

This administration has targeted community pharmacy for 90% of the Medicaid cuts-although those expenses account for only 2% of the Medicaid budget- in the form of reduced payments for generics.

I thank you for this opportunity to express my concerns:



Mel Brodsky R.Ph.
CEO

2

Fino's Pharmacy

PRESCRIPTION DRUGGIST

32 N. Main Street — Phones: 655-1489 — 655-1480

Pittston, Pa. - 18640

January 16, 2007

Centers for Medicare + Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P

P.O. Box 8015

Baltimore, Md. 21244-8015

Dear Ms. Leslie V. Norwalk, Esq.

I am taking this opportunity to
comment on the proposed rule changes
that will implement the provisions
of the Deficit Reduction Act of
2005 (DRA).

The attached pages contain
my specific comments.

Allowing each State to set Professional Fees:

Many cost surveys have been published over the past few years showing that the actual costs by the Pharmacy Community to dispense a prescription are in the range of \$9.50. With each State having its own budgetary problems, these surveys have been ignored and there is no reason to think that the States will mandate a fair reimbursement. This would be an excellent opportunity for CMS to mandate a \$10.00 professional Fee for Brand products and a \$15.00 Professional Fee for generics. This would assure that generic utilization increases and access by the consumer of their prescription needs would not be seriously affected. Also at the same time, rather than instituting a complicated method of calculating AMP by manufacturers, why not use the present Wholesale Acquisition Cost (WAC) which is a much better picture of a stores acquisition cost and is already readily available and published by the pricing guides. Of course, the above mandated Professional Fees must also be included in the formula.

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*I thank you for this opportunity
to express my concerns.*

Yours Truly,

*Vincent J. Beck R. Ph.
Fino's Pharmacy*

CSL Behring
1020 First Avenue
PO Box 61501
King of Prussia, PA 19406-0901

Tel 610 878 4000
www.cslobehring.com

CSL Behring

January 12, 2007

The Honorable Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8015
Baltimore, MD 21244-8015

ATTN: (CMS-2238-P) Medicaid Program; Prescription Drugs

Dear Administrator Norwalk:

CSL Behring is a leading researcher and manufacturer of life-saving biotherapeutics including immune globulins, which are used in treating conditions such as immune deficiencies; blood clotting factors to treat bleeding disorders, including hemophilia and von Willebrand disease; and alpha₁-proteinase inhibitor, used to treat alpha₁-antitrypsin deficiency, which is commonly referred to as genetic emphysema. These therapies are created by pooling and manufacturing donated human blood plasma into lifesaving therapies or through the development of recombinant DNA technology.

Thank you for allowing ZLB Behring the opportunity to comment on the proposed rule implementing provisions of the Deficit Reduction Act of 2005. CSL Behring does not have comment with regard to the proposed calculation requirements for Average Manufacturers Price (AMP) and Best Price. However, we desire to comment on a policy that CMS did not mention within the proposed rule, but one that we feel must be referenced in the final rule in order to preserve access to care for a very small but specific Medicaid population.

CSL Behring asks CMS to incorporate a provision within the final rule referencing the need for state Medicaid programs to adopt a furnishing fee for blood clotting factors in the form of a separate payment added into the determined payment rates. This provision should be modeled on current Medicare law that has preserved patient access and allowed people with bleeding disorders the ability to obtain their blood clotting factor. CSL Behring believes such a reference to the Medicare provision in the final rule will provide proper guidance for state Medicaid programs utilizing AMP figures to determine Medicaid reimbursement rates. Such a provision will also allow Medicaid programs to recognize the unique attributes associated with the administration and utilization of blood clotting factors; as Medicare has.

CSL Behring

Medicare Precedent for Blood Clotting Factor Furnishing Fee

The Medicare provision can be found at Section 303 (e)(1) of the Medicare Modernization Act (PL 108-173) that created a furnishing fee for blood clotting factor reimbursement under the Medicare program. The statute provides the clear rationale of the additional furnishing fee and states as follows:

In the case of clotting factors furnished on or after January 1, 2005, the Secretary shall after reviewing the January 2003 report to Congress by the Comptroller General of the United States entitled 'Payment for Blood Clotting Factor Exceeds Providers Acquisition Cost', provide for a separate payment, to the entity which furnishes to the patient blood clotting factor, for items and services related to the furnishing of such factors in an amount that the Secretary determines to be appropriate. Such payment amount may take into account any or all of the following:

- (i) The mixing (if appropriate) and delivery of factors to an individual, including special inventory management and storage requirements.*
- (ii) Ancillary supplies and patient training necessary for the self-administration of such factors.*

For blood clotting factors furnished in 2006 and beyond, the statute requires that the separate payment under Medicare is to be equal to that of the previous year in addition to the percentage increase in the consumer price index for medical care for the 12-month period ending in June of the previous year.

Medicare published an initial blood clotting factor furnishing fee based solely on the Comptroller General report in the 2005 Physician Fee Schedule proposed rule, but increased the figure for the final rule, based on dialogue with medical providers of blood clotting factor and data tabulated by the Lewin Group. As a result, CMS determined the per unit additional payment for blood clotting factor under Medicare as follows:

2005: \$0.140 per unit
2006: \$0.146 per unit
2007: \$0.152 per unit

These separate payments apply for each class of blood clotting factors and have been incorporated into the Medicare reimbursement rate for each class.

CSL Behring

Same Principles Apply for Medicaid Reimbursement

The rationale for providing the additional furnishing fee for blood clotting factors under Medicare also applies for Medicaid. Providing blood clotting factors for treatment requires the same services, regardless of the individual's specific type of insurance. Without reference to the need for such a furnishing fee under Medicaid, the danger exists that states will incorporate the AMP methodology for reimbursement without a furnishing fee like that in Medicare. This would in turn create a substantial discrepancy between Medicare and Medicaid reimbursement in addition to creating access problems for Medicaid beneficiaries with bleeding disorders.

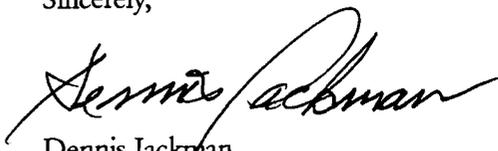
Without inclusion of a Medicaid furnishing fee for blood clotting factors, patients in need of this life-saving therapy will undoubtedly face access difficulties, as reimbursement will not reflect the true costs of providing this therapy. If reimbursement is inadequate, providers will have great difficulty being able to afford and supply blood clotting factor; thus, creating a situation where the individual may not be able to obtain the therapy to treat a bleed. The furnishing fee provision under Medicare has served to prevent such issues and has maintained both access to care and an appropriate medical standard of quality care. It is rational and consistent with established CMS and congressional policy to incorporate such a provision under Medicaid, especially if AMP is to be used in determining reimbursement payment rates.

There are approximately 6000 Medicaid beneficiaries nationally with hemophilia who rely on blood clotting factors. Unlike other therapies with mass utilization, hemophilia is a rare disorder, so incorporating a Medicaid furnishing fee should not impose substantial costs. The Congress and CMS have put in place a precedent under the Medicare program establishing a separate payment in the form of a furnishing fee that has been an unequivocal success in maintaining access to therapy. CSL Behring urges CMS to consider referencing a furnishing fee for blood clotting factors in the Medicaid proposed rule in order to provide state Medicaid programs with proper guidance in order to preserve access to high quality services for these beneficiaries.

CSL Behring

Thank you for your consideration and attention to this matter. If there are any questions or if I may be of assistance, please feel free to contact me directly at 610-878-4583 or Patrick Collins at 610-878-4311.

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis Jackman". The signature is written in a cursive style with a large, looping initial "D".

Dennis Jackman
Senior Vice President, Public Affairs



NORTH MISSISSIPPI MEDICAL CENTER

4

January 26, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

To Whom It May Concern:

On behalf of North Mississippi Medical Center (NMMC), I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. NMMC is a 650 bed hospital located in Tupelo, MS, that qualifies as a disproportionate share hospital ("DSH") under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program. Our principal concerns about the proposed regulations are threefold.

First, the proposed regulations would create enormous administrative and financial burdens for our hospital by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. If the NDC requirement was expanded to hospital Medicaid claims for drugs, NMMC's Outpatient Infusion Department would be burdened with new system developments which may interfere with patient access and care. NMMC's Outpatient Infusion treats 1,300 patients and has experienced continued growth over the last year. Business success and patient service could be disturbed by unnecessary change to work processes.

Second, CMS's proposed policies would significantly decrease the savings our hospital achieves through participation in the 340B program, to the extent that the new rules may result in States imposing manufacturer rebate obligations. This would require 340B hospitals to forego the benefit of 340B discounts on hospital outpatient clinic drugs that should be treated as exempt from rebate requirements.

Third, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price ("AMP"), as currently drafted, could drive up the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing. NMMC provides charity care and medications to over 4,000 patients annually during their stay in the hospital. The loss of nominal pricing contracts in our non-340B parts of the hospital would be devastating to the amount of service we could continue to provide.

We hope that you will give serious consideration to the problems addressed in this letter, and that the proposed regulations published on December 22 will be clarified and revised as a result.

Sincerely,

Harold Kornfuhrer, B.S.
Director of Pharmacy Services
North Mississippi Medical Center