NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

NCPA NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

July 20, 2010

Donald Berwick, M.D.
Administrator, Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Subject: Implementation of Medicaid AMP Pharmacy Reimbursement Provisions of P.L. 111-148

Dear Dr. Berwick:

Congratulations on your appointment as Administrator of the Centers for Medicare and Medicaid Services (CMS). We look forward to working with you during your tenure at the agency. Community retail pharmacies are a critical access point to health care services for Medicaid beneficiaries. In 2009, approximately 300 million prescriptions were dispensed to Medicaid beneficiaries by community retail pharmacies. Pharmacies will become an even more important source of health care related services for Medicaid beneficiaries as new health care reform provisions are implemented.

As you move forward with implementation of the Patient Protection and Affordable Care Act (PPACA), the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) are writing to provide our views on Section 2503 of PPACA, *Providing Adequate Pharmacy Reimbursement*. Due to its complexity, we urge you to utilize formal rulemaking with a reasonable public comment period, as opposed to a sub-regulatory guidance, to implement this important provision. We believe this rulemaking should be completed before CMS implements Section 2503, even if a delay in the October 1, 2010 effective date is required. The agency used this approach when implementing the pharmacy reimbursement provisions of the Deficit Reduction Act (DRA), and we believe this method of implementation is appropriate in this case as well.

It is in the spirit of strengthening the link between community pharmacy and the Medicaid program that we offer the attached recommendations on the implementation of Section 2503. In particular, our comments focus on:

- Average Manufacturer Price (AMP) Calculations
- Whether to Calculate a Federal Upper Limit (FUL)
- Amount of FUL
- Whether a FUL Applies to Particular Drug Products
- Public Availability and Posting of AMPs and Retail Survey Prices (RSPs)

In providing clear guidance to drug manufacturers on the calculation of AMPs, we believe it is of the utmost importance to reverse the "adequate documentation" provision of the AMP rule. *See* 72 Fed. Reg. 39142 (July 17, 2007). This provision states that manufacturers should include all sales in the calculation of AMPs unless they have adequate documentation proving the sales should be excluded. This provision of the AMP rule does not comply with current law. PPACA clearly sets forth sales that should not be included in AMP calculations. Including this adequate documentation provision in rulemaking or other regulatory guidance would be in conflict with the intent of Congress in passing PPACA and inconsistent with current law. Instead, CMS should provide guidance in rulemaking that sales should be excluded from AMP calculations unless manufacturers have adequate documentation to show that the sales fit the statute's definition of AMP.

We appreciate the opportunity to share our views, and are committed to working with you to implement these important provisions in a manner that complies with current law and maintains access to prescription drugs and services for Medicaid beneficiaries.

Sincerely,

Douglas Hoey, R.Ph., MBA
Acting Executive Vice President and CEO
National Community Pharmacists Association

Steven C. Anderson, IOM, CAE
President and CEO
National Association of Chain Drug Stores

cc: The Honorable Max S. Baucus
The Honorable Charles E. Grassley
The Honorable Henry A. Waxman
The Honorable Joseph L. Barton

Cindy Mann, Director, CMCSC, CMS
Larry Reed, CMS Medicaid Pharmacy Team
Carol Steckel, Commissioner, Alabama Medicaid / Chair, NASMD
Ann Kohler, Director of Health Services, NASMD

NECESSARY REVISIONS TO CURRENT AMP RULE

CMS issued its current Average Manufacturer Price (AMP) rule in 2007. *See* 72 Fed. Reg. 39142 (July 17, 2007). A federal court identified several legal problems with the AMP rule, and as a result the court halted implementation of the rule for purposes of Medicaid reimbursement to pharmacies. In addition, the Patient Protection and Affordable Care Act (PPACA) and the Health Care and Education Reconciliation Act will require other revisions to the AMP rule, such as amending the definition of AMP and revising the method of calculating Federal Upper Limits (FULs) on reimbursement for multiple source (generic) drugs. The following is a summary of some of the revisions that CMS should make to the current AMP rule to help ensure that the rule complies with the law.

1. **AMP Calculations.**
    a. Include only (i) prices paid by wholesalers to the original manufacturer (not repackers, etc.) only for drug products the wholesalers distributes to "retail community pharmacies" (RCPs), and (b) prices paid by RCPs for direct sales by the original manufacturer.
    b. Revise the AMP rule's definition of "retail pharmacy" consistent with PPACA's definition of RCP. Note that the statute's list of entities that are not RCPs is not exhaustive, and that any sales to entities that do not sell to the general public (e.g., sales to specialty pharmacies or pharmacies that serve particular plans or populations) should also be excluded from AMP calculations.
    c. Revise the AMP rule's definition of "wholesaler" consistent with PPACA's definition of "wholesaler."
        i. Note that the reference to "wholesale distribution" is intentional and important, because it tracks the language in the Food Drug and Cosmetics Act and implementing FDA rules. The FDCA and the FDA rules have a licensure requirement for wholesalers engaged in wholesale distribution. See 21 U.S.C. § 353(e)(2)(A); 21 C.F.R. § 205.1 et seq. Therefore, the revised AMP rule should provide that an entity is a "wholesaler" only if it is required to be licensed as a wholesaler. This same licensure requirement has also always been included in the definition of "wholesaler" in the 340B and ADAP programs with regard to AMP.
        ii. The AMP rule should also state that prices paid by repackers and other entities listed in the PPACA definition of "wholesaler" may be included in AMP calculations only to the extent those entities distribute the drug products directly to RCPs.
    d. Importantly, reverse the "adequate documentation" provision of the AMP rule, which provides that manufacturers should include all sales unless they have adequate documentation proving that the sales should be excluded because they do not satisfy the definition of AMP. Instead, the law requires that sales must be specifically excluded from AMP calculations unless manufacturers have adequate documentation to show that the sales satisfy the requirements of the law as described above. For example, in the case of a facility that fulfills the requests of both mail and retail patients, only the manufacturer's sales to the retail pharmacy should be included.

e. Establish a tight schedule for updating and reporting AMPs in the first seven days of each month, with little or no lag time and enforcement against delays.
f. Exclude the specific transactions listed in PPACA, such as:
    i. Bona fide service fees, those included in PPACA, as well as other fees, such as those pertaining to data agreements.
    ii. Reimbursement for returned goods.
    iii. Transactions with PBMs, MCOs, HMOs, insurers, long term care providers, etc.
    iv. Manufacturer discounts provided in the Medicare Coverage Gap Discount program (section 1860D-14A of the Social Security Act).
g. In particular, CMS should revise section 477.504(g) of the current AMP rule to eliminate the following transactions from AMP calculations:
    i. Sales to patients.
    ii. Sales to physicians.
    iii. Sales to hospital pharmacies, clinics and affiliated entities.
    iv. Sales to other manufacturers not acting and licensed as wholesalers.
    v. Sales to surgical centers.
    vi. Sales to ambulatory care centers.
    vii. Sales to clinics.
    viii. Sales to dialysis centers.
    ix. Sales to mental health centers.
    x. Sales to other medical outpatient facilities.
    xi. Sales to home infusion providers.
    xii. Sales to specialty pharmacies.
    xiii. Sales to home health providers.
    xiv. Sales to mail order pharmacies.
    xv. Sales and rebates to pharmacy benefit managers (PBMs).
    xvi. Fees paid to group purchasing organizations (GPOs).
    xvii. Nominal price sales to "any entity".
    xviii. Rebates and discounts "associated with" these sales.
    xix. Sales reimbursed by certain third parties.
    xx. Sales to patient assistance programs.

2. Whether to Calculate a FUL.

a. CMS should only calculate a FUL for a multiple source drug if three or more (as opposed to two or more, which was the requirement under DRA) therapeutically and pharmaceutically equivalent multiple source drug products (A-rated drug products) are listed in the most current edition of FDA's Orange Book.
b. CMS can only calculate a FUL if these minimum three products are available for purchase by RCPs on a nationwide basis. If only two equivalent products are available on a nationwide basis, then a FUL cannot be calculated. We believe that drug products should be considered to be available on a nationwide basis if they are readily available for purchase by RCPs across the nation in sufficient quantities to supply the needs of the nation's RCPs.

Products that are in short supply, or those that are marketed or sold by regional or niche manufacturers or suppliers, should not be considered nationally available.

c. CMS should create a process for CMS (not states or pharmacies) to determine on a regular schedule whether products are available on a nationwide basis. For example, one test might be whether the products are stocked by two of the three national wholesalers.

3. Amount of FUL.

a. The FUL for each multiple source drug should be calculated as no less than 175% of weighted AMP based on national sales utilization for all the nationally-available equivalent multiple source drug products. Three such products must be nationally-available for CMS to calculate a FUL.

b. CMS should establish a process that would permit a more frequent change in the FUL – or suspension of the FUL – when product availability changes. For example, products may no longer be nationally available, or a product could be in short supply. In these cases, such changes should occur more frequently than monthly with little or no lag time.

c. We also recommend a smoothing process similar to that adopted for the calculation of ASP for lagged discounts. This will help prevent a sudden reduction in a manufacturer's AMP in a month for a particular multiple source drug if a large amount of discounts are paid in a particular month, but have been earned over a period of time. Before reporting the AMP amount, the manufacturer should determine a percentage based on the most recent 12-month rolling average of legitimate lagged discounts for a particular multiple source drug. The percentage amount should be applied to the AMP calculated for that quarter.

d. CMS should create a method for determining when to exceed 175% of the weighted average AMP and discuss its criteria for doing so as part of the regulation we are requesting. For example, even if AMP was smoothed using a 12-month rolling average of lagged discounts, we would expect reported AMPs to move sharply from month to month, particularly for generic drugs. This fact makes AMP, as reported, a poor benchmark for establishing reimbursement for ingredient costs. It may be possible to further smooth variation by taking a rolling average of the reported AMP value. To implement any solution, however, CMS will need to use its statutory authority to pay more than 175% of AMP to prevent drastic reduction in reimbursement in months when AMPs plummet. CMS should establish a contact person to whom information could be directed in this regard by interested parties once the provisions of the statute have been implemented

4. Whether a FUL Applies To Particular Drug Products.

a. FULs can apply only to pharmaceutically and therapeutically equivalent (A-rated) multiple source drug products. Currently CMS applies FULs to non-equivalent B-rated products. CMS should not apply FULs to non-equivalent B-rated products whose AMPs were not used to calculate the FUL.

b. FULs can apply only to multiple source drugs that are "covered outpatient drugs" so CMS should not establish FULs for drugs listed in 42 U.S.C. § 1396r-8(k)(3).

5. **Publication of AMP and RSP Data**
   - **a.** The statute does not permit either CMS or the State Medicaid programs to publish any AMP data for individual drugs. Rather, the statute only permits CMS to publish weighted average AMP data for multiple source drugs that are subject to FULs. There are no provisions for the publication of AMP data for single source drugs. Moreover states are not themselves permitted to disclose any individual AMP data. When providing individual AMP data to states, CMS should include the weighted AMP information for comparison purposes, and should make clear to states that individual AMP data may not be disclosed.
   - **b.** We strongly urge CMS to review several months of weighted average AMP data before making them public. We believe that this will give CMS the ability to review the consistency and validity of the data before they are made public. We also urge CMS to assure that any public website include prominently-displayed and clear language regarding the meaning of the weighted average AMP data. For example, the language should make clear that these data do not reflect prices paid by retail pharmacies. As weighted average AMPs, they are an average aggregate of market prices paid by wholesalers to manufacturers, not the individual higher prices paid by community retail pharmacies. There are other costs involved in pharmacies' purchasing the drugs that are not included in the AMP data, and different pharmacies have different prices for purchasing and delivering the same generics. The website should also caution that the posted prices do not include the pharmacies' costs to dispense the medications, which studies show are in the range of $11 per prescription.
   - **c.** With respect to Retail Survey Price (RSP) data, it is important for CMS to only publish weighted average RSPs for multiple source drugs subject to a FUL, and only include reimbursements paid to community retail pharmacies. In our view RSP should reflect the total amount received by the pharmacy for the prescription including dispensing fees and copays if the prescription is paid for by a third party. The RSP should not include long term care or mail order reimbursements, or the other prices paid by non retail pharmacies, but should include cash paid and third party prescriptions. CMS should also post a prominently-displayed explanation of the meaning of RSP data. This should explain that these are total reimbursements paid to pharmacies for dispensing the prescription, and any difference between the AMP for the drug and the total reimbursement received is not the pharmacy's profit. While the difference may include a small profit component, the difference primarily accounts for the pharmacy's fixed costs of dispensing the prescription.
   - **d.** If the existing AMP definition is modified by statute to allow for the calculation of AMPs for infusion, injection, and inhalation drugs not sold by community retail pharmacies, the only instances in which prices paid by other than community retail pharmacies' can be used to calculate such AMPs is if the manufacturer does not sell any of the products to retail pharmacies. If any of the sales of the manufacturers are to retail pharmacies, the manufacturer cannot include the non retail sales in the AMP calculation. Any AMPs calculated for infusion, injection, and inhalation drugs not sold by community retail pharmacies should not be used to calculate FULs.

The views presented here are not exhaustive of all the issues that will need to be addressed to implement the new law consistent with the intent of Congress. Because of the complexity of these issues, and to give state Medicaid programs, manufacturers, pharmacies and the marketplace sufficient time to adjust to the new law, we urge that a proposed rule with comment period be published so that the reimbursement approach is fair to all parties involved.