



## Safety Net Hospitals for Pharmaceutical Access

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August 31, 2009

Ms. Alberta J. Dwivedi  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1414-P  
Mail Stop C4-26-05  
7500 Security Blvd.  
Baltimore, MD 21244-1850

**Re: Proposed Regulations CMS-1414-P – Proposed Changes to the  
Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates:  
Reimbursement Rates for Outpatient Drugs and Related Pharmacy Services**

Dear Ms. Dwivedi:

Safety Net Hospitals for Pharmaceutical Access (SNHPA) represents close to 500 disproportionate share hospitals (DSH) throughout the country that qualify for federal drug discounts under the 340B program due to the large volume of services they provide to Medicare, Medicaid and indigent patients. We are writing to voice support for the Centers for Medicare and Medicaid Services' (CMS') decision, under the proposed Medicare Hospital Outpatient Prospective Payment System (HOPPS) regulations for 2010 cited above, to reimburse 340B hospitals for outpatient drugs at the same rates as those paid other hospitals. We believe this decision is justified in view of the unique mission of 340B hospitals to stretch Federal resources – such as 340B program drug discounts – to improve access to health care for the poor and uninsured.

We are also supportive of suggestions offered by the Pharmacy Stakeholder Group, of which SNHPA is a part, in comments filed with CMS and presented to the Ambulatory Payment Classification Advisory Panel earlier this month regarding the methodology for determining the average sales price (ASP) markup for packaged and separately payable outpatient drugs under the Medicare HOPPS system. In those comments the Pharmacy Stakeholder Group urged that CMS:

- (1) increase the reallocation of pharmacy overhead costs from packaged drugs to separately payable drugs beyond the \$150 million specified by CMS in the proposed regulations;
- (2) use a first-quarter ASP file that is better aligned with claims and cost report data to determine the ASP markup for drugs for 2010;
- (3) reimburse the acquisition cost of all separately payable drugs at not less than ASP plus 6%, in accordance with the Part B law, and at ASP plus 6% for packaged drugs, at least until the statutorily mandated survey of drug costs can be performed by CMS;
- (4) in the event that CMS does not reimburse the acquisition cost for separately payable drugs at not less than ASP plus 6% and for packaged drugs at ASP plus 6%, and reallocate a larger share of pharmacy service costs to separately payable drugs, exclude

the cost of outpatient drugs dispensed or administered by qualified 340B covered entity hospital departments or sites from the hospital-reported data used in setting the ASP markup for Medicare outpatient drug reimbursement, while continuing to pay all hospitals at the same rates; and

- (5) freeze the threshold for differentiating reimbursement for packaged drugs from separately payable drugs at \$60, rather than increase it to \$65 as proposed.

### **340B Program Was Intended to Help Safety Net Providers Stretch Scarce Resources**

As previously mentioned, SNHPA represents the majority of the more than 800 disproportionate share hospitals that participate in the 340B program by virtue of providing large volumes of indigent care. These hospitals either are owned or operated by state or local governments or have a statutory or contractual obligation to provide care to low-income populations on behalf of state or local governments. They include large inner-city public hospitals, academic medical centers, rural hospitals, high-Medicaid urban hospitals, and other safety net institutions.

While 340B hospitals only represent a small portion of the total number of hospitals in the country, they are responsible for a significant amount of the uncompensated hospital care provided. Uncompensated care costs constitute at least 20 percent of the annual expenses of safety net hospitals as opposed to only five percent of expenses for all other hospitals, according to the National Association of Public Hospitals and Health Systems (NAPH).

In addition, NAPH found in 2006 that its member hospitals' share of uncompensated care costs borne by hospitals nationwide was 20 percent. SNHPA, which represents the majority of the hospitals participating in the 340B program, represents not only the public hospitals included in the NAPH membership, but also several hundred other public and private nonprofit disproportionate share hospitals. Thus, SNHPA members' share of total uncompensated care costs borne by hospitals nationwide are significantly higher than 20 percent.

The Federal 340B drug discount program lowers pharmaceutical costs for safety net providers that rely largely on government funding to provide health care services. Congressional intent in enacting the 340B statute was to enable covered entities to use these drug discounts to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."<sup>1</sup> Any move by CMS to reduce drug reimbursement to 340B hospitals under the Medicare HOPPS program would offset the savings that such hospitals receive under 340B, thereby undermining the purposes of the 340B program.

### **Pharmacy Stakeholder Group Proposals and Moran Analysis**

We support and appreciate CMS's attempts to reallocate \$150 million in overhead charges from packaged drugs to separately payable drugs in an attempt to offset costs inappropriately assigned to packaged drugs. However, we do not believe the magnitude of that reallocation was sufficient, given the quality and quantity of the data utilized.

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<sup>1</sup> H.R. Rep. 102-384, 102d Cong., pt. 2, at 12 (2d Sess. 1992).

We believe the Moran Company's analysis of the data utilized by CMS in determining the proposed ASP markup for hospital outpatient drugs affords a number of reasons for supporting the Pharmacy Stakeholder Group's proposals. That analysis suggests:

- Different allocations of pharmacy overhead dollars using the current CMS methodology based on fourth quarter 2008 manufacturer ASP reports produce payments ranging from ASP minus 2% (no overhead allocation) to ASP plus 14% (allocation of the entire \$395 million in the CMS overhead pool).
- The use of first quarter manufacturer ASP data, rather than fourth quarter data, results in a different ASP markup.
- Excluding data from hospitals participating in the 340B program can have a material effect on the calculation of the ASP markup.
- ASP markups are sensitive to even relatively minor changes in calculations, assumptions, or overhead allocation methodologies.

**CMS Methodology Without Policy Variation** –When the Moran Company replicated CMS' proposed rule methodology without policy variations, its analysts found that there were 222 HCPCS separately paid drugs with ASPs, ranging from ASP minus 7% to ASP plus 1643%, and 278 HCPCS coded packaged drugs with ASPs, ranging from ASP minus 92% to ASP plus 6755%. While the CMS calculation is based on drugs with HCPCS codes and ASPs, Moran found that significant drug and biological spending in the HOPPS fell outside this definition; specifically, spending for drugs without HCPCS codes totaled \$576 million and spending for drugs and biologicals with HCPCS codes, but no ASPs, represented \$207 million in spending. When all drugs—separately paid, packaged, HCPCS code but no ASP, and no HCPCS code—were included in the calculation, Moran calculated mean costs equivalent to ASP + 31%.

**Lost HCPCS Codes** - As Nimitt Consulting noted in its testimony earlier this month, there is no particular requirement that hospital providers report HCPCS codes for packaged drugs and, in fact, HCPCS codes generally do not print to the bill sent to CMS because of how provider billing systems are set up. In these cases, CMS does not receive the HCPCS code level information for packaged drugs for the agency to use in establishing the HOPPS pharmacy handling/overhead cost pool. HCPCS codes also do not print on the bill sent to CMS when the fiscal intermediary or other payer edits them out or directs the provider to remove them, a frequent occurrence in some regions. In these cases as well, CMS does not receive the HCPCS code level information for packaged drugs to use in establishing the pharmacy handling/overhead cost pool.

**Using First Quarter Data** – Using ASP data from the first quarter of 2008 instead of the fourth quarter of 2008 also had a material impact on the ASP markup calculation. Without any additional allocation of overhead spending, using the first quarter ASP data, Moran calculated a payment rate for separately paid drugs of ASP plus 0%, as opposed to the CMS calculation of ASP minus 2%. Adding the \$150 million overhead calculation to this calculation resulted in a payment rate of ASP plus 5%, as opposed to CMS' ASP plus 4%. Allocation of \$197.5 million (one half of \$395 million) resulted in a payment rate of ASP plus 7%. Allocating the full \$395 million overhead pool resulted in a rate of ASP + 15%.

**Removing 340B Data** – Removing 340B hospital data from the claims used to calculate the payment rates for separately paid drugs had a significant impact under the Moran Company analysis. Using the CMS methodology with no overhead allocation but removing 340B data, Moran calculated a payment rate of ASP plus 3%. Adding the CMS \$150 million overhead pool to this calculation

resulted in a payment rate of ASP plus 12%. Combining removal of 340B data with the use of first quarter 2008 ASP figures produces payment rates ranging from ASP plus 4% to ASP plus 17%, depending on the choice of overhead reallocation.

We believe that each of these factors argues for a recalculation by CMS of the appropriate magnitude of its pharmacy overhead reallocation from packaged drugs to separately payable drugs.

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SNHPA has appreciated this opportunity to again provide CMS with information about the 340B program. We are pleased that CMS has considered the purposes of the 340B program in choosing not to misdirect the savings from 340B-priced drugs to subsidize the costs of Medicare Part B, setting a Part B reimbursement schedule for drugs dispensed or administered by 340B hospitals that differs from the reimbursement schedule for non-340B hospitals.

Further, we thank CMS for its efforts to reallocate overhead costs from packaged drugs to separate payable drugs under the proposed regulations. However, we join other participants in the Pharmacy Stakeholders Group in urging that CMS:

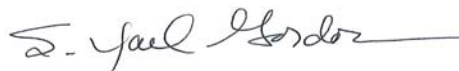
- (1) increase the reallocation of pharmacy overhead costs from packaged drugs to separately payable drugs beyond the \$150 million reallocated in the proposed regulations;
- (2) use a first quarter ASP file that is better aligned with claims and cost report data to determine the ASP markup for drugs in the final rule for 2010;
- (3) reimburse for the acquisition cost of all separately payable drugs at not less than ASP plus 6% in accordance with the Part B law, and at ASP plus 6% for packaged drugs, at least until a survey of drug costs can be performed by CMS;
- (4) if CMS does not reimburse the acquisition cost for separately payable drugs at not less than ASP plus 6% and for packaged drugs at ASP plus 6%, and reallocate a large share of pharmacy service costs to separately payable drugs, exclude the cost of outpatient drugs dispensed or administered by qualified 340B covered entity hospital departments or sites from the hospital-reported data used in setting the ASP-based Medicare outpatient drug reimbursement, while continuing to pay all hospitals at the same rates; and
- (5) freeze the threshold for differentiating reimbursement for packaged drugs from separately payable drugs at \$60, rather than increase it to \$65 as proposed.

Thank you for the opportunity to offer these recommendations.

Sincerely,



William von Oehsen  
President and General Counsel



Stuart Yael Gordon  
Director, Legal and Regulatory Affairs