



Safety Net Hospitals for Pharmaceutical Access

March 10, 2008

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-4133-P
P.O. Box 8010
7500 Security Boulevard
Baltimore, MD 21244-8010

Re: Comments on Separate Prescription Drug Premium Amounts for Low-Income Subsidy Individual Under 42 C.F.R. § 423.780; Reference CMS-4133-P

To: Centers for Medicare and Medicaid Services

This letter responds to the Centers for Medicare and Medicaid Services' ("CMS") solicitation of comments to its proposed revision of 42 C.F.R § 423.780, permitting a Prescription Drug Plan ("PDP") sponsor to establish a separate premium for low-income subsidy ("LIS") individuals. These comments are submitted on behalf of Safety Net Hospitals for Pharmaceutical Access ("SNHPA"), an association of over 400 hospitals that serve a high percentage of indigent patients and participate in the federal drug discount program administered under section 340B of the Public Health Service Act. SNHPA member hospitals are driven by a mission to serve patients regardless of their ability to pay. As a result, the pharmacies owned and/or operated by member hospitals fill high volumes of prescriptions for low-income populations, including low-income Medicare beneficiaries and dual eligibles.

We proffer these comments on behalf of SNHPA and its member hospitals in support of the proposed regulation, mindful of CMS's objectives to ensure continuity of care for LIS individuals and overall program stability. We extend our broad support to these objectives and wish to expand upon a couple of issues that reiterate the necessity of the proposed revisions. In particular, the reduction of beneficiary reassignments is vital to facilitate the administration and dispensation of medications, and also to secure the health and well-being of LIS-enrollees by ensuring uninterrupted access to medications.

Reducing the number of LIS beneficiary reassignments will alleviate the undue burden on SNHPA member pharmacies that administer and dispense medications. Our

hospital pharmacists are already encumbered by efforts to monitor and verify LIS-eligibility. Reassignments only exacerbate these efforts by requiring further assessments to determine whether medications should be distributed to a particular enrollee who, but for the reassignment, would otherwise receive medications. Moreover, the onus rests with the pharmacies to explain to enrollees why they may not receive, or have to change, medications under their reassigned PDPs. This is particularly troublesome for safety net hospitals that must contend with a host of socio-economic challenges among their patient populations, including language and cultural barriers, lack of transportation, mental illness, homelessness, etc.

Reduced reassignments will immensely benefit LIS-enrollees by minimizing disruptions in access to medications. The current process is burdensome and unnecessary, especially for enrollees who would otherwise receive medications but for the reassignment. Consequently, patients are confronted with the prospect of incurring out-of-pocket expenses to obtain their drugs, or risk interruption in treatment. For most LIS-enrollees, unanticipated co-payments are not a feasible option and belie Congressional intent to facilitate access to medications for low-income populations. The current system essentially penalizes LIS-enrollees by potentially precluding them from enjoying continued access to medications owing to an unpredictable bidding process. The proposed rule streamlines the process by increasing the number of zero-premium PDPs, thereby reducing the number of potential reassignments and promoting continuity of care.

Reducing reassignments may also ensure that waivers or reductions in Part D cost-sharing by pharmacies will count towards beneficiaries' True Out-of-Pocket expenses ("TrOOP"). Under CMS's current policy, voluntary waivers or reductions of prescriptions drug charges to Part D beneficiaries by many safety net pharmacies are often excluded from TrOOP. We have previously urged CMS to adopt a policy that allows waivers or reductions in Part D cost sharing by public entities to count towards TrOOP expenditures (as it does for commercial pharmacies), unless the costs are reimbursed through funding from a public program that explicitly covers pharmaceutical costs. When beneficiaries face unaffordable co-payments, they often take their prescriptions to a safety net pharmacy where they can get their prescriptions filled. Although safety net pharmacies may waive or reduce a patient's cost-sharing obligation to ensure that he or she receives prescribed medications, these subsidies are often excluded from the individual's TrOOP expenditures. Moreover, additional beneficiaries presenting to safety net providers only compounds existing problems of long waiting lines and lack of adequate reimbursements to sustain pharmacy operations.

Enabling LIS-enrollees to remain with their current plans will also avoid the common problem of having to drop or change medications because of formulary differences between the old and new PDPs. When beneficiaries are reassigned to a new PDP, they may potentially be required to discontinue their previous course of treatment and settle for a clinically equivalent substitute. Drugs within a class, however, are not

necessarily interchangeable and providers prescribe medications after considering evidence of clinical benefits and safety. Furthermore, while two drugs may be clinically equivalent, one may simply be more effective than the other. Additionally, the administrative burden to place enrollees on new medications will be taxing, requiring patients to seek another prescription from their providers, or pay out-of-pocket. As a result, frustrated beneficiaries will approach their local safety net providers.

Reassignment may create another kind of problem if the Part D beneficiary is enrolled in a state pharmaceutical assistance program (“SPAP”) that provides wraparound benefits to defray Part D out-of-pocket expenditures incurred by the beneficiary. Some SPAPs only provide coverage for select Part D plans and not others. Consequently, reassigning LIS-enrollees may end up depriving them of the wraparound benefits that they would otherwise enjoy under their old plans (that is, prior to reassignment). If enrollees are reassigned to PDPs that are not covered under a state’s SPAP, they will have to bear the cost of medications and pay out-of-pocket. Again, complications such as these tend to drive Part D enrollees to safety net pharmacies that are already overburdened in trying to meet the pharmacy needs of a growing uninsured population.

For the above reasons, we would like to express our strong support for CMS’s proposed changes to 42 C.F.R § 423.780, and reiterate our support of efforts to ensure continuity of care for LIS individuals and overall program stability. We appreciate consideration of these views by CMS and would be pleased to discuss these comments or provide any further information that would facilitate agency deliberations to finalize the proposed rule. Please feel free to contact Bill von Oehsen at 202-872-6765.

Sincerely,



William von Oehsen
President and General Counsel