



Safety Net Hospitals for Pharmaceutical Access

March 17, 2009

Ms. Sabrina Teferi and Mr. Barry Brook
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1561-IFC
Mail Stop C4-26-06
7500 Security Boulevard
Baltimore, MD 21224-1850

RE: CMS-1561-IFC (RIN 0938-AP59): Medicare Program; Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies by Certain Provisions of MIPPA

Dear Ms. Teferi and Mr. Brook:

Thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS's) above-referenced interim final rule implementing the new Round One of the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program. SNHPA asks that these regulations be amended to permit safety net hospital outpatient clinics and infusion and therapy programs to continue providing DMEPOS to former hospital inpatients by allowing those providers to accept as reimbursement – without submission of a bid or registration as a DMEPOS provider – the price set through the competitive bidding process for DMEPOS products. We believe this change would assure continuity of care while providing additional savings to the Medicare program.

Safety Net Hospitals for Pharmaceutical Access (SNHPA) is an organization of over 500 public and private non-profit hospitals and health systems throughout the U.S. that participate in the Public Health Service 340B drug discount program. SNHPA, which was originally named the Public Hospital Pharmacy Coalition, was formed in 1993 to increase the affordability and accessibility of pharmaceutical care for the nation's poor and underserved populations. When Congress was creating the 340B program in 1992, SNHPA took the lead role in ensuring that hospitals were included in the program and the organization has been representing the interests of 340B hospitals ever since. SNHPA monitors, educates, and serves as an advocate on federal legislative and regulatory issues related to drug pricing and other pharmacy matters affecting safety net providers. SNHPA is dedicated to educating its members and others about the 340B program and creating new opportunities for members to save on pharmaceuticals and improve access to pharmaceutical care.

As safety net providers, our member hospitals are in a unique position to assist Medicare beneficiaries with their durable medical equipment, prosthetic, orthotics, and supplies (DMEPOS) needs and to assess outcomes related to their use. In addition to furnishing

DMEPOS supplies, SNHPA member hospitals are key providers of support services at and around the time of hospital discharge, and on a continuing basis after discharge through hospital-based ambulatory clinics, home infusion and outpatient pharmacy programs, and through other outpatient therapy programs. Multi-disciplinary teams of physicians, pharmacists, nurses, and others provide needed support and continuing care for the most ill and most vulnerable patients in their service areas. Continued participation of safety net hospitals and their pharmacies in serving Medicare patients with DMEPOS support should be a priority for the Medicare program.

Continuity of Care Will Suffer if Hospitals Cannot Serve Former Inpatients

While SNHPA supports the competitive bidding program's goal of achieving program savings, we are concerned that these regulations could impact those savings by limiting the ability of safety net hospitals to continue to provide necessary DMEPOS and associated support services to former inpatients after those patients are discharged. The restrictions imposed under these regulations would have a significant impact on the continuity of care required to ensure that patients make the best and most effective use of these devices and supplies in order to improve their clinical outcomes.

The exemptions for hospital-provided DMEPOS implemented under new 42 C.F.R. § 414.404(b)(1) are limited to durable medical equipment and orthotics provided during an inpatient hospital stay and at discharge. We are concerned that patients such as transplant patients and patients receiving care for diabetes, who continue after discharge to be treated by the same hospital providers in the hospital's outpatient clinics and infusion and therapy programs, might no longer be able to obtain their DMEPOS from the providers they have grown to trust. Forcing these patients to obtain their DMEPOS from other non-hospital sources would create a break in the continuity of care upon which these patients depend for their long-term health outcomes. We believe that CMS has the regulatory authority to apply the MIPPA hospital exemption after patient discharge to DMEPOS provided to former hospital inpatients still receiving related treatment in the hospital's outpatient settings. Such an application would make good policy sense, and would ensure that the savings from competitive bidding are not lost when continuity of care is lost.

Proposed Hospital-Based DMEPOS Option at Competitively Bid Prices

SNHPA recommends permitting safety net hospital outpatient clinics and infusion and therapy programs to continue providing DMEPOS to former inpatients by allowing those providers to accept as reimbursement – without submission of a bid or registration as a DMEPOS provider – the price set through the competitive bidding process for DMEPOS products. This proposal would particularly benefit patients who need patient education and support in the proper use of the DMEPOS and who otherwise would struggle with fragmented care as a result of a host of socio-economic and cultural challenges. The patients served by safety net hospitals often have a limited proficiency in English and a lack of available transportation options that render them in particular need of easily accessed education and support. Our hospitals are specially trained

and equipped to serve this disenfranchised and hard-to-reach population and provide the necessary assistance in a manner that ensures continued positive clinical outcomes. The approach we propose would recognize the unique community role that safety net hospital providers play, and ensure the continued availability of services for these patients. This modest but sensible change to the competitive bidding program would allow safety net hospitals to continue serving their patients without additional cost to the Medicare program.

Such support is especially critical for medically complex patients who need more advanced DMEPOS to be able to return home safely. Without being able to rely on the hospital for comprehensive post-discharge DMEPOS services, patients who need more specialized DMEPOS and customized care and support might not be sent home by the treating physician in a timely fashion, leading to greater inpatient costs for the Medicare program. In addition, because large DME vendors place less emphasis on the training, education, and ongoing technical support needed for this type of DMEPOS, a lack of comprehensive patient and caretaker education and technical support could result in the inappropriate and unsafe use of outpatient DMEPOS, and greater, not reduced, costs to the Medicare Part B program.

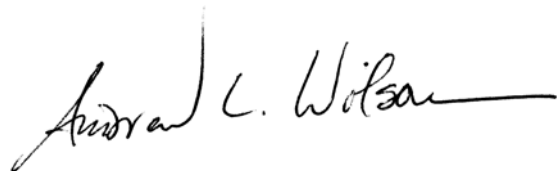
To ensure that Medicare beneficiaries who have been discharged from safety net hospitals have timely access to DMEPOS and comprehensive supportive services, we urge that you allow these hospitals to continue participating in the Medicare DMEPOS program by providing DMEPOS at the bid cost to former inpatients served in the hospitals' outpatient settings, without the need to submit a bid. This would benefit Medicare patients without adding costs to the program that might result from patients returning for additional inpatient care.

We thank you for the opportunity to comment on this interim final rule. If you have any questions, please contact SNHPA's Director of Pharmacy and Educational Services, Dr. Andrew Wilson, at andy.wilson@safetynetrx.org or 202-552-5857.

Sincerely,



William von Oehsen
President and General Counsel



Andrew Wilson, PharmD., FASHP
Director of Pharmacy and Educational Services