



Safety Net Hospitals for Pharmaceutical Access

July 15, 2008

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-4131-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare Program: Revisions to the Medicare Advantage and Prescription Drug Benefit Programs, CMS 4131-P

To Whom It May Concern:

Safety Net Hospitals for Pharmaceutical Access (SNHPA) appreciates the opportunity to offer comments on the proposed revisions to 42 CFR Parts 422 and 423, particularly those governing the definition of “negotiated price,” setting Part D enrollee co-payments based on negotiated prices, addressing provider distribution of plan comparison materials, and modifying procedures for establishing a patient’s eligibility for low-income subsidies and determinations or re-determinations of drug coverage. We have concerns about the application of the first two provisions, and believe that the third is inconsistent with rules recently adopted by CMS. While we applaud the last provision, we would ask that it be further modified to permit dispensing providers, as well as prescribing providers, to assist enrollees with seeking eligibility and drug coverage determinations.

SNHPA is a national association of hospitals that, based on the high percentage of indigent patients they serve, are qualified to participate in the federal drug discount program administered under § 340B of the Public Health Service Act. Many of those hospitals have outpatient pharmacies that participate as network pharmacy providers in the Part D program. Others would like to participate in the Part D program but find it difficult to negotiate Part D provider participation agreements that often fail to acknowledge and accommodate the specific provider requirements of the 340B program.

Negotiated Price, Patient Cost-Sharing, and 340B Penny Pricing

The discussion of the definition of “negotiated price” demonstrates the lack of interoperability between the Part D and 340B program components. SNHPA is concerned that the proposed rule preamble and rule language defining “negotiated price” to be the price passed through to the enrollee¹ could pose difficulty in circumstances where a Part D plan demands of network-participating 340B pharmacies that the negotiated price for a drug be the 340B price. Those 340B prices are often as low as 50 cents. In fact, under unwritten Office of Pharmacy Affairs (OPA) penny pricing rules,

¹ See discussion at 73 Fed. Reg. 28,563 through 25,568 (May 16, 2008)(to be codified at 42 C.F.R. § 423.104(g).

the 340B price can drop as low as 1 cent when manufacturer price increases exceed general inflation, and the resulting penalties imposed by the government drop the price of the drug below zero.²

We are concerned that the preamble discussion and interpretation of “negotiated price” could encourage Part D plans to believe that they must set negotiated prices at 340B prices for 340B-participating Part D network pharmacies. Unfortunately, 340B prices will not be available for drugs dispensed to Part D enrollees who do not qualify under the 340B program definition of “patient,” and drugs dispensed to non-340B patients at 340B prices will create significant losses for 340B pharmacies who must obtain those drugs at prices well above 340B levels.

This possible perceived license for Part D plans to access 340B prices would be troublesome enough, but then requiring a 340B pharmacy to charge a 340B drug’s price as patient cost-sharing when that price is lower than plan or LIS co-pays could eliminate the value of the co-pay as a means of shaping patient utilization. A patient is likely to push for normally more expensive brand name drugs in all cases if he or she knows that those brand name drugs – advertised on television as highly effective – can be obtained for pennies -- or even a single penny. 340B prices change quarterly, and that pricing advantage could soon be lost, but only after the patient has achieved a positive therapeutic outcome with the now more-expensive drug.

Further, because 340B prices change quarterly, pharmacies required to charge the 340B price as the patient co-payment would face the daunting task of having to constantly adjust co-payments manually for virtually all their inventory, creating an unreasonable administrative burden for the pharmacy and – more importantly – creating confusion and distrust in the mind of the Part D enrollees charged constantly fluctuating prices. This administrative burden and increased customer stress could discourage 340B pharmacies from participating in the Part D program and, in turn, threaten access to Part D drugs in communities where 340B providers are among the only providers.

In May 2008, drug manufacturer Schering-Plough notified OPA it would be rationing its allocation of an oral contraceptive to 340B providers out of concern the “penny price” set for that drug by OPA would disrupt the marketplace. The manufacturer worried that 340B providers could stockpile the drug at the very low penny price so that it is not available in sufficient quantities to sell to other health care providers. As a result of the manufacturer’s decision, patients participating in the 340B program will likely lose at least some access to that drug.

SNHPA can perceive of a similar but even more pervasive scenario occurring if Medicare Part D plans require network-participating 340B providers to charge enrollees the 340B price as the pass-through price. If these pharmacies are now required to charge Part D enrollees, as well as 340B patients, prices as low as a penny, manufacturers are even

² The penny pricing approach adopted by OPA has been supported by the Health and Human Services’ Office of the Inspector General (OIG) in its reviews of OPA’s administration of the 340B program, most recently in its July 2006 “Review of 340B Prices,” OEI-05-02-00073.

more likely to limit access to those drugs for 340B covered entities and their patients as manufacturers react to this increased demand by rationing the availability of 340B drugs. We ask that CMS clarify the application of this rule to specify that Part D plans may not require 340B providers to provide the 340B price to Part D plans under 42 C.F.R. § 423.104(g), and they need not charge Part D enrollees the 340B price as the co-payment under 42 C.F.R. § 423.782(c) when that price is lower than the cost-sharing that would otherwise be due from the enrollee.

Apparent Reversal of Policy on Access to Comparative Marketing Materials

We are also troubled that it appears the proposed rules³ have dropped a change only recently adopted by CMS that limits the documents that a Part D provider must make available to Part D enrollees to limit its liability for distributing marketing materials. The final Part D technical rules published in April 2008⁴ modified 42 C.F.R. § 423.50(f) to state that a provider such as a pharmacy provider displaying and distributing comparative plan marketing materials need only display printed information from plans with which the provider contracts. However, the proposed rules under discussion here appear to have dropped this clarification. Proposed 42 C.F.R. § 423.2268(j) states that it is a prohibited activity for a plan to use provider, provider groups, or pharmacies to distribute printed information comparing plans unless the providers “*accept and display materials from all Part D plan sponsors*” [emphasis added].

SNHPA hopes this is an oversight. We welcomed the earlier change which relieved our members from the responsibility of having to display materials for all Part D plans, even plans with which the provider did not contract as a network provider. We viewed the earlier change as a reasonable accommodation that would protect prospective enrollees from steering while avoiding the imposition of a heavy administrative burden on the provider. We trust the failure to include this change here was an oversight, and that the intent was not to reverse that earlier very reasonable approach. We ask that CMS add language to 42 C.F.R. § 423.2268(j) that mirrors the language recently added to 42 C.F.R. § 423.50(f).

Best Available Evidence and Provider Assistance in Establishing Eligibility, Coverage

Proposed 42 C.F.R. §§423.772 and 432.800 would allow Part D enrollees and prescribing providers acting on their behalf to offer, and require Part D plans to accept, the “best available evidence” that an enrollee does, in fact qualify for the Part D low-income subsidy. SNHPA believes that imposing an obligation on plans to take reasonable steps to respond to documentation offered by the enrollee or his/her provider will help to ensure important access to necessary subsidies for low-income enrollees when enrollees are not correctly identified as subsidy-eligible.

Similarly, SNHPA’s members also are pleased to see that CMS is proposing to allow prescribing providers other than physicians to seek these appeals and redeterminations.

³ Proposed 42 C.F.R. § 423.2268(j).

⁴ 73 Fed. Reg. 20486, 20505 (April 15, 2008).

Prescribing physicians have often been instrumental over the first three years of the program in ensuring that Part D enrollees have access to the drugs they need. The proposed new provisions acknowledge that some Part D enrollees may not always have the necessary economic and psycho-social resources, education, experience, or understanding to effectively seek the reconsiderations necessary to ensure that they have access to the prescription drug products and services to which they are entitled. Low-income Part D enrollees such as those served by SNHPA members and other 340B entities often need this assistance, and we believe that any program change designed to expand the resources available to them is commendable.

SNHPA's only reservation is that we would like to see the same authority granted to dispensing providers, since prescribing providers may not always have the time under certain circumstances to devote to an effective administrative appeal of an erroneous coverage or eligibility determination. Dispensing pharmacies and medical personnel assisting in administering physician-administered drugs should also be permitted to assist enrollees in safeguarding access to drugs crucial to their safety and health. We ask that this clarification be added to this provision.

Conclusion

In order to ensure continued Part D enrollee access to 340B pharmacy providers participating in Part D plan networks, SHNPA believes it is crucial that CMS further clarify the interaction of 340B drug prices with determinations of Part D negotiated prices, particularly as both are impacted by the new Part D cost-sharing rules proposed under 42 C.F.R. § 423.782(c). Patient access also will be safeguarded if dispensing and administering providers as well as prescribing providers are authorized to seek coverage and eligibility determinations, redeterminations, and exceptions. Finally, the Part D program will ensure that prospective enrollees have the information they need to make informed selections of plans if providers are required to distribute and display only information about the plans in which they participate as network providers, and we ask that these regulations be amended to conform to Part D regulations adopted just months ago.

Thank you for your attention to these important issues.

Sincerely,

A handwritten signature in black ink, appearing to read "Stuart Yael Gordon", with a long horizontal line extending to the right.

Stuart Yael Gordon
Director, Legal and Regulatory Affairs
SNHPA