



Public Hospital Pharmacy Coalition

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(A Coalition of the National Association of Public Hospitals and Health Systems)

May 10, 2004

VIA FACSIMILE

Dr. Mark B. McClellan
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. McClellan:

This letter is being sent on behalf of the Public Hospital Pharmacy Coalition (PHPC). PHPC is an organization of over 200 safety net hospitals and health systems that participate in an outpatient drug discount program established under Section 340B of the Public Health Service Act. The Coalition was formed to increase the affordability and accessibility of pharmaceutical care for the nation's poor and underserved populations. We are writing to request two policy clarifications regarding participation of our 340B hospital members in the Medicare drug discount card program. PHPC understands that the Centers for Medicare and Medicaid Services (CMS) has developed a policy urging discount card sponsors to include federally qualified health center (FQHC) pharmacies in the sponsors' pharmacy networks. The Coalition's first recommendation, therefore, is for CMS to expand this policy in order to encourage broader participation of 340B disproportionate share hospitals (DSH) in discount card networks. The second clarification that PHPC seeks is to allow card sponsors to offer separate co-branded discount cards to beneficiaries who are existing patients of a 340B provider and are therefore eligible to receive 340B-discounted pricing. This alternative model for offering and financing a Medicare discount card should improve both the affordability and continuity of pharmaceutical care for low-income Medicare patients. These two proposals are discussed in greater detail below.

Background

Established by Congress and signed into law by President George H.W. Bush in 1992, the Public Health Service 340B program was designed to assist federally-funded safety net providers and programs expand access to pharmaceutical care by giving them access to deeply discounted drugs. 340B discounts are approximately half of average wholesale prices. In addition to eleven categories of federal grantees and sub-grantees, a number of disproportionate share hospitals that provide large volumes of indigent care are eligible to participate in the 340B program. These hospitals are either owned by state or local government or have a contractual relationship with state or local government to provide care to low-income populations. There are currently over 200 DSH hospitals participating in the 340B program and most of them are teaching facilities.



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Although 340B hospitals constitute less than 5 percent of all hospitals in the United States, they provide over 25 percent of the uncompensated health care for Americans. DSH hospitals also provide an enormous volume of care to Medicare beneficiaries, particularly low-income beneficiaries who often lack pharmaceutical coverage. Close to two million Medicare patients are treated at 340B hospitals each year and 340B hospital pharmacies are responsible for almost all of the pharmaceutical care for these patients. Due to the existing relationships between 340B hospital pharmacists and their patients, these professionals are in a unique position to monitor drug utilization, provide culturally sensitive pharmacy counseling services, and ensure compliance with drug regimens. Yet, 340B hospitals face ever-increasing budgetary constraints which, when coupled with the double digit increases in pharmaceutical costs, have forced many of them to consider limiting access to medically necessary drugs for the indigent and vulnerable populations that they serve.

Encouraging Participation of DSH Pharmacies

CMS recently released guidance to general discount card sponsors encouraging them to include federally qualified health centers as part of their pharmacy networks. Although neither the Medicare discount card statute nor its implementing regulations specifically exclude 340B entities from participating in the discount card program, we are concerned that CMS's FQHC-focused guidance may have the unintentional effect of discouraging discount card sponsors from contracting with non-FQHC 340B pharmacies. The refusal of some manufacturers to give rebates to sponsors for drugs that have already been deeply discounted under the 340B program, may further discourage sponsors from offering participation agreements to 340B hospitals and other covered entities. If 340B pharmacies are excluded from Medicare card sponsor networks, continuity of care will be compromised and patients may suffer adverse health consequences which, among other things, could end up increasing costs to the Medicare program.

Like FQHCs, many PHPC member hospitals serve patients who are likely to qualify for the \$600 transitional assistance and to use it to purchase necessary medication prior to the implementation of the drug benefit in 2006. 340B hospital pharmacists are in a unique position to educate patients about the new card program and to help them navigate through the various choices. In addition, most 340B hospital pharmacies already meet standard pharmaceutical benefits manager (PBM) participation requirements and have existing agreements with PBMs and managed care networks. Therefore, we request that CMS broaden its guidance on FQHC participation in general sponsor drug discount card pharmacy networks to include all 340B entities, especially 340B DSH hospitals, in the guidance document.

Advantages of a 340B-Based Co-Branded Discount Card

PHPC is convinced that the 340B program offers an enormous opportunity for discount card sponsors to develop specialized card programs that will promote continuity of care for low-income Medicare patients while lowering the cost of drugs well below the discounts advertised on the CMS website. These specialized card programs would be built around a 340B provider – typically a DSH hospital, FQHC or a combination of DSHs and FQHCs – that is already serving a large population of low-income Medicare patients. We understand that the Medicare discount

law already explicitly authorizes this model for Indian tribes and health clinics. The Coalition's interest is in expanding this model to DSH hospitals, FQHCs, and other 340B providers. There are at least three advantages of such a program.

First, if the target Medicare population chooses to sign up with the 340B provider's card, patients could continue using the 340B entity's pharmacy both during the initial participation period when their \$600 transitional assistance subsidies are available to pay for drugs, and after the subsidies are exhausted and the cardholders find themselves unable to afford retail pharmacy prices, even at the sponsor's discounted rates. In the absence of such a program, many low-income Medicare beneficiaries will have to change pharmacies after their \$600 subsidy is depleted, returning to their original 340B pharmacy provider where they are assured of getting their prescriptions filled. Unlike retail pharmacies, DSH and FQHC pharmacies are required by law to serve all patients, regardless of their ability to pay. Allowing patients within this vulnerable population to keep their pharmacy "home" at the 340B provider will avoid the inevitable switching of pharmacies after their transitional assistance is used up. This, in turn, will avoid disruptions in pharmaceutical care, especially since a change in pharmacies may end up forcing patients to change drugs because of the different formularies maintained by the pharmacies.

The second advantage of a DSH- or FQHC-based discount card is that the covered entity's pharmacy will almost always be able to offer prices at or below the discounted prices typically available to Medicare beneficiaries who sign up for a discount card program. 340B discounts are often double (or even triple) the discounts that non-340B pharmacies will be able to offer to cardholders. Not only would cardholders benefit from these deeply discounted rates, manufacturers would not have to pay rebates to help card sponsors make their drugs more affordable. The affordability of the drugs available through the DSH or FQHC card would result from their acquisition through the 340B program, not from the use of manufacturer rebates to lower a participating pharmacy's drug costs.

The third reason why CMS should support a 340B-based discount card program is that it would help strengthen this nation's safety net. DSH hospitals and FQHCs represent the backbone of our country's health care system for the poor. As the number of uninsured Americans climbs and availability of taxpayer revenue to pay for health care shrinks, 340B providers often find themselves at the brink of financial collapse. It is therefore not surprising that these safety net institutions want their Medicare patients to use transitional assistance dollars on their own pharmacy services rather than spending the \$600 elsewhere. Helping to direct this new source of federal revenue to 340B providers would further the mission of safety net institutions in meeting the needs of the underserved both today and for future generations.

CMS Clarifications Requested

Assuming that CMS finds the above advantages of a 340B-based discount card program as compelling as PHPC does, PHPC requests that CMS issue a couple of policy clarifications in order to make the proposed program possible. The first clarification would ensure that the program complies with a fundamental requirement of the 340B program, namely, that a 340B entity may only dispense its discounted drugs to its own patients. PHPC understands the

problems that would ensue if a discount card sponsor's participating pharmacies were permitted to turn away beneficiaries who sign up with the sponsor's card. But this is not the relief that PHPC is seeking. Because 340B providers cannot meet CMS standards for becoming sponsors of their own discount card programs, they would have to partner with a CMS-approved sponsor, such as a pharmaceutical benefits manager (PBM), a claims processor or a Medicare Advantage Plan, in order to launch their 340B-supported discount card. This means that the 340B provider's card would actually serve a subset of the Medicare population served by the CMS-approved sponsor with which the 340B provider has partnered. The 340B provider's card would be "co-branded" with the CMS sponsor's card, i.e., it would bear the name and identification of both the sponsor and the 340B provider. And although the 340B provider would only market its co-branded card to its own patients, the beneficiary enrollment process would not deviate from existing CMS procedures. Beneficiaries would be enrolled in the sponsor's discount card program according to standard enrollment procedures, even if the beneficiaries' ultimate interest is to sign up for the co-branded card.

The clarification that PHPC seeks relates not to the discount card enrollment process but rather to a cardholder's choice of participating pharmacies after he or she is enrolled. In particular, PHPC seeks an assurance by CMS that, with respect to discount card programs in which a 340B entity offers a co-branded discount card option, the card sponsor can limit enrollment into the co-branded card option to only those cardholders that are "patients" of the 340B entity within the meaning of the 340B statute and implementing guidelines. CMS endorsement of this policy is essential to the success of the proposed 340B-based discount card model because, under the 340B anti-diversion provision, the proposed 340B providers are prohibited from selling or otherwise transferring their discounted drugs to anyone other than their own patients. If cardholders who are not patients of the 340 provider are permitted to sign up with the 340B entity's card, the 340B provider would be saddled with having to choose between two equally unattractive options: augment the 340B pharmacy's infrastructure to allow it to maintain two inventories of drugs (340B and non-340B) or violate the 340B prohibition against dispensing discounted drugs to non-patients.

A better option, we believe, is to direct 340B non-patient cardholders to the sponsor's standard discount card so that the 340B co-branded card is limited to exclusively 340B-eligible patients. Of course, the sponsor's non-340B pharmacy network would meet geo-access standards for cardholders turned away from the 340B pharmacy so the inability to sign up for the 340B co-branded card would not adversely impact the non-340B cardholders. With respect to cardholders who do qualify as patients of the 340B DSH hospital or FQHC, the sponsor and 340B provider would like this group auto-assigned to the co-branded card plan. No one within the group would be required to sign up with the 340B card, so an auto-assigned 340B cardholder would always have the option to transfer to the sponsor's non-340B card program.

Another aspect of the proposed 340B-based discount card model that deserves CMS's attention, if not explicit approval, relates to how the co-branded card's operations would be funded. In contrast to the traditional Medicare discount card, the 340B co-branded card could be financed without payment of manufacturer rebates. The discounts available to the 340B provider are well below the range of discounts extended to Medicare beneficiaries through the discount card program. That means that the 340B pharmacy would not need any subsidy from the sponsor or

drug companies to maintain the financial viability of its card program. This is important because manufacturers are unlikely to give rebates on drugs for which they have already given a 340B discount. Because sponsors typically fund their activities by using a portion of the rebates paid by manufacturers, the sponsor's operations would be financed not by manufacturers but rather by its 340B partner. In particular, the 340B provider would pay transaction fees to the sponsor to compensate it for the loss of revenue from supplier rebates. The transaction fees would be negotiated based on fair market value of the sponsor's services and the payment arrangement would otherwise be structured to avoid exposure under federal and state anti-kickback laws.

Conclusion

In summary, PHPC asks that CMS clarify its drug discount card policies in order to facilitate, or at least not hinder, partnerships between approved sponsors and 340B entities so that the 340B drug discount program could be used to fund a specialized co-branded card for cardholders who are patients of the 340B entities. Prior to launching such a card, the 340B provider community and their discount card partners, seek assurances from CMS that eligibility for a 340B-based co-branded card can be limited to existing "patients" of the 340B provider and that the discounts made available to 340B-eligible cardholders, and the cost of the sponsor's operations, can be financed exclusively from the savings achieved by purchasing the drugs through the 340B program. Absent confirmation from CMS that these deviations from the typical discount card model are permissible, PHPC suspects that the proposed 340B-based discount card model would never be implemented. PHPC wants to avoid this outcome based on the anticipated benefits for patient access and continuity of care. We hope that CMS will work with PHPC in pursuing this exciting model for expanding pharmaceutical access and stretching scarce resources for low-income Medicare beneficiaries. PHPC also requests that CMS's current policy encouraging card sponsors to include FQHC pharmacies in their discount card pharmacy networks be expanded to incentivize sponsors to also offer participating agreements to 340B hospitals and other covered entities.

PHPC is ready to answer questions or otherwise lend its support with respect to the above matters. I can be reached at (202) 466-6550 or via email william.vonoehsen@ppsv.com.

Sincerely,



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Counsel

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