Public Hospital Pharmacy Coalition
www.phpcrx.org
(A Coalition of the National Association of Public Hospitals and Health Systems)

May 13, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore MD 21244-1850

Re: 340B Pharmacies and the Medicare Part D Program

Dear Dr. McClellan:

The Public Hospital Pharmacy Coalition (PHPC) would like to take this opportunity to follow up on the comments that it submitted in response to the Medicare Part D regulations issued earlier this year. PHPC is an organization of over 275 safety net hospitals and health systems that participate in an outpatient drug discount program established under Section 340B of the Public Health Service Act and administered by the Health Resources and Services Administration (HRSA). The Coalition was formed to increase the affordability and accessibility of pharmaceutical care for the nation's poor and underserved populations.

PHPC is writing because 340B hospital pharmacies potentially play a valuable role in the Medicare Part D program, but, in order for 340B hospitals to participate in this program, the Centers for Medicare & Medicaid Services (CMS) must address certain issues. First, CMS needs to eliminate potential obstacles to 340B hospital pharmacy participation in Part D networks, such as by ensuring that Part D plan contracts do not include language which effectively precludes participation by 340B hospital pharmacies. Second, CMS should educate Part D plan sponsors on the 340B program and encourage the inclusion of 340B pharmacies in Part D plan networks. Third, CMS should allow Part D plan sponsors to partner with 340B providers in establishing co-branded drug benefit programs that are offered exclusively to Part D beneficiaries who are patients of the 340B provider. We understand that HRSA has attempted to assist CMS with each of these challenges by providing, for example, sample contract language that Part D plan sponsors can use in contracting with 340B pharmacies and educational material explaining the opportunities and benefits of including 340B pharmacies in Part D pharmacy networks. PHPC urges CMS to finalize these materials and publicize them as soon as possible among the managed care and pharmacy benefit organizations that are likely to bid on the Part D business.

I. 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 pharmaceuticals. 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 (DSH) 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.

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. Participating 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 significant 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.

II. CMS Should Prohibit Part D Plan Sponsors from Excluding 340B Hospital Pharmacies from Part D Plan Networks.

The final Part D regulations, at 42 C.F.R. § 423.120(a)(8), state that "[i]n establishing its contracted pharmacy network, a Part D sponsor offering qualified prescription drug coverage -- (i) Must contract with any pharmacy that meets the Part D plan's standard terms and conditions ...." On its face, this section appears to protect pharmacies from potential discriminatory conduct by Part D plan sponsors. However, plan sponsors can craft certain "terms and conditions" that, whether intentional or not, have the effect of excluding 340B provider pharmacies from plan networks. For example, a condition of participation that the pharmacy serve all plan enrollees would conflict with a covered entity's obligation under the 340B statute not to sell or otherwise transfer its 340B-discounted drugs to anyone other than its own patients. If enrollees who are not patients of the 340B provider are permitted to fill prescriptions at the 340B pharmacy, 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. Price disclosure requirements or billing terms could also prevent 340B pharmacies from contracting with Part D plan sponsors.

At this time, PHPC has received numerous reports from member hospitals indicating that they have received offers for their pharmacies to participate in 340B networks, but that the network terms and conditions include language that would preclude their participation (*e.g.*, a requirement to offer their prices to all enrollees). PHPC requests that CMS address this problem by informing all sponsors that they must amend their terms and conditions to allow participation of 340B hospital pharmacies (either by amending the plan's standard network terms and conditions, or by offering special terms and conditions to 340B hospital pharmacies). Toward this end, we understand that HRSA has developed some sample contractual language, in the form of a contract "addendum," that would solve this problem if used by Part D plan sponsors. We strongly recommend that CMS finalize this document and disseminate it as soon as possible within the managed care and pharmacy benefit communities.

III. CMS Should Promote the Inclusion of 340B Hospital Pharmacies in Part D Plan Networks.

In promoting the Medicare discount card program, CMS has already recognized the vital role that FQHCs, DSH hospitals, and other 340B providers play in caring for low-income seniors and disabled Americans. Indeed, CMS issued specific guidance urging drug card sponsors to reach out to FQHCs and other 340B providers in building their pharmacy networks. These same 340B pharmacists are in a unique position to educate low-income Medicare patients about the new Part D benefit and to help them navigate through the various choices. If 340B pharmacies are excluded from the networks of Medicare Part D plans, 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.

However, Part D plan sponsors may find that adding 340B hospital pharmacies to their networks involves added complexities. For example, 340B hospital pharmacies receive substantial discounts under the 340B program. Accordingly, manufacturers may be unwilling to provide additional discounts or rebates to Part D plans with respect to drugs dispensed through 340B hospital pharmacies. By including 340B hospital pharmacies in their networks, Part D plan sponsors may achieve savings through lower pharmacy costs, rather than manufacturer rebates. Furthermore, Part D plan sponsors may need to create unique financial agreements with such pharmacies (*e.g.*, the 340B hospital pharmacy may negotiate to share a portion of its 340B discount with the Part D plan).

Because of the added complexities of including 340B hospital pharmacies in their networks, Part D plan sponsors may choose to avoid contracting with such pharmacies whenever possible. PHPC urges CMS to continue its policy of promoting use of the 340B program by Medicare patients. We understand that HRSA has drafted a background document providing information about the 340B program and how its intersection with the Part D program affords

Part D plans an opportunity to build membership and promote continuity of care by including 340B pharmacies in their networks. PHPC recommends that CMS educate Part D plan sponsors regarding the 340B program, including potentially advantageous means of including such pharmacies in Part D plan networks. As with the sample contract addendum, we strongly recommend that CMS finalize HRSA's educational materials and distribute it to the managed care and pharmacy benefit communities. PHPC would be more than willing to assist CMS with this endeavor.

IV. CMS Should Promote the Creation of Co-Branded 340B Part D Drug Benefit Cards.

Since the launch of the Medicare drug discount card, several 340B providers have partnered with discount card sponsors to develop a co-branded discount card giving cardholders access to 340B-discounted pricing. These specialized card programs are 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. Initial reports suggest that these co-branded care programs have been successful in promoting continuity of care for low-income Medicare patients while lowering the cost of drugs well below the discounts advertised on the CMS website. These co-branded discount card partnerships between 340B providers and card sponsors would like to transition into the Part D program in 2006.

With respect to discount card programs in which a 340B entity offers a co-branded discount card option, you have already endorsed in writing that the card sponsor can limit enrollment into the co-branded card option to only those cardholders who are "patients" of the 340B entity. A copy of your letter dated July 27, 2004 is attached. CMS endorsement of this policy was essential to the success of the 340B-based discount card model because, under the 340B anti-diversion provision, the 340B providers are prohibited from selling or otherwise transferring their discounted drugs to anyone other than their own patients. PHPC simply seeks an extension of this policy to the new Part D benefit so that Part D plans can offer special 340B-based drug benefits to enrollees who are patients of 340B providers. There are at least three advantages to this model.

First, if the target Medicare population chooses to sign up with the 340B provider's co-branded drug benefit, patients could continue using the 340B entity's pharmacy during the so-called donut hole or during other gaps in coverage when the enrollees would otherwise find themselves unable to afford retail pharmacy prices, even at the plan's discounted rates. In the absence of such a program, many low-income Medicare beneficiaries will have to change pharmacies after their coverage is depleted, returning to their original 340B pharmacy providers, where they are assured of getting their prescriptions filled. 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 340B co-branded drug benefit is that the covered entity's pharmacy will almost always be able to offer prices at or below the discounted prices typically available to low-income Medicare beneficiaries who sign up for the Part D benefit. 340B discounts will likely be deeper than the discounts that non-340B pharmacies will be able to offer to enrollees. Not only would beneficiaries benefit from these deeply discounted rates, manufacturers would not have to pay rebates to help card sponsors make their drugs more affordable. Accordingly, Part D plan sponsors would obtain savings through lower prices on drugs purchased at 340B pharmacies, rather than through manufacturer rebates. This, in turn, would allow the plan sponsor to abandon or diminish the use of formularies for enrollees eligible for the co-branded benefit.

The third reason why CMS should support a 340B-based co-branded benefit 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 drug benefit dollars on their own pharmacy services rather than using their coverage 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.

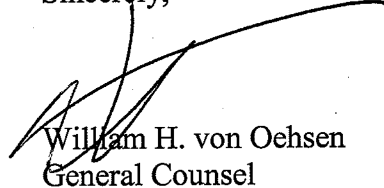
PHPC is concerned that the current Part D regulations include potential obstacles to creating a co-branded 340B Part D plan. First, PHPC is concerned about application of Section 423.272(b)(2) because access to the co-branded card is limited to the subset of cardholders who are "patients" of the 340B partner within the meaning of the 340B statute and implementing guidelines. The prohibition in Section 423.272(b)(2) against discouraging enrollment by certain Part D eligible individuals could be construed as prohibiting the co-branded partnership model that both 340B providers and prospective Part D sponsors would like to establish in the Part D program. Second, the final regulations, at 42 C.F.R. § 423.120(c), require that a Part D card "must comply with standards CMS establishes." PHPC is concerned that CMS standards may prevent Part D plan sponsors from creating a co-branded 340B drug benefit card. Based on these concerns, PHPC requests that CMS issue guidance promoting the partnership of Part D plan sponsors and 340B entities, and the creation of co-branded drug benefit cards. Alternatively, you could issue a letter similar to your July 27, 2004 letter approving the 340B co-branded model for the Medicare drug discount program. Either way, the communication should explicitly state that creating a co-branded 340B benefit will not be construed as beneficiary discrimination under 42 C.F.R. § 423.272(b)(2). Finally, we ask that CMS's upcoming standards for Part D cards include a statement permitting – and, if possible, promoting – the use of co-branded 340B Part D drug benefit cards.

V. Conclusion

The 340B drug discount program is an integral part of this nation's health care delivery system. It is imperative that the new Medicare Part D program include 340B entities, both for the benefit of low-income Medicare beneficiaries and for these safety-net entities. PHPC requests that CMS issue guidance: (1) prohibiting Part D plan sponsors from using pharmacy terms and conditions that preclude participation of 340B pharmacies; (2) promoting the inclusion of 340B hospital pharmacies in Part D plan networks; and (3) providing for partnerships between Part D plan sponsors and 340B entities, including co-branded drug benefits.

PHPC appreciates your attention to this matter. Please do not hesitate to contact me at (202) 466-6550 if you have any questions or need additional information.

Sincerely,



William H. von Oehsen
General Counsel

Enclosure

cc: Elizabeth Duke, Administrator, HRSA
Jim Mitchell, Director, Office of Pharmacy Affairs, HRSA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

JUL 27 2004

Mr. William von Oehsen
Public Hospital Pharmacy Coalition
1875 Eye Street, NW, Twelfth Floor
Washington, DC 20006

Dear Mr. von Oehsen:

Thank you for your letter regarding participation of the Public Hospital Pharmacy Coalition (PHPC) in the Medicare-approved prescription drug discount card program.

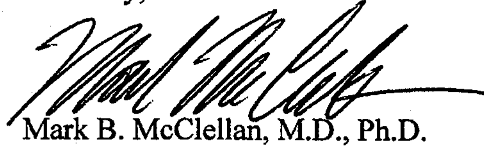
I am pleased to inform you that the Centers for Medicare & Medicaid Services (CMS) has been working closely with the Health Resources and Services Administration (HRSA) regarding the potential to further enhance cost savings opportunities for the nation's low-income and underserved Medicare populations that could qualify for both a Medicare-approved drug prescription drug discount Card and 340B outpatient drug discounts. We have determined that Medicare-approved sponsors may recognize 340B prices as the drug card discount prices to be applied at the point of sale, including when the $600 credit is applied to the transaction. Enabling such low prices to be realized under the Medicare- approved drug discount card program will assure that those eligible for 340B discounts will continue to receive their low drug prices while also benefiting from the $600 in transitional assistance, thus potentially expanding the ability of 340B covered entities to serve vulnerable individuals. Further, pharmacies participating in the network of a Medicare-approved card will still be prohibited from providing drugs obtained through 340B covered vendors to beneficiaries who do not qualify for 340B discounts.

We have already begun providing information to the Medicare-approved drug card program sponsors about the 340B covered vendors and encouraged them to include such pharmacies in their networks. Similarly we are providing information to HRSA to share with 340B covered entities to help them understand how the Medicare drug card programs work and how to contact the sponsors of these card programs to join their networks. Both the 340B covered entities as well as the Medicare-approved sponsors will voluntarily decide whether they wish to take advantage of this opportunity to provide continuity for the important and vulnerable populations they serve. We are aware that at least several sponsors are in an active dialogue with 340B covered entities. CMS will continue to work with HRSA and provide technical support to these interested parties as they explore how best to arrange their operations to maximize the cost savings of these programs.

Thank you for your interest in the Medicare-approved drug discount card program and your continued support of programs to assure health care access for the low-income and underserved Medicare populations.

I hope you find this information helpful.

Sincerely,



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