



February 17, 2006

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Room C1-25-27
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Sent via facsimile: 410-786-6301

**Re: Prescription Drug Plan Contracting Problems
for 340B Pharmacies Under Medicare Part D**

Dear Dr. Tudor:

We are writing on behalf of the Public Hospital Pharmacy Coalition (“PHPC”) and the National Association of Community Health Centers (“NACHC”) to raise our mutual concern about various obstacles that our members have encountered in contracting with prescription drug plans (“PDPs”) under the Medicare Part D program. Although we do not know how widespread these contracting problems are, the frequency of member complaints received by our organizations, as well as the seriousness of the allegations being made, has convinced us that the Centers for Medicare and Medicaid Services (“CMS”) should implement measures to respond to these problems as soon as possible. Specifically, we recommend that CMS (1) issue further guidance to PDPs to remove barriers and otherwise facilitate contracting with pharmacies participating in the federal 340B drug discount program, (2) provide warnings to PDPs that refuse to contract with such pharmacies, and (3) amend the regulations to require PDPs, if requested by a 340B safety net provider, to conform their standard terms and conditions with the *Model Safety Net Pharmacy Addendum to Pharmacy Contracts* (“*Model Addendum*”) that CMS and the Health Resources and Services Administration (“HRSA”) jointly developed last year.

Background

NACHC is a national, non-profit organization representing Federally Qualified Health Centers (“health centers” or “FQHCs”) that receive Section 330 federal grants under the Consolidated Health Centers Act to provide preventive and primary health care services to medically underserved communities. As safety net providers for the most vulnerable populations in the country, health centers are eligible to purchase prescription drugs at discounted prices under the 340B drug discount program. Over 1,000 health center organizations provide health services through approximately 5,000 clinic sites located throughout the country and U.S. territories.

The vast majority of the 15 million patients served by health centers have incomes below 200% of the federal poverty level (“FPL”), and 40% of them are uninsured. Nearly 65% of patients served are minorities. Approximately 350 health centers operate their own licensed, in-house pharmacies to dispense drugs to their patients. Most health centers with licensed pharmacies are seeking to join Medicare Part D prescription drug networks so that they may continue to dispense drugs to the health center patients they currently serve. Additionally, of the over 15 million individuals utilizing health center services, including pharmacy services, it is estimated that between 1.5 and 2 million are now eligible for Medicare Part D. Of those, an estimated 500,000 to 1 million are Medicare and Medicaid dual eligible recipients, and the vast majority of the remaining individuals are low-income.

PHPC is an organization of over 350 safety net hospitals and health systems that participate in the 340B drug discount program administered by the HRSA. PHPC was formed to increase the affordability and accessibility of pharmaceutical care for the nation's poor and underserved populations. More than half of PHPC's member hospitals either operate or have contracts with outpatient ambulatory care pharmacies. These safety net pharmacies have historically filled prescriptions for low-income populations, including low-income Medicare patients and the dual eligibles. 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 participating in the 340B program 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.

The pharmacies owned by or under contract with community health centers, disproportionate share hospitals and other safety net providers participating in the 340B program have a critical role to play in the Part D program. Due to the existing relationships between 340B pharmacists and their patients, these professionals are in a unique position to manage medication-based therapies, monitor drug utilization, provide culturally and linguistically competent pharmacy counseling services, and ensure compliance with drug regimens. Additionally, many individuals who rely on safety net providers have limited means of transportation and, therefore, rely on access to pharmaceutical services at the site of their medical care. This continuity of care improves health outcomes while reducing costs – goals important to Medicare beneficiaries, providers and the federal government.

Reports of Contracting Problems

Our organizations have fielded numerous calls and e-mails from members who are reporting problems that they have encountered in contracting with Medicare PDPs. Each of our organizations is surveying its members in order to assess the impact of the Part D program and the ability of member pharmacies to participate in PDP pharmacy networks. Neither organization has completed its Part D survey; as such, we have to rely on compelling anecdotal evidence.

The evidence we have to date suggests that safety net pharmacies have had mixed success contracting with Part D plans. Clearly some member pharmacies have been successful in contracting with PDPs and have otherwise made a relatively smooth transition to Part D. Others, however, have been less fortunate, especially the smaller hospitals and health centers. A significant number of 340B pharmacies have informed us that they are experiencing contracting problems. These contracting problems for 340B pharmacies have taken several different forms.

First, we are aware of at least one PDP that has expressed disinterest in contracting with 340B pharmacies based on a concern that the pharmacies' low-income patient base may expose the plan to disproportionately high costs.

Second, at least one PDP includes terms in its standard contract requiring pharmacies to certify that they do not receive 340B discounts.

Third, many 340B pharmacies have informed us of their inability to receive PDPs' standard contracts and, therefore, their inability to participate in such PDPs' networks despite repeated telephone calls and e-mail messages to the individuals that are listed as the appropriate contacts at the PDPs.

Fourth, some PDPs include terms in their standard contracts that are problematic for 340B pharmacies. With respect to this last point, many PDPs include “open pharmacy” requirements in their standard terms and conditions whereby an interested pharmacy must serve all plan members. Such requirements preclude many 340B pharmacies from participating because, pursuant to the 340B program, a 340B pharmacy must only serve patients of the 340B entity (unless the pharmacy chooses to maintain a separate inventory of non-340B drugs, an administratively burdensome and costly process). Many 340B pharmacies have experienced difficulties with persuading PDPs to amend these problematic contract terms, even after sharing with the PDPs the *Model Addendum*, which CMS and HRSA specifically developed to facilitate contracting between PDPs and 340B pharmacies.

Potential Part D Violations

In our view, these problems are sufficiently serious that they may trigger one or more violations under the Part D program. Specifically, the PDPs’ actions may constitute discrimination against low-income beneficiaries and may violate the any willing pharmacy provision under Part D. A discussion of these potential Part D violations follows.

Discrimination Against Beneficiaries

The Medicare Part D statute and regulations prohibit CMS from approving a PDP bid if the design of the plan is “likely to substantially discourage enrollment by certain part D eligible individuals under the plan.” 42 U.S.C. § 1395w-111; 42 C.F.R. § 423.272(b)(2).

By erecting contracting barriers against 340B entities, plans are discouraging enrollment by certain populations of Part D eligible individuals. For example, by definition, a 340B hospital serves a disproportionate share of low-income individuals. To be eligible for the 340B program, a hospital must have a high disproportionate share adjustment (exceeding 11.75 percent). Health centers serve approximately 1.5 to 2 million Medicare patients, a majority of whom are among the lowest income beneficiaries and likely are dual eligibles. The vast majority of health center patients have incomes below 200% of the FPL, receive Medicaid or Medicare, or are uninsured. Many have low literacy rates, speak languages other than English, do not have easy access to transportation, and face other poverty-related barriers to receiving health care.

These individuals are among the most vulnerable Medicare beneficiaries with the least capabilities to change providers and pharmacies, and often need additional

assistance in understanding new rules or changes in their health care regimens. It appears that some PDPs may be intentionally excluding such 340B providers in order to discourage enrollment by the low-income populations traditionally served by these providers. If true, such conduct represents intentional and impermissible discrimination against low-income beneficiaries.

Similarly, many PDPs employ standard contract terms that are discriminatory in effect, such as open pharmacy requirements. Such PDPs may not be intentionally excluding 340B pharmacies, but this is nevertheless the impact of such a provision. By excluding 340B entities, even unintentionally, PDPs are discriminating against low-income beneficiaries because these beneficiaries often rely on safety net providers for pharmacy services. This is impermissible under the Medicare regulations as the regulations prohibit plans that have a discriminatory effect on beneficiary enrollment, without regard to whether such bias is intentional.

PDP discrimination against low-income beneficiaries forces such beneficiaries to make a problematic choice. As mentioned earlier, safety net providers, such as 340B entities, provide a host of services to low-income populations (*e.g.*, culturally sensitive and linguistically competent health care, social services, translation services, transportation assistance), all of which substantially improve patient compliance and health outcomes. PDPs' reluctance or unwillingness to contract with 340B entities reduces the Part D options that patients of 340B entities can choose from and still remain with their trusted safety net provider. Indeed, the PDP that offers the best drug benefit for a particular beneficiary may not have a contract with the beneficiary's safety net provider. The beneficiary is then forced to choose between the safety net provider with which he or she has a longstanding relation or the PDP that may provide the most appropriate drug benefit. Either option disadvantages the beneficiary, the safety net provider, or both.

Furthermore, Medicare Part D regulations state that, "[i]n conducting marketing activities, a Part D plan may not . . . (ii) [e]ngage in any discriminatory activity such as, including targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas." 42 C.F.R. § 423.50(f). An integral part of a PDP's marketing is its network design. A PDP's marketing strategy often involves the location and/or convenience of its pharmacy network. Additionally, pharmacies represent an avenue of marketing (*e.g.*, many beneficiaries may learn about a PDP by visiting a pharmacy with which the PDP contracts). By excluding 340B pharmacies that would encourage low-income beneficiaries to enroll in the plan, a PDP is indirectly marketing towards higher income beneficiaries.

Any Willing Pharmacy

The Medicare statute provides that “[a] prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.” 42 U.S.C. § 1395w-104(b)(1)(A); *see also* 42 C.F.R. § 423.120(a)(8)(i). Additionally, the Medicare regulations require that a PDP “agree to have a standard contract with *reasonable* and *relevant* terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy.” 42 C.F.R. § 423.505(b)(18) (emphasis added).

The statutory and regulatory “any willing pharmacy” provisions prohibit a PDP from categorically excluding 340B pharmacies. Pursuant to the any willing pharmacy law, a 340B pharmacy that is willing to accept the PDP’s standard terms and conditions should be entitled to participate in the PDP’s network. Moreover, if the PDP sponsor includes standard terms and conditions that preclude a 340B pharmacy’s participation, CMS should hold that such conditions are unreasonable and irrelevant and, therefore, violate 42 C.F.R. § 423.505(b)(18).

We contend that a certification requirement, *e.g.*, the requirement that a pharmacy certify that it does not receive 340B-discounted drugs, violates the any willing pharmacy provision if it is used to exclude 340B pharmacies from the PDP’s network. Such a requirement may only be “reasonable” and “relevant,” pursuant to 42 C.F.R. § 423.505(b)(18), if pharmacies that are unable to make the certification are immediately offered an alternative contract with reasonable terms and conditions (including a reasonable fee schedule).

Additionally, terms that indirectly preclude participation by 340B pharmacies are also unreasonable and violate the any willing pharmacy requirement. For example, we contend that an open pharmacy provision violates 42 C.F.R. § 423.505(b)(18) unless it includes a good cause exemption or unless the PDP is willing to amend the clause through the *Model Addendum*. Without such an exemption or amendment, an open pharmacy provision will exclude any 340B pharmacy that operates as a closed pharmacy in order to avoid impermissible diversion of 340B drugs to non-patients of the 340B entity. The only exception is if the pharmacy maintains dual inventories of 340B-discounted and non-340B-discounted drugs, a process that is impractical for many small pharmacies because of the associated costs and administrative burdens. Accordingly, an open pharmacy provision is unreasonable because it penalizes pharmacies for participating in a federal health care program, namely, the 340B program. Likewise, any fee schedule that unduly penalizes 340B pharmacies through patently unreasonable rates would constitute a violation of this regulatory provision.

Note that open pharmacy requirements are not only unreasonable because they exclude 340B pharmacies, they are unreasonable because they exclude many non-profit

providers and state- or locally-owned providers. These entities often maintain closed pharmacies in order to obtain discounted drugs under the Robinson-Patman and Non-Profit Institutions Acts. *See Jefferson County Pham. Ass'n v. Abbott Laboratories et al.*, 460 U.S. 150 (1983) (holding that state and local entities are not eligible for discounts under the Robinson-Patman Act if they are competing with private enterprises, *e.g.*, maintaining an open pharmacy); *see also* 15 U.S.C. § 13c (limiting non-profit institutions' discounts on drugs to the non-profit's "own use").

Finally, Medicare beneficiaries under the Medicare statute are entitled to FQHC services; thus FQHCs are expected to assure access to pharmacy services. As such, when a health center seeks to contract with a PDP, CMS should compel the PDP to contract with the health center to ensure that Medicare beneficiaries are not unduly discriminated against and their rights are not violated. In circumstances where the PDP's standard contract includes terms that preclude the FQHC from participating in the PDP's network, CMS should require the PDP, upon request, to adopt the *Model Addendum* (CMS has already adopted a similar measure at 42 C.F.R. § 423.120(a)(6) to ensure access for pharmacies that are operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization ("I/T/Us") – while Congress expressly permitted CMS to recognize the special status of I/T/U pharmacies at Section 1860D-4(b)(1)(C)(iv) of the Social Security Act, the statute does not preclude similar treatment of other unique types of pharmacies).

Access to PDPs' Standard Contracts

The Part D regulations require each PDP to develop a standard contract "whereby any willing pharmacy may access the standard contract and participate as a network pharmacy." 42 C.F.R. § 423.505(b)(18). We believe that many PDPs are failing to meet this condition of participation by making it difficult, if not impossible, for safety net pharmacies to access this standard contract.

A number of our members have indicated an inability to obtain standard contracts from PDPs. Such pharmacies have made numerous calls and sent e-mails to PDP contracting personnel, but have not received responses. While this problem is not specific to 340B pharmacies, it is especially problematic for the many safety net providers that do not have existing relations with PDPs and do not have resources to devote to arduous communications with unresponsive PDPs. In contrast, many retail pharmacies have longstanding relations with the PDPs (through participation in the PDPs' pharmacy benefit management networks prior to implementation of Part D) and have personnel devoted to network contracting.

While CMS has created a number of tools to aid pharmacies in contracting with PDPs, many safety net providers are nonetheless having difficulty getting through to appropriate individuals at the plans in order to obtain network participation contracts. For

example, a review of the plans' contact list which is posted on the CMS website found that the contact information was incorrect. Additionally, while CMS has provided a website in which pharmacies can express their interest in contracting with PDPs, we have received reports that such postings have been ineffective.

When a PDP does not respond to a pharmacy's requests for a contract, it is violating the condition of participation set forth at 42 C.F.R. § 423.505(b)(18) because it is not providing access to its standard contract. Additionally, it is violating the intent of the any willing pharmacy provision.

Recommendations

We recommend that CMS take a number of steps to resolve the problems outlined above:

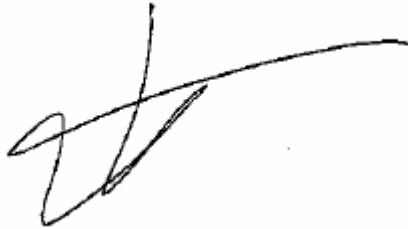
1. Issue guidance to PDPs stating that the categorical exclusion of 340B entities represents impermissible discrimination against low-income beneficiaries, in violation of 42 C.F.R. §§ 423.50(f) and 423.272(b)(2), and represents a violation of the any willing pharmacy law set forth at 42 C.F.R. §§ 423.120(a)(8)(i) and 423.505(b)(18);
2. In instances where CMS is made aware of discrimination against 340B pharmacies, issue warnings to such discriminatory PDPs and, if such warnings go unheeded, exclude such PDPs from continued participation in the Part D program;
3. Amend 42 C.F.R. § 423.120(a) by adding a subparagraph, similar to § 423.120(a)(6), that requires PDPs, upon request, to offer 340B pharmacies standard contracting terms and conditions that conform to the *Model Addendum* that CMS and HRSA jointly developed;
4. Develop and widely publicize a toll-free phone number for pharmacies to contact when they are experiencing difficulties with contracting with specific PDPs; and
5. When CMS receives reports of PDPs failing to provide their standard contracts, make such PDPs aware that they are in violation of their conditions of participation and that they risk penalties, such as termination of their Part D contract, if they do not remedy the problem.

We believe that such actions are necessary in order to ensure that low-income Medicare beneficiaries have access to the Part D program, and that 340B pharmacies are not unfairly excluded from this program.

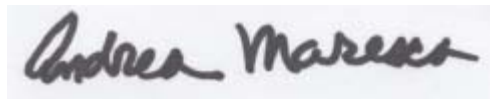
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If you have any questions or would like to discuss this matter further, please feel free to contact William von Oehsen, General Counsel for PHPC, at (202) 872-6765 or Andrea Maresca, Associate Director for Medicare and Medicaid Regulatory Affairs for NACHC, at (202) 296-0929.

Sincerely,



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