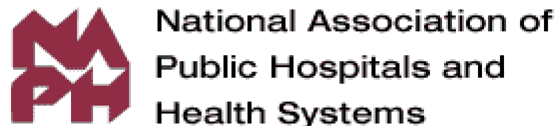

September 18, 2006

VIA ELECTRONIC MAIL

Cynthia Tudor, Ph.D.
Medicare Drug Benefit Group
Centers for Medicare and Medicaid Services
Room C1-25-27
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Baltimore, MD 21244-1850
PartDBenefitImpl@cms.hhs.gov

Re: Comments on Draft, Chapter 5 of the Medicare Prescription Drug Benefit Manual
Ref: Section 30 *et seq*., Counting of TrOOP and Safety Net Providers

Dear Dr. Tudor:

We are writing on behalf of the Public Hospital Pharmacy Coalition ("PHPC") and the National Association of Public Hospitals and Health Systems ("NAPH") to provide comments on the above referenced draft of Chapter 5 of the Medicare Prescription Drug Benefit Manual ("the Manual"). As we have previously communicated to the Centers for Medicare and Medicaid Services ("CMS") in previous correspondence of February 23, 2006,[1] and comments dated July 14, 2006 on draft Coordination of Benefits ("COB") Guidelines, we are especially concerned about CMS' policies respecting the counting of true out-of-pocket expenses ("TrOOP") for Part D beneficiaries, and guidance to Part D Prescription Drug Plans regarding contracting with safety-net pharmacies. Although we think the recently disseminated draft Manual provisions provide some helpful clarifications of CMS policies on these topics, we continue to believe that, based on the governing law and regulations, some further clarification and modification of CMS policy as currently articulated in the draft is in order.

PHPC is an organization of over 350 safety net hospitals and health systems that participate in the 340B drug discount program. 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 offer outpatient pharmacy services and have historically filled prescriptions for low-income populations,

[1] This paper bearing this date was entitled "The Impact on TrOOP Expenditure Calculations of Waivers or Reductions in Medicare Part D Cost-Sharing by Entities Receiving Public Funds."

including low-income Medicare patients and the dual eligibles. These safety net pharmacies are well positioned to play an important role in Medicare Part D by using their long-standing, trusted patient-provider relationships to assist this vulnerable patient population with plan enrollment and low-income subsidy applications.

The National Association of Public Hospitals and Health Systems (NAPH) represents more than 100 metropolitan area safety net hospitals and health systems. Our members are significant providers of care to low-income and uninsured patients. For example, approximately 28 percent of the outpatient services provided by NAPH members is to Medicaid recipients, approximately 16 percent is provided to Medicare patients and another 38 percent is provided to uninsured patients. NAPH members also provide certain essential specialized services to their entire communities, such as emergency and trauma care, burn care, and neonatal intensive care. Our members are multifaceted health systems, often operating facilities at multiple sites and frequently serving as major training centers for medical residents and interns.

Calculation of TrOOP

We have already explained, in previous comments on the draft COB Guidelines, our reasons for taking issue with CMS' position that voluntary waivers or reductions of prescription drug charges to Part D beneficiaries by safety-net pharmacies should be excluded from TrOOP. We will not reiterate in full here our rationale for this position, but refer you to our previous correspondence and comments, which are attached to this letter. A central point that appears to have been overlooked in formulating CMS policy as set forth in the draft Manual, as those previous submissions explain, is that Section 1860D-2(b)(4)(C)(ii) of the Social Security Act indicates a Part D beneficiary's costs of prescription drugs are countable towards TrOOP if they are paid for by the Part D eligible individual or another person on the individual's behalf and are not reimbursed through any of various possible sources constituting "third-party payment arrangements[s]."

Since, according to duly promulgated regulations implementing Part D Medicare provisions, a "third party payment arrangement" means "any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs,"[2] it follows that Part D beneficiary costs waived or reduced by a pharmacy are countable towards TrOOP unless the expense incurred by the pharmacy is reimbursed or funded according to some contractual or other legal obligation. In order to be consistent with federal statute and regulation and to support important public policy goals, CMS should adopt a policy that waivers or reductions in Part D cost sharing by public entities and others that receive public funds will count towards beneficiaries' TrOOP expenditures (as it does for commercial pharmacies) unless the costs are reimbursed through funding from a public program that explicitly cover pharmaceutical costs..

Even putting this continuing issue aside, however, we believe there are other aspects of TrOOP-counting policies for safety-net pharmacies that need clarification. Some confusion results, for example, from the point that the term "program" – which is

[2] 42 C.F.R. 423.100

repeatedly used in defining the concept of a "government funded health program" – is never separately defined. We believe that this term should be defined to make clear that, while hospitals or their pharmacies may carry out or be funded by "programs" of one type or another, neither hospitals nor pharmacies are "programs" *per se*. Thus, a hospital that is funded in whole or in part by government funds does not by mere virtue of this fact become a "government-funded health program" for Part D purposes, and would only meet the criteria for that designation if it used a government funding stream to covers some costs of waiving or reducing Part D beneficiaries' drug payments.

We also point out that in footnote 1, now appearing on page 20 of the draft Manual, the second sentence should be revised to reflect that if an entity pays for *a Medicare beneficiary's drugs under Part D of that program* (not if it simply pays for "drugs" of any description) using a mix of private and public funds, this Part D drug spending would be excluded from TrOOP.

In addition, although the draft Manual provides helpful clarification on the point that neither DSH hospital nor 340B hospital pharmacies are automatically assumed to act through or as a government-funded health program when they voluntarily waive or reduce Part D beneficiary co-payments, the Manual should expressly set forth the same clarification with respect to hospitals that are owned or operated by state or local governments. Consistent with the principles and definitions presently articulated in the draft Manual, if a government-owned or government-operated hospital funds its pharmacy's voluntary waivers or reductions of Part D beneficiaries' co-payments entirely through private donations or some other non-government funding stream, those cost waivers or reductions would be properly countable towards TrOOP.

Public hospitals and pharmacies, much like the rest of healthcare industry, utilize funds from a variety of sources including cross-subsidization from other payers (commercial payers, Medicare, Medicaid, SCHIP, etc.), charitable contributions, and revenue from non-patient care sources (flower and gift shops, parking garages, etc.). In some but not all cases, public hospitals may also receive subsidies from local or state governments, but these subsidies never cover all of the institution's unreimbursed costs and virtually every public hospital must aggressively pursue other sources to support. Thus, it is important that Chapter 5 be clarified to avoid any inaccurate misperception that Part D cost waivers or reductions by safety-net pharmacies in government-owned or government-operated facilities are necessarily TrOOP-excluded.

Further, we wish to reiterate our conviction that the suggestion that safety-net pharmacies should be encouraged or required to set up manual systems for recording and counting TrOOP entirely miscomprehends the level of difficulty, administrative burden, and disruption of services that would be associated with this task. CMS appears to have recognized these problems and adjusted TrOOP-counting policies accordingly in connection with retail pharmacies,[3] and the same considerations should shape TrOOP

[3] See Preamble to Medicare Part D Final Rule at 70 Federal Register 4240 (explaining the policy of permitting retail pharmacy's waivers or reductions of Part D costs to count towards TrOOP in part on the

policy with respect to safety-net pharmacies that, in this respect, contend with the same logistical challenges as private industry.[4]

Contracting With Safety-Net Pharmacies

Finally, we believe the discussion in the Manual of the "any willing pharmacy" requirement inadequately reflects CMS' obligation and commitment to enforce this statutory standard. By stating that it is "best left between the parties" to determine whether a Part D sponsor has permitted a pharmacy an opportunity to participate in its network, or whether a pharmacy can meet or has met contract terms that are "reasonable and relevant" as required by federal law and regulations, CMS appears to abdicate its proper regulatory and enforcement role. As we have previously commented in other documents, it is important that CMS issue clear guidance establishing that standard contracting terms are not "reasonable and relevant" and cannot be insisted upon by Part D Plans to the extent that they necessarily disqualify 340B covered entities or other safety-net pharmacies from a Part D Sponsor's network (such as by demanding a certification that the pharmacy does not participate in the 340B program or by requiring an open formulary).[5]

Notwithstanding the generally applicable principle of non-interference in Part D Plan contracting, this principle must be reconciled with implementation and enforcement of the any-willing-pharmacy requirement.[6] Such enforcement demands meaningful oversight by CMS to assure that safety net pharmacies are not excluded from Part D networks through standard terms and conditions that are overly restrictive, and clearer guidance to the effect that such terms and conditions will not be considered "reasonable and relevant" in compliance with programmatic standards of contracting. Absent such guidance, many safety-net pharmacies, especially 340B participants, are likely to be excluded from Part D participation, to the detriment of low-income beneficiaries and the Part D program as a whole. Not only would such exclusion deny low-income beneficiaries, a group especially likely to have limited transportation resources, the opportunity to fill their prescriptions at the same physical site where they receive health care, but it would interfere with the potentially important role safety net pharmacies can

basis that *not* making waivers or reductions of beneficiaries' cost-sharing count towards TrOOP would make counting of TrOOP too burdensome for Part D Plans).

[4] Indeed, it is difficult to comprehend how a safety net hospital could, on its own, comply with the TrOOP counting provisions of the Manual as currently drafted, unless and until a Part D plan were to develop the requisite system for recording, communicating and properly categorizing co-pay waivers and reductions.

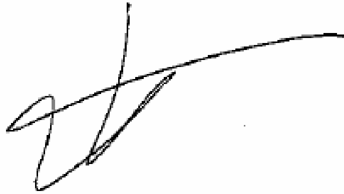
[5] As we have noted in previous communications, 340B pharmacies are precluded by 340B program requirements from offering open formularies, and therefore can be *de facto* excluded from contracting with a Part D plan insisting on this element in its standard contract with network pharmacies.

[6] CMS has a legal obligation to ensure that PDPs operate within the applicable requirements and standards of Part D. *See* 42 U.S.C. § 1395w-112(b). Consistent with that obligation, CMS has required its contracts with PDPs to include certain requirements, one of which is the "any willing pharmacy" rule. *See* 42 C.F.R. § 423.505(B)(18). Failure to meet any of those requirements is grounds for termination by CMS. § 423.509(a)(1). Thus, CMS has direct and explicit authority to enforce the "any willing pharmacy" rule.

play in assisting CMS and Part D plans to reach out to the difficult-to-enroll population of low-income Medicare beneficiaries.[7]

We thank you for your time and attention to this letter, and hope that you will give serious consideration to the points and recommended policy revisions suggested above.

Sincerely,



William von Oehsen General Counsel Public Hospital Pharmacy Coalition	Larry S. Gage President National Association of Public Hospitals and Health Systems

[7] As a study recently published in the journal *Health Affairs* recently confirmed, currently those with no prescription drug insurance coverage prior to Part D are among the populations with the lowest Part D enrollment rates. See articles at http://content.healthaffairs.org/cgi/content/abstract/hlthaff.25.w344.