



National Association of
Public Hospitals and
Health Systems



July 14, 2006

VIA ELECTRONIC MAIL

Cynthia Tudor, Ph.D.
Medicare Drug Benefit Group
Centers for Medicare and Medicaid Services
Room C1-25-27
7500 Security Boulevard
Baltimore, MD 21244-1850
drugbenefitimpl@cms.hhs.gov

Re: COB Guidelines; “Safety Net Providers”

Dear Dr. Tudor:

We are writing to comment on the draft 2007 Draft Continuation of Benefits (COB) Guidelines released for comment by the Centers for Medicare and Medicaid Services (CMS) on June 22, 2006.¹ We strongly urge CMS to reconsider its policies as reflected in the guidelines with regard to Safety Net Providers.²

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.

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

¹ CMS Memorandum, “Subject: 2007 Draft COB Guidelines.” From Cynthia Tudor, Ph.D., Acting Director, Medicare Drug Benefit Group to “All Part D plans” (June 22, 2006). Available at: <http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/NextYearCOBGuidelines.pdf> [Hereinafter “Draft COB Guidelines”]

² See Section of Draft COB Guidelines entitled “Safety Net Providers at 43-44.

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, 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.

Calculation of TrOOP

The members of our respective organizations have serious concerns about the TrOOP policy CMS is contemplating and the impact this policy would have on safety net institutions and the patients they serve. Not only do we believe such a policy would exceed CMS' legal authority, we also believe there are important operational and policy concerns that would support adoption of a much narrower policy.

Specifically, we believe CMS should exclude from TrOOP calculations only health care providers' waivers or reductions in Part D cost-sharing where the costs are actually reimbursed or paid through funding from a public program that provides coverage for pharmaceutical costs for individually identifiable patients. Using this rationale, we urge CMS to clarify in the COB guidelines that safety net pharmacies, including those based at public hospitals, are not generally considered "government-funded health programs." If they receive and use public funds for the purpose of covering pharmaceutical costs of low income patients including those enrolled in Part D, then the waiver or reduction of co-pays by the pharmacies should be excluded from TrOOP. Mere receipt of public funding alone, however, is not sufficient to establish the pharmacy itself as a government funded health program. Nor is a pharmacy's status as part of a public entity sufficient. Only if the pharmaceutical costs are reimbursed or paid by a public funding source distinct from the pharmacy or health care provider of which it is a part should such assistance be excluded from TrOOP.

Except for this situation, waivers or reductions in Part D cost-sharing by public entities and others that receive public funds would generally be included in TrOOP, just as CMS has already agreed to allow similar waivers or reductions by commercial pharmacies. The attached position paper, which has previously been provided to CMS, provides a detailed description of many of our legal, operational, and policy concerns.

Especially central to our concerns, however, is the spectre of a construction of CMS regulations and guidelines under which any receipt of funds not expressly ear-marked for a non-health care purpose by a safety net provider would disqualify that provider's pharmacy from affording TrOOP-eligible waivers or reductions of cost sharing amounts to indigent Part D beneficiaries, *irrespective of whether any public funds are actually used to reimburse or otherwise pay for those pharmacy expenses.* Implementation of any such policy would severely disadvantage and discriminate against safety net pharmacies and the indigent populations they serve, and would effectively but irrationally make a

safety net provider's acceptance of only modest public funding work to the detriment of the provider and its patients.

Such a policy would not implement the legitimate goal of preventing Part D Medicare benefits from supplanting other pre-existing sources of health care assistance. Instead it would unfairly burden safety net providers with potentially unending pharmaceutical care of indigent patients who cannot afford Part D cost-sharing, whose pharmaceutical treatment needs have in fact accumulated beyond the catastrophic level, but who are forever stalled in the Part D “doughnut hole.” It is noteworthy that relevant federal regulations define a “government-funded health program” as a “program” established, maintained, or funded – in whole or in part – by the Federal government or the governments of states or their political subdivisions, or any “agency or instrumentality” of these governments that “uses public funds” in whole or in part to provide to, or pay on behalf of, an individual the cost of Part D drugs.³

There is no rational basis for regarding a hospital or a safety-net pharmacy as a “program” within the meaning of this definition. Furthermore, even if a health care provider were deemed, potentially, to be a “program” in some sense “by virtue of arguably acting in some contexts as “agency” or “instrumentality” of government,” it is clear that the regulatory term “government-funded health program” could properly apply only when the entity in question “uses” some amount of public funds for Part D drug costs. We therefore ask that CMS revise its policy guidance to make clear that safety-net pharmacies’ waivers or reductions of Part D cost-sharing for indigent individuals should only be excluded from TrOOP where the pharmacy *actually uses public funds* to cover these waivers or reductions. The policy should be clear that mere receipt of some amount of public funding for indigent care by a safety net provider does not affect the counting of TrOOP for its patients, unless the facts support a conclusion that public funds are actually used in the provider’s pharmacy operations to fund Part D cost sharing reductions or waivers.

In addition below, we provide suggested edits to the COB discussion of safety net providers to clarify this issue:⁴

However, we clarify that, to the extent that the party paying for cost-sharing on behalf of a Part D enrollee is a group health plan, insurance, government-funded health program, or party to a third party payment arrangement that pays for covered Part D drugs, that party’s payment will not count toward TrOOP. Thus, payments made for beneficiary cost-sharing by any entity – including a safety-net pharmacy– that has an obligation to pay for covered Part D drugs on behalf of Part D enrollees, or which is reimbursed by or uses public funds (from Federal, State, and/or local government funding sources) for that purpose, will not count toward that beneficiary’s TrOOP expenditures.

³ See 42 CFR § 432.100

⁴ Draft COB Guidelines at 44.

Safety net pharmacies, including those based at public hospitals, are not generally considered government-funded health programs. However, if they receive public funds and use those funds for the purpose of covering pharmaceutical costs of low income patients including those enrolled in Part D, then the waiver or reduction of co-pays by the pharmacies should be excluded from TrOOP, because in that circumstance the public government source of funding constitutes a government funded health program. To the extent that safety-net pharmacies use government-funded health programs or other TrOOP-ineligible funding sources to waive or reduce any applicable Part D enrollee cost-sharing after payment of a claim by the Part D plan, that claim (whether electronic or paper, to the extent some of the more remote safety net pharmacies lack electronic capability), must be flagged such that any applicable beneficiary cost-sharing that is waived or reduced by the pharmacy is not added to a beneficiary's TrOOP balance.

In addition, we would like to express deep concern about CMS' proposal to recommend that Part D plans "set up manual processes with safety-net pharmacies in their network in order to accurately maintain beneficiary TrOOP balances."⁵ Such a recommendation conflicts directly with the current automated delivery and auditing systems that are integral to pharmacy delivery throughout the United States. Furthermore, given the volume of pharmaceutical care provided at large urban safety-net hospitals and other safety-net providers, such a "manual system" would create an enormous burden on safety-net providers that would result in a significant obstacle to the receipt of pharmaceutical care by Part D enrollees. We note that this burden has been clearly acknowledged by CMS in the preamble to the 2005 Medicare Part D Final Rule and, in part, serves as the basis for permitting the waiver or reduction in Part D cost-sharing requirements by commercial pharmacies to count towards TrOOP.⁶ **We urge CMS to reconsider this proposed recommendation and to recommend instead that Part D plans develop automated systems that will track TrOOP expenditures related to government-funded health programs and other sources of third-party coverage.**

Contracting with Safety Net Providers

NAPH and PHPC also take exception to the statement in the Draft COB Guidelines that "Part D sponsors are not required to contract with safety-net providers."⁷ There are occasions when Part D plans are required to accept safety-net providers into their pharmacy networks, namely, when failure to do so would violate the "any willing pharmacy" provision in the Medicare Part D statute.

⁵ Draft COB Guidelines at 44.

⁶ See 70 Fed. Reg. 4240 where CMS states "We will allow waivers or reductions in Part D cost-sharing by pharmacies to count toward TrOOP. Not allowing such waived or reduced cost-sharing to count toward TrOOP would make it more burdensome for Part D plans given the need to track down whether cost-sharing was actually incurred by a beneficiary rather than a pharmacy."

⁷ Draft COB Guidelines at 43.

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.”⁸ Additionally, the Medicare regulations require that a Part D plan “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.”⁹

The statutory and regulatory “any willing pharmacy” provision prohibits a Part D sponsor from categorically excluding safety net providers. Pursuant to the any willing pharmacy law, a 340B pharmacy that is willing to accept the plan’s standard terms and conditions should be entitled to participate in the plan’s network. Moreover, if the Part D sponsor includes standard terms and conditions that preclude a safety net provider’s participation, CMS should hold that such conditions are unreasonable and irrelevant and, therefore, violate the “any willing pharmacy” provision.

For example, 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 plan’s network. Such a requirement may only be “reasonable” and “relevant” 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 safety net providers are also unreasonable and violate the any willing pharmacy requirement. For example, we contend that an open pharmacy provision violates CMS regulations unless it includes a good cause exemption or unless the Part D plan is willing to amend the clause through the *Model Safety Net Pharmacy Addendum* that CMS developed jointly with the Health Resources and Services Administration last year. 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.

⁸ 42 U.S.C. § 1395w-104(b)(1)(A); *see also* 42 C.F.R. § 423.120(a)(8)(i).

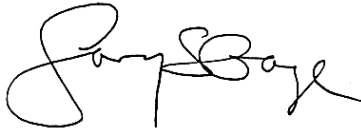
⁹ 42 C.F.R. § 423.505(b)(18) (emphasis added).

For the above reasons, we believe that the Draft COB Guidelines should be amended to clarify that there are situations when Part D plans are required to contract with safety net providers. We recommend that the language read as follows:

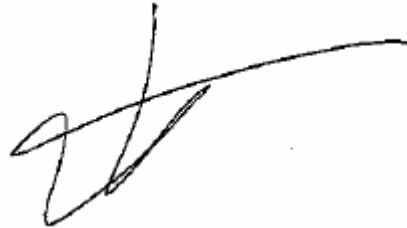
Part D sponsors are not required to contract with safety net providers unless the providers are willing to enter into a sponsor's standard contract and the terms and conditions of participation set forth in the contract are reasonable and relevant.

Thank you for your consideration in this matter. If you have any questions about these comments, please contact Frederick Isasi at (202) 624-3969 or fisasi@pogolaw.com or Bill von Oehsen at (202) 872-6765 or William.vonOehsen@ppsv.com .

Sincerely,



Larry S. Gage
President
National Association of Public Hospitals
and Health Systems



William von Oehsen
General Counsel
Public Hospital Pharmacy Coalition