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Re: Medicare Prescription Drug Benefit Manual – Draft of Chapter 5

Dear Dr. Tudor:

The following is submitted in response to your memorandum of September 5, 2006 requesting comment on the draft of Chapter 5 of the Medicare Prescription Drug Benefit Manual. These comments address the following sections of the draft of Chapter 5:

Section 30.3 Summary of TrOOP-Eligible and TrOOP-Ineligible Payers
Section 50.8.1 Any Willing Pharmacy Requirement

We request that the Centers for Medicare and Medicaid Services (CMS) consider these comments prior to issuing the final version of Chapter 5.

Background

The National Association of Community Health Centers (NACHC) is a membership organization representing Federally Qualified Health Centers (FQHCs) nationally. At present, more than 1,000 FQHCs with more than 5,000 sites serve approximately 15 million patients across the country, the vast majority of whom are impoverished individuals living in medically underserved areas. More than one million of these FQHC patients are Medicare recipients.

Section 30.3 Summary of TrOOP-Eligible and TrOOP-Ineligible Payers

Table 5 of this section includes FQHCs in the list of TrOOP-Excluded Entities. We believe that FQHCs should not be included in this list.

FQHCs do not necessarily use government funds, in whole or in part, to pay the cost of Part D drugs. Rather, FQHCs are non-profit charitable corporations that rely on a variety of sources to provide health care services, including revenue from private payers, public charitable donations, and State Pharmaceutical Assistance Programs. Moreover, so-call FQHC “look-a-likes” do not receive any federal grant funds under Section 330 of the Public Health Service Act despite meeting the qualifications for eligibility for such grant funds.

The other “entities” on the excluded list are distinctly federally-funded health care programs, such as Medicaid, Medicaid 1115 demonstrations, State Children’s health Insurance Program (S-CHIP), AIDS Drug Assistance Programs (ADAPs), Patient assistance programs (PAPs), TRICARE, and Federal Employee Health Benefits Program (FEHBP) plans. In contrast to such federal programs, FQHCs are a type of provider entity that must meet rigorous federal requirements to qualify for certain benefits and to become eligible for grant funding.

Section 30.4 (Pharmacy Waiver/ Reduction of Cost-Sharing and Applicability toward TrOOP) of the draft chapter states:

Receipt of Medicaid or Medicare Disproportionate Share Hospital (DSH) payments by a hospital does not, in and of itself, render a DSH facility (and any Part D network pharmacy it owns or operates) a “government-funded health program.” We view Medicare and Medicaid DSH funds essentially as adjustments to the Medicare and Medicaid reimbursements these facilities already receive for covered services, and not akin to government grants and funding that are used, in whole or in part, to provide to (or pay on behalf of) an individual the costs of Part D drugs.

This means that such Medicaid and Medicare DSH payments do not automatic designate a hospital as a TrOOP-excluded entity.

Applying this same logic to FQHC provider types, the receipt of Medicare and Medicaid revenue for covered services should not automatically result in the designation of an FQHC as a TrOOP-excluded entity.

For those reasons, FQHCs should not be automatically designated as a TrOOP-excluded entity.

Section 50.8.1 Any Willing Pharmacy Requirement

This section states that “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 in compliance with the law and our regulations (citation omitted) are fact-specific questions that are best left between the parties.”

In point of fact, 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 AWP 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 AWP rule.

Moreover, Congress’s inclusion of the AWP provision in the Part D statute reflects recognition that PDPs -- despite even the best efforts of CMS to encourage them to contract with safety-net pharmacies-- may sometimes be unwilling to contract with qualified pharmacies. *See*

Section 1860d-4(b)(1)(A) of the Social Security Act (“the Act”), 42 U.S.C. § 1395w-104(b)(1)(A). In such cases, there would be no contract if matters were actually left to the parties. Congress included the AWP provision in the Part D statute to prevent qualified pharmacies from being excluded from participation in Medicare Part D.

Accordingly, when a pharmacy requests protection under the AWP rule, CMS should inquire whether the contract terms offered to the pharmacy contain “reasonable and relevant terms and conditions of participation” that allow such pharmacy to participate in the network. 42 C.F.R. § 423.505(b)(18). Often, the standard retail contract offered by PDPs contains terms which conflict with the federal statute and regulations governing safety net pharmacies, preventing them from participating in the network. By declining to address what it calls the “fact-specific questions” raised by the standard retail contract, CMS has turned the AWP rule on its head, allowing it to be a mechanism for excluding certain pharmacies from participation rather than for including them.

We therefore request that this policy be reconsidered.