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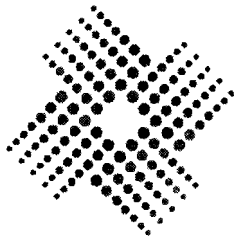

LTCPA

Long Term Care
Pharmacy Alliance

CMS-10185

August 7, 2007

RECEIVED
8/7/07

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Mr. Herb Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Bldg.
200 Independence Ave., SW
Washington, DC 20201

Re: Comments on Draft Medicare Part D Reporting Requirements for Contract Year 2008

Dear Administrator Kuhn:

The Long Term Care Pharmacy Alliance (LTCPA) represents the leading providers of comprehensive pharmacy services to residents of long-term care facilities. LTCPA members provide pharmacy services to more than 60 percent of America's nursing home residents.

We are pleased to have the opportunity to comment on these draft reporting requirements. Our comments will follow the outline of the draft document:

Introduction: CMS states that "*these requirements will be in effect for Contract Year 2008 and are subject to change at the discretion of CMS.*" We are concerned that, having taken the time to solicit feedback from stakeholders, that CMS has essentially created an escape clause that allows it to alter the requirements without further engaging the affected entities.

This is especially relevant, since CMS significantly altered its 2007 reporting requirements guidelines relative to long-term care pharmacy (LTCP) rebate reporting following submission to the Office of Management and Budget (OMB) without providing opportunity to comment on the additional burden implied by adding language that CMS reserved the right to require NDC-level data that was not included in the Federal Register notice under the Paperwork Reduction Act (PRA) submission to OMB.

Contractors and sponsors have an appropriate interest in knowing what is required prior to the beginning of the plan year, without wondering what additional information will be required later.

Section 1: LTC and Home Infusion Pharmacy Access: We believe it is critically important that CMS track Part D sponsors' LTC and home infusion pharmacy networks to assure that LTC-resident beneficiaries have appropriate access to services.

However, the level of reporting CMS envisions in the draft requirements is inadequate to ensure that networks are adequate. Because of the differences in pharmacy capacity and current relationships with nursing facilities, CMS should require plans to report the following information in addition to the information proposed in the draft document:

- ***Pharmacy capacity***: How many LTC residents can the pharmacy accommodate, given its location, physical size and employee configuration?

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- ***Pharmacy Contracts***: How many nursing facilities does the pharmacy currently contract with?

- ***Pharmacy Coverage***: How many residents of LTC facilities does the pharmacy currently serve within the region?

We believe the addition of this information will provide a more complete picture of the number of LTC residents for whom the Part D plan can provide appropriate pharmacy services. For example, if a plan reports that it has 10 LTC pharmacies under contract, but each pharmacy has the capacity to provide services to 500 residents, the total capacity of the LTC pharmacy network will be 5,000 residents. This would clearly be inadequate if the region contained 100,000 LTC beds.

Conversely, if the total capacity of the LTC pharmacy network was 90,000 beds, the appropriate inference would be that the network was of adequate size and scope to provide services to the majority of the residents within the region.

Section IV: Reversals: The experience of many LTC pharmacies during 2006, and continuing into 2007, has been that Part D sponsors have routinely misadjudicated claims based on the following general reasons:

- They do not have appropriate LIS status for institutionalized dual eligibles.
- They have not appropriately interpreted their obligations to provide coverage during the transition period.
- They have not provided appropriate access for beneficiaries whose prescriptions should be covered pending disposition of a medical exceptions or appeals request.

When the pharmacy attempts to re-bill the claim, the claim frequently reverses, but does not appropriately re-process with the correct payment.

We believe CMS could appropriately track this behavior by requiring plans to submit the reason for claim reversals, as well as the actual number of reversals processed.
If, for example, a plan had a high number of claim reversals for LTC pharmacies and the primary reason was "drug not covered", CMS could flag this as a key to determine whether these claim reversals were within the transition period and, therefore, were inappropriately reversed.

Section V: Medication Therapy Management Programs: It would be helpful and instructive for CMS to collect information from Part D sponsors on MTM program characteristics directed toward LTC residents. The collection of these data would demonstrate the extent to which plans have included this population in their MTM outreach efforts and indicate the impact of these programs on the quality of services provided to LTC residents under the benefit.

Section VIII: Grievances: Because of the medical condition of most residents of LTC facilities, combined with the responsibilities assumed by the caregivers, residents may not be aware of, or able to communicate, grievances that have the potential to impact their care.

For example, if a necessary drug is prescribed by the resident's attending physician and the plan does not follow the appropriate rules in determining coverage, the resident will not necessarily be aware of the problem. Most frequently, the caregiver, physician or pharmacist will attempt to intervene in order to obtain coverage for the necessary medication. In these instances, the beneficiary will not be in a position to file a grievance, thereby understating the problems associated in identifying coverage issues with any particular plan sponsor.

We believe, in the case of LTC residents, that caregivers should be allowed and encouraged to report grievances on behalf of a beneficiary related to cases in which the plan has clearly not fulfilled its obligation to provide appropriate service. These should be reportable by the plans and should be identified as specific to residents of LTC facilities.

Section X: Transition: We are pleased that since the previous draft, CMS had added reporting fields requiring plans to report their transition policies. Given the problems experienced by LTC residents in obtaining access to prescribed drugs during the transition period, we believe it is also important for CMS to require plans to submit data on the actual execution of those transition policies.. This will provide CMS with appropriate information to determine whether a plan's number of LTC beneficiaries is consistent with the number of prescriptions authorized for treatment under the transition rules.

In addition, to measure the effectiveness of the transition period in protecting beneficiaries, we urge CMS require an additional data element which would report the number of prescriptions denied during transition periods within the reporting period.

Section XI: Exceptions: The information requested in this section would be very useful, especially as it applies to residents of LTC facilities. Therefore, we would propose that CMS collect this information, segregated by ambulatory population and residents of LTC facilities.

Section XII: Appeals: The information requested in this section would be very useful, especially as it applies to residents of LTC facilities. Therefore, we would propose that CMS collect this information, segregated by ambulatory population and residents of LTC facilities.

Section XV: Long Term Care Pharmacy (LTCP) Rebates.

LTCPA is pleased that CMS has dropped the proposed new fields for "justification," "description" and "value" that were included in the previous draft. However, LTCPA continues to believe the LTCP rebate reporting requirements place an improper, unnecessary and counterproductive burden on long term care pharmacies, while providing no benefit to the Part D program. The reporting requirements also undermine market forces and threaten to significantly increase the costs of the Medicare and Medicaid programs. Therefore, we urge CMS to remove the entire section on LTCP rebate reporting form the 2008 Reporting Requirements.

Violation of the Noninterference Clause. The collection of LTCP rebate information constitutes an unacceptable interference by CMS in the "...negotiations between drug manufacturers and pharmacies and PDP sponsors..." which is specifically prohibited by the statute.[1]

CMS is well aware that LTC pharmacies negotiate confidential rebates and discounts with pharmaceutical manufacturers. CMS is also well aware that the release of Q&A # 6326 severely impacted the market negotiations between those parties. CMS is surely just as aware that each of those rebate and discount contracts are carefully structured to be compliant with express safe harbor provisions of the OIG antikickback regulations, 42 C.F.R. § 1001.952, and that each of the contracts contains strict confidentiality provisions prohibiting the disclosure of those terms to third parties.

Section 1860D-11(i) of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) explicitly prohibits CMS from interfering in any way with any price negotiations between manufacturers and pharmacies. The statutory language is quite plain:

> (i) Noninterference – In order to promote competition under this part and in carrying out this part, the Secretary - (1) **may not interfere with the negotiations between drug manufacturers and pharmacies** and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs *.Id.*, 42 U.S.C. § 1395w-111(i) (emphasis added).

The mandate to CMS is clear – it may not interfere with the competitive model that underlies Part D, or interfere with any negotiations between manufacturers and pharmacies on any topic, which would include rebates and discounts. Rather, Congress explicitly chose to leave pharmaceutical manufacturers, PDPs,

[1] § 1860D-11(i)

and pharmacies participating in Part D to engage in private negotiations about price concessions, including rebates. The language proposed by CMS in the draft 2008 Reporting Requirements flies in the face of this prohibition.

Not only is the statute clear on this point, CMS regulations amplified the Congressional proscription. More specifically, CMS incorporated this statutory prohibition into its reasoning in the promulgation of the Final Rule implementing the program. In addressing private sector price negotiation and formulary design, the agency stated that:

> The Act envisions that most price **negotiation including discounts, rebates, or other direct or indirect subsidies or remunerations** will take place between PDP sponsors or MA organizations (or their subcontractors) and pharmacies and pharmaceutical manufacturers. **We believe the Congress used the terms direct and indirect to be all inclusive in defining subsidies. Section 1860D-11(i) of the Act precludes us from interfering with negotiations between drug manufacturers and pharmacies**, or PDP sponsors, or requiring a particular formulary or pricing structure. 70 Fed. Reg. 4194, 4298 (Jan. 28, 2005).[2]

In addition, CMS noted that private negotiations between PDP sponsors and prescription drug manufacturers will be able to achieve savings comparable to or better than those that would result from negotiations between the government and manufacturers. 70 Fed. Reg. 4298 and 4468.

CMS' duties with respect to prescription drug prices are even further limited by regulation. In reviewing plans' bids, if CMS finds that a particular plan's price data differ significantly from those of other plans, the agency may exercise its authority under Section 1860D-11(b)(10(C) of the MMA to ensure the reasonableness of bids and ask the plan to provide information about its pricing structure and the nature of its aggregated price concessions from pharmaceutical manufacturers, including rebates, in order to determine whether the plan has negotiated "as vigorously as possible." 70 Fed. Reg. 4299. Procedures for these disclosures, which by rule are explicitly restricted to PDPs, and do not include LTC pharmacies, are reflected in 42 C.F.R. 423.104(g)(3).[3] CMS has assured stakeholders that it does not intend to use this authority as a "back door price control mechanism" to circumvent the prohibition on interference in Section 1860D-11(i). 70 Fed. Reg. 4300. Yet, that is precisely what CMS proposes to do here.

Clearly, CMS is prohibited by Congress and by its own rules to interfere *in any way* with negotiations between PDPs and pharmaceutical manufacturers and pharmacies, including long term care pharmacies. Although the agency speculated in the Preamble to its Final Rule that the competitive design of the Medicare Prescription Drug Program and the shift in formulary management from pharmacy to PDP might result in a change in who receives rebates from pharmaceutical manufacturers, with manufacturers being unlikely to continue to pay rebates both to large long term care pharmacy chains and PDPs (*See* 70 Fed. Reg. 4507-8), this agency speculation demonstrates that CMS is aware that its draft rebate disclosure requirements, if finalized, would have the effect of impacting the very pharmacy negotiations that Congress has prohibited CMS from addressing. Again, changes in LTC pharmacy rebate practices are reserved by Congress, and recognized by the CMS Final Rule, to be a matter solely between pharmaceutical manufacturers and long term care pharmacies. Only Congress can change that. For that

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[2] CMS reiterates this view multiple other times in the Preamble to the Final Rule. *See* 70 Fed. Reg. 4245-6, 4290, 4300-1 and 4396.

[3] Disclosure. (i) A Part D sponsor is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers, as well as data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers that are passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies paid by CMS on behalf of low-income individuals described in § 423.782, or in the form of lower monthly beneficiary premiums or lower covered part D drug prices at the point of sale. 42 C.F.R. § 423.104(g)(3).

reason, CMS's proposal contradicts the clear Congressional restriction on its interference with LTC pharmacy purchasing.

We have carefully considered CMS's statement that it has understood Congress to have intended the MMA to ensure that all pharmacy rebates and discounts are passed on to beneficiaries or the government (presumably by passing them through the PDPs). *See, e.g., Draft PDP Call Letter* at 8-9. CMS, however, has cited no authority for that proposition, nor is there any. Even if such legislative history existed, which it does not, it would necessarily fall in favor of the countervailing and explicit MMA language prohibiting CMS from interfering directly or indirectly with pharmacy-manufacturer negotiations, which necessarily includes rebates.

In the final regulation implementing the MMA, CMS had the opportunity, though notice and comment rulemaking, to regulate rebate reporting (although not the negotiations involving rebates). The agency chose not to exercise that authority.

Further, in his October, 2005, *"Report to Congress – Review and Report on Current Standards of Practice for Pharmacy Services Provided to Patients in Nursing Facilities,"* Health & Human Services Secretary Michael Leavitt provided Congress with an in-depth examination of LTCP rebates. The report explains how LTC pharmacies (LTCPs) acquire rebates and how LTCPs' "specialized services are likely partially subsidized by manufacturer rebates to the LTCP...."

In submitting his report, Secretary Leavitt informed Congress of his plans:

> *Section 107(b) of MMA requires a description of the plans of the Secretary to implement Part D, in a manner consistent with applicable State and Federal laws designed to protect the safety and quality of care of LTC facility patients. On January 28, 2005, CMS published the Final Rule implementing Title I (CMS-4068-F) and creating Part D plans (42 CFR Part 423). Taken together, the Final Rule and pertinent guidance materials constitute the plans of the Secretary, which are designed (a) to ensure the ongoing safety of LTC facility patients, consistent with applicable laws, (b) to encourage drug manufacturer rebate savings to be passed on to the patient, and (c) to reduce incentives for over-utilization that may exist when consultant pharmacists are not independent from the pharmacy."*

Further, in making his recommendations to Congress, the Secretary stated:

> *Section 107(b) requires the Secretary to provide recommendations regarding necessary actions and appropriate reimbursement to ensure the provision of prescription drugs to Medicare beneficiaries residing in LTC facilities, in a manner consistent with existing patient safety and quality of care standards under applicable State and Federal laws. The plans of the Secretary address the reimbursement and patient safety issues raised by the study conducted by CMS of current financing and delivery standards of practice. Consequently, the Secretary has no legislative recommendations at this time. However, given that Part D is a new program, it will be essential to monitor broadly early experiences with implementation. Specific issues to monitor carefully include (1) the degree to which LTC facilities will influence beneficiary plan choice and the ease with which beneficiaries make that choice, (2) the impact of Part D formularies on current drug regimens of beneficiaries and the smoothness of the transition to Part D, (3) whether LTC facilities will have to change LTCPs or work with multiple pharmacies, and if so, the impact of this shift from the one-to-one model, (4) the effectiveness with which LTC facilities and LTCPs manage multiple formularies, (5) the effectiveness with which plans manage the benefit in the LTC setting, (6) the effectiveness with which plans control drug costs for beneficiaries, (7) the financial impact on LTC facilities and LTCPs, (8) whether there will be increased competition among LTCPs, and (9) the degree to which LTCPs or Part D plans will have greater negotiating leverage. If necessary, the Secretary will make recommendations for actions based upon the implementation and early operational experiences of the Part D program.*

Therefore, as of October, 2005, Secretary Leavitt, based on a report prepared by CMS, reported to Congress that LTCP rebates had been examined in depth and that the final rule was designed "to encourage drug manufacturer rebate savings to be passed on to the patient." Also, in listing nine areas that required further monitoring, he did not list manufacturer rebates paid to LTCPs as an area that needed to be monitored.

In spite of the Secretary's October *Report to Congress*, CMS issued a Q&A document in November of 2005, questioning the practice LTCP rebates. This occurred after negotiations on network participation between pharmacies and PDP sponsors had been completed. Had CMS exercised its regulatory authority, through formal rulemaking, to regulate this practice, the negotiations between Part D plans and pharmacies would have been significantly different.

LTCPA filed comments objecting to the 2007 rebate reporting requirements issued by CMS. The 2008 draft reporting requirements represent an even more onerous burden on pharmacies compared to the 2007 requirements and, we believe, are not justified. The 2008 draft adds a mandate to report rebates at the 11-digit NDC level. This exceeds the current requirement and appears to exceed the level of information CMS expects plans to report on rebates received by plans from manufacturers. This, we believe is both contrary to statute, as previously described, and represents overreaching by the agency.

Interference in the Market: The MMA was a bold attempt by Congress and the Administration to allow the market, rather than federal government intervention, to provide an affordable drug benefit for Medicare beneficiaries.

CMS has expressed concern, belatedly, that the presence of rebate relationships between LTC pharmacies and manufacturers has the potential to create incentives for pharmacies and manufacturers to work against the interests of the drug plans and the government. We dispute this contention, based on the findings of Secretary' Leavitt's *Report to Congress*, in which the Secretary clearly pointed out that rebates are important in helping pharmacies provide services to residents that could not have been supported by reimbursement for ingredient costs and dispensing fees.

If CMS, or Congress, had made it clear that the practice of negotiated rebates between manufacturers and pharmacies was either contrary to policy or required extensive regulation, pharmacies would undoubtedly have negotiated marginally higher reimbursement to compensate for the reduction in expected rebate payments. This would have resulted in higher bid amounts by plans and higher costs to the government.

Given CMS' stated concern, it would appear that the market offers opportunities to guard against this perceived problem. First of all, the presence of institutional pharmacy rebates is well understood in the industry. Even if this were not the case, CMS' observations in the preamble to the final rule would have made even the casual observer aware of the practice.

Secondly, the market offers incentives for Part D plans, manufacturers and pharmacies to cooperate in using rebates as a tool to encourage formulary adherence and optimal outcomes.

LTC pharmacy formularies are lists of drugs that have a demonstrated record of efficacy in the LTC population. LTC pharmacies have the ability to influence the utilization of drugs within a formulary to the most appropriate drugs for institutionalized beneficiaries that provide optimal outcomes.

Part D plans, however, have significant power to enforce formularies through the power of the purse. If they deny payment for non-formulary drugs or erect barriers (e.g., prior authorization or step therapy) to access, the plan is capable of policing drug product selection.

Part D plans walk a tenuous line between rebate maximization, which helps control costs, and relatively open formularies, which increase the plan's appeal to beneficiaries. Manufacturers understand this process quite well. They realize that broad formularies are incompatible with sizeable rebates.

Since all parties to the transaction understand this process and the interrelationships among the various incentives, one possible outcome would be for the Part D plans to work with the manufacturers and the pharmacies to create incentives for appropriate drug product selection that results in maximizing the interests of all parties.

However, we should note that pharmacies have little opportunity to engage in what CMS believes is the major threat to the program related to pharmacy rebates: pharmacies working in opposition to the interests of the plan. It is simply not cost effective for pharmacies, motivated solely by rebate maximization, to attempt to encourage providers to change drug product selection. Indeed, since nursing homes are subject to comprehensive oversight by state agencies, such activity would soon be uncovered by surveyors and the nursing homes (who contract with pharmacies) would find themselves subject to enforcement action by the states.

Lack of confidentiality. Finally, the 2008 reporting requirements undermine the market function by essentially requiring LTCPs to make all of their drug manufacturer rebate data public, and threaten to increase the cost of the Part D program.

The 2008 reporting requirements require all plans to acquire data on all manufacturer rebates on all drugs from all of their network LTC pharmacies. It requires that the data be transferred from pharmacies to plans, rather than from pharmacies to CMS. In practice, all pharmacies would be required via their contracts with plans to submit identical comprehensive rebate data to every plan they contract with.

In neither its 2007 nor 2008 reporting requirements has CMS guaranteed confidentiality of this data or required PDPs to maintain confidentiality. There have been no guarantees that plans will not make this data publicly available, or that it won't be shared with drug manufacturers or other LTCP pharmacies. In fact, it could be reasonably assumed that this is CMS' intent for requiring this data to be reported to plans rather than to CMS – to allow the data to be used by plans in negotiations with other pharmacies and drug manufacturers.

Public disclosure of LTCP rebate data obviously distorts the marketplace, and would drive up the cost of the program. CMS should certainly understand this, as it has argued against providing drug pricing data to Congress[4] on the basis that public disclosure of drug pricing information makes it harder to negotiate lower prices from manufacturers, results in collusion, and drives up the cost of the program.

Increased Costs to Medicare & Medicaid. As noted in Secretary Leavitt's *Report to Congress*, LTCPs' "specialized services are likely partially subsidized by manufacturer rebates to the LTCP...." To the extent that such rebates are reduced, the cost of those additional services would have to be passed on to beneficiaries, plans and ultimately the Part D program; or to other providers such as nursing homes, which are funded by Medicaid.

As explained in the Leavitt report:

> *In today's environment, LTCPs provide many services to nursing facilities at little or no charge. ...Pharmacies can afford to offer extensive service to nursing facilities at no charge and still achieve acceptable margins because they can acquire and dispense drugs at costs that are substantially lower than their reimbursement rates for Medicaid and Medicare Part A, which cover the majority of nursing facility residents. In addition, to the extent that LTCPs can direct market share to specific drugs, they can also collect rebates from drug manufacturers. ....*
>
> *.... However, with the implementation of Medicare Part D, drug coverage for dual eligibles will no longer be provided by Medicaid and will instead be provided through a Prescription Drug Plan (PDP) or a Medicare Advantage plan that offers drug coverage (MA-PD). When this transition occurs, PDPs and MA-PDs will be the source of coverage for the great majority of nursing facility residents. This transition is likely to reshape the industry dynamics, as LTCPs may not be able to*

[4] See letter from CMS Acting Administrator Norwalk to Congressman Tom Davis, March 1, 2007

> *maintain as large a difference between drug acquisition costs and reimbursement, and may also not be eligible for rebates if the PDP or MA-PD sets the formulary. This raises the question of whether LTCPs will be able to continue providing customary services at little or no charge to nursing facilities or payers.*

In its June 2007 Report to Congress, MedPAC raises the same concerns:

> *Disclosing rebates could change the way LTCPs do business. Rebate information is highly proprietary, and we do not know the magnitude of those revenues. However, given that LTCPs have the capacity to achieve significant formulary compliance, it is reasonable to assume that rebates have been sizable (Lueck 2006). If manufacturers begin to reduce or eliminate rebates, LTCPs may need to begin charging explicit fees for services such as drug regimen reviews. In turn, this could have implications for other payers such as Medicaid.*

On the other hand, doing away or discouraging LTCP rebates would not save money for Part D plans and the Part D program. As discussed, LTCP rebates do not compete with rebates received by Part D plans. As LTCPs must adhere to Part D plan formularies, LTCP rebates do not subtract from Part D plans' ability to secure their own rebates. If LTCP rebates went away or declined, there would be no incentive for manufacturers to transfer the money spent on LTCP rebates to Part D plans. The result would be that a key saving to the program – manufacturer rebates used by LTCPs to finance unfunded mandated special services required by CMS – would be gone from the program, and the cost of the program would in fact have to be increased, or services decreased, or the cost passed on elsewhere, such as on to the nursing facility and Medicaid.

Also, it is worth noting that CMS's concerns regarding the impact of LTCP rebates runs counter to the judgment of state Medicaid programs which previously provided drug coverage for nursing home duals. LTCP rebates existed under the previous state Medicaid funding model and even though states, like PDPs under the Part D program, maintained their own formularies and received manufacturer rebates, they did not take action to block or discourage LTCP rebates. This suggests that CMS's speculation is out of line with the judgment of state Medicaid administrators who previously paid for LTCP services.

LTCP Rebates, Formularies and Utilization.

CMS states it is requiring plans to collect LTCP rebate data as "evidence that they are managing and monitoring drug utilization." Why CMS believes mandating collection of this data provides any such evidence is unclear.

Under a competitive system, it should not be necessary for CMS to drive plans to contain costs. If plans believe they would save money by having access to LTCP rebate data, they could pursue such a requirement via the contracting process, subjecting the plans and pharmacies to a negotiation over the costs and benefits of collecting and providing such data. Further, while plans are required to collect the data, the mere collection of it isn't "evidence" of anything other than the simple fact that it was collected. It is not clear that plans see any benefit in having the data, intend to the use the data, or even know how to use the data – or even if the data means anything to them.

According to the MedPAC June 2007 Report to Congress, "CMS is concerned the separate rebates LTCPs receive directly from drug manufacturers could interfere with the formularies Part D plans use and could raise program costs."

CMS incorrectly assumes LTCP formularies are akin to, and often in conflict, with PDP formularies. Equating LTCP and PDP formularies is an apples to oranges comparison, In general[5], PDP formularies have restrictions primarily for economic considerations, such as favoring less costly drugs over more costly drugs. PDPs can enforce their formularies by not paying for drugs that are not covered, or when their drug utilization management requirements are not met. In a competitive marketplace, PDP

[5] PDP do enforce some restrictions based on safety considerations.

formularies must balance the tension between having a broad enough formulary to attract enrollees, and a restrictive enough formulary to reduce costs. Having PDPs manage that tension was a key goal of Congress, which recognized its own limitations in managing that tension itself.

Unlike PDP formularies, LTCP formularies are advisory and primarily clinical in orientation. Some of the largest LTCPs have their formularies developed by outside professional organizations, as noted in the Leavitt Report to Congress:

> *Formularies created by LTCPs are developed specifically for the nursing facility population, taking into account the dynamics associated with the process of aging. These formularies are developed collaboratively among a committee of physicians, consultant pharmacists, and other health care professionals who have expertise in geriatrics and geriatric pharmacotherapy.*

MedPAC's Report to Congress also recognized the differences between LTCP and Part D plan formularies:

> *The nature of LTCP formularies differs somewhat from formularies that pharmacy benefit managers (PBMs) use. PBMs' formularies are continually updated lists of medications that a plan or payer will cover. A PBM covers all drugs listed on its formulary in some way; however, most formularies do not list all drugs and enrollees must pay out of pocket for drugs that are not listed. In addition, PBMs' formularies typically set different levels (tiers) of cost sharing or require that a particular condition is met before certain drugs or groups of drugs will be covered. By comparison, LTCPs' formularies are more advisory in the sense that the pharmacy generally does not decline to cover prescriptions, except for limited circumstances.*

In general[6], LTCPs do not decline to fill prescriptions for drugs that are not on an LTCP's formulary, except for significant clinical reasons. Therefore, LTCP formularies are not in conflict with a PDP formulary. Even when an LTCP formulary recommends a different drug than a PDP formulary does, the PDP holds the ultimate decision making power because it decides whether or not to approve the claim. LTCPs may have influence within a PDPs formulary, but do not have the practical ability to override or ignore it. Manufacturers may offer rebates as an incentive to LTCPs, but PDPs offer a greater economic incentive in deciding which claims are paid. Further, through use of drug management tools, such as requiring prior authorization, PDPs can make it cost ineffective for LTCPs to spend the time and resources required to influence the prescribing of a drug disfavored by a PDP. LTCPs typically receive rebates based on volume and market share.

CMS has also argued that it wants rebates reported for the purpose of having plans monitor utilization, suggesting that rebates provide an incentive for excess utilization. However, no evidence has been presented that rebates drive greater utilization. Utilization is determined primarily by the prescribing physicians, not the pharmacist, and physicians do not receive rebates. Further, consultant pharmacists are professionally obligated to make appropriate therapeutic recommendations, and it is often the case that those recommendations are for decreased utilization, not increased utilization.

Rebate Reporting Burden: In its Supporting Statement, CMS estimates the burden of complying with its Reporting Requirements to be: "Annualized wage burden per respondent = 60.11715 hours * $21.04/hour =$1,264.86"

Of course, this burden is the estimate for the Part D plans to comply with the full Reporting Requirements. What is not taken into account in this estimate is that in the case of LTCP rebate reporting, for example, almost the entire regulatory burden falls on the LTCP, not the Part D plan. The cost of compiling and reporting rebate information, particularly at the level of detail proposed by CMS, far exceeds the burden estimate just for rebate reporting alone. Simply in administrative terms, reporting rebate information as proposed under the Reporting Requirements is tremendously costly in terms of time, labor and expertise for the pharmacy to provide to the Part D plan.

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[6] In some cases, LTCPs may decline to fill a prescription for safety reasons.

Conclusion. In conclusion, we believe CMS' intention to continue to require LTC pharmacy rebate information to be reported to Part D plans is contrary to statute, violates fundamental market principles, creates unnecessary administrative costs and burdens, and threatens to drive up the cost of the Part D program. We urge CMS to eliminate the LTC rebate reporting requirement entirely.

Sincerely,

Darrell McKigney KJT

Darrell McKigney
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CMS-10185

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August 7, 2007

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RE: Medicare Part D Reporting Requirements for Contract Year 2008

Dear Ms. Harkless:

Aetna welcomes and appreciates the opportunity to comment on the 2008 Part D Reporting Requirements. We have reviewed the requirements (last updated 5/22/2007) and have included below for your consideration our comments and recommendations.

1. Section V, MTMP, data element J indicates "The number of beneficiaries whose participation status in the MTMP is ***pending*** during the specified time period above"; can CMS clarify how the term "pending" is defined for the purposes of this data element?
2. Section V, MTMP, regarding the data file to be submitted to CMS; the reporting timeline table only indicates a Period 2 submission. Was this intentional (i.e. a file will only be required for the Jan-Dec period), or was Period 1 inadvertently omitted from this table?
3. Section X, Transition, similar to the question above; the reporting timeline table only indicates a Quarter 1 submission. Was this intentional (i.e. data will only be required for Quarter 1), or were Quarters 2-4 inadvertently omitted from this table?
4. Section III, Vaccines, please confirm element F should read "....data elements B through **E**" (this measure currently indicates B through **F**).

If you have any questions regarding the information provided, please contact me at (215) 775-6617 or at LambertBA@aetna.com.

Sincerely,

Brett A. Lambert
National Regulatory and Compliance Manager