CMS-10185

(1)

November 9, 2007

CIGNA

OMB Human Resources and Housing Branch
Attention: Carolyn Lovett
New Executive Office Building, Room 10235
Washington, DC 20503

900 Cottage Grove Rd,
Bloomfield, CT 06002 3722E
Telephone 615.792.1313
linda.potts@cigna.com

RE: Draft 2008 Part D Reporting Requirements for public comment

Dear Ms. Lovett,

Below are CIGNA HealthCare Medicare Part D comments relating to the draft 2008 Part D Reporting Requirements published for public comment in the federal register on October 12, 2007.

Section III. Vaccines

Reporting Item B - The number of Part D vaccines administered in a clinic setting (e.g. physician's office) where the beneficiary retrospectively files paper receipts for reimbursement of the vaccine during the time period specified above.

CIGNA Comment: We do not have the ability to differentiate if a vaccine was administered in a clinic setting, this data is not captured by current business process nor would the data be available to us.

Reporting Item D - The number of vaccines processed through a paper enhanced process, where the provider used or navigated a process that facilitated out-of-network access during the time period specified above.

CIGNA Comment: Current business process does not process claims that providers submit, therefore no such claims are captured or can be measured for reporting.

Section V. Medication Therapy Management Program

I. Data elements

Reporting Item J - The number of beneficiaries whose participation status in the MTMP is pending during the specified time period above. This should be a subset of the number of beneficiaries who met the criteria for the MTMP in the specified time period and should only apply to period 1.

CIGNA Comments: Not applicable based on current program business processes. Within current program processes, we do not currently place members in "pended"

status. For purposes of reporting, can we designate as non-applicable, as our process for member enrollment is opt-out and we do not place members in pended status?

II. Data file to be uploaded using Gentran or Connect Direct at the Contract level.

CIGNA Comments:
Data file is new requirement; at present do not have data structure to support current feed. Please advise as to the acceptable file type. Must obtain Gentran or Connect-direct software for uploading file. Please advise as to preferred method and software. As a PDP plan, do not know if member is LTC resident. Cannot populate the LTC Enrollment field (Y or N).

Section VII: Home Infusion

CIGNA Comments:

As PDP plan, we do not know if a product has been administered by IV (assuming this means intravenous administration). Medication can be identified as injectables, however, depends on the drug and patient specific clinical needs, an injectable can be given subcutaneous, intramuscular, IV push or IV infusion.

As PDP plan, we do not pay for home infusion devices, i.e. IV pump, therefore we can not identify the beneficiary or the claim associated with home infusion drugs dispensed as part of a bundled service under a Part C supplemental benefit.

If the intent is to measure the number of members as well as their injectable drugs dispensed out of network home infusion pharmacies based on level of service (home infusion), that data are captured based on today's business process, though development work is needed to be able to report on those metrics.

If you need additional information related to these comments, please contact me at 615.792.1313.

Sincerely,

Linda Potts
Compliance Manager, CIGNA Senior Care
Medicare Part D

(2)

PRESCRIPTION PATHWAY℠
Medicare Prescription Drug Plans

Comments for 2008CY Draft Reporting Requirements.

Comments are on behalf of Pennsylvania Life Insurance Company, S5587 and American Progressive Life & Health Insurance Company of New York, S5825

Section I LTC and HI Pharmacy Access: This section requires the uploading of network lists for the reporting periods of 1/1-6/30 and 7/1-12/31. CMS is requiring the percentage of beneficiaries living within 2 miles of a pharmacy in urban areas. As pharmacies can be added and terminated to lists during each reporting period, we would recommend that the reporting requirement be "AS OF THE LAST DAY OF THE REPORTING PERIOD" for the period January – March 2008. The same reporting structures should be in place for suburban and rural areas as well.

Section II Access to Extended Day Supplies at Retail Pharmacies: Similar to Section 1, we recommend that reporting of TriCare standards be "AS OF THE LAST DAY OF THE REPORTING PERIOD" as it is a snapshot in time

Section III Vaccines: This section requires the number of vaccines processed, whether processed in a MD office, and how the vaccine was processed (paper, online, paper enhanced, web tool, etc.). We request CMS define the term "vaccine" to include only combination claims (vaccine and administration together on the same claim) and product-only claims to avoid duplicate reporting of the same vaccine event. Also, please define the terms "paper-enhanced", "provider", and "clinical setting" to clearly indicate what types of vaccine claims must be reported under which element.

Section VII Home Infusion Utilization: This section requests number of unique beneficiaries that have received infusion drugs as well as the total number of infusion doses. As there is not a clean definition of home infusion drugs, we would recommend that this element be modified to the number of claims filled by a home infusion pharmacy. Regarding total number of infusion doses, this element would be problematic, as number of doses is not supported by NCPDP billing at this time.

Section XV Long-Term Care Rebates: This section has been updated to allow sponsors to exercise discretion for requiring LTC Pharmacies to report rebate information if they serve less than 5% of LTC beds in the state which the pharmacy operates. If the LTC Pharmacy qualifies, the sponsor is then required to state, "Not required to report" in their submission. However, if the LTC is required to report, the sponsor must indicate "Noncompliant" on the report to CMS if no rebate information has been received. This whole section could be problematic, as it requires a sponsor to determine if a LTC Pharmacy serves more than 5% of LTC beds in the state. Sponsors do not currently have this type of information. "LTC claims" would be a better measure than "beds served", as a sponsor has access to LTC Pharmacy claim information.

BlueCross BlueShield of Texas

Medicare Contract Office (MCO)
901 S. Central Expresswy
Richardson, Texas 75080

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FAX COVER SHEET

DATE	11/13/2007	If you do not receive this transmission in its entirety, please call:			
NUMBER OF PAGES (including cover sheet)	3	Dinese Wilson	At	972-766-1641	

TO:	Attention: Carolyn Lovett OMB Human Resources and Housing Branch New Executive Office Building, Room 10235 Washington, DC 20503		FROM:	Dinese Wilson
PHONE:			PHONE:	972-766-1641
FAX:	202-395-6974		FAX:	972-766-0342 (x60342)
CC:			E-MAIL:	Dinese_Wilson@bcbstx.com

REMARKS: ☐ Urgent ☒ For Your Review ☐ Reply ASAP ☐ Please Comment

Message: Comments from HISC for the Medicare Part D 2008 Reporting Requirements

Medicare Part D 2008 CMS Reporting Requirements Review and Comments

Reporting Requirements Section		Changes
I.	Retail, Home Infusion, and Long-Term Care Pharmacy Access	• Under Section X Transition, it states only one quarter of data will be collected annually, is this the same concept for this section (i.e. this report is annual.)? • Is this where to find the current file for PDP? http://www.cms.hhs.gov/PrescriptionDrugCovContra/04_RxContracting_ApplicationGuidance.asp#TopOfPage Then on this page select the 2008 PDP Application [ZIP, 3.5MB] file, then select Medicare Beneficiaries by State, Region, ZIP 09302006 v2.xls. Is this a "national file"? How often is this file updated? • Is this where to find the current file for MA-PD? http://www.cms.hhs.gov/PrescriptionDrugCovContra/04_RxContracting_ApplicationGuidance.asp#TopOfPage Then on this page select the 2008 MA-PD Application [ZIP, 3.9MB] file, then select Medicare Beneficiaries by State, Region, ZIP 09302006 v2.xls Is this a "national file"? How often is this file updated? • If we do not own and operate our own retail pharmacy, do we indicate in HPMS 'No Data to report' or 'Zero,' in Section C & D?
II.	Access to Extended Day Supplies at Retail Pharmacies	• Please clarify that CMS is interested in the number of retail pharmacies that offer mail order rates for extended days supply only.
III.	Vaccines	• Does CMS only want the number of paper claims filed when specifically administered in a "clinic setting" or all paper claims filed on administrations. Why does the second part of the requirement state "reimbursement of the vaccine"? Is CMS interested in paper claims for administration or the vaccine or both combined, etc? Can you please define clinic? • We contract with DSI to act as an online vaccine clearinghouse between the physicians and our PBM, does this constitute as a web based tool?
V.	Medication Therapy Management Programs	• Regarding the Beneficiaries Eligible for MTMP Record Layout, will CMS allow null values or blanks in the "**Date MTMP enrollment**" field? Per the requirements this is a DATE REQUIRED field. This field could/should be empty for eligible non-participants. There will be no enrollment date when a participant declines enrollment to MTM. • Regarding the Beneficiaries Eligible for MTMP Record Layout, will CMS allow null values or blanks in the "**Date MTMP participation was declined**" field? Per the requirements this is a DATE REQUIRED field. This field could/should be empty for enrolled participants.

Reporting Requirements Section		Changes
		• Regarding the Beneficiaries Eligible for MTMP Record Layout, will CMS allow null values or blanks in the **"Date MTMP participation discontinued MTMP"** field? Per the requirements this is a DATE REQUIRED field. This field could/should be empty for enrolled participants. • Regarding the Beneficiaries Eligible for MTMP Record Layout, will CMS allow null values or blanks in the **"Reason participant discontinued MTMP"** field? Per the requirements this is a TEXT REQUIRED field. This field could/should be empty for enrolled participants.
VII.	Home Infusion Utilization	• Does "Part C" mean MA-PD plans only? • Does "Part C" mean just the sponsor's MA-PD plan?
XIV.	Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions	• Since rebates are reported at a point in time, in the case of any reinstatements due to reporting errors, when approved by CMS, will incorporation of prior rebates into the pending or received rebate buckets be allowable?
XV.	Long-term Care (LTC) Rebates	• Would CMS consider allowing LTC rebate reporting at the PBM level due to contracting arrangements?
XVII	Drug benefit analyses	• When performing Drug Benefit Analysis reporting for non-calendar year employer groups, what does CMS want plans to use as the starting date for the accumulation of TrOOP and year-to-date Covered Drug Costs? For Non-Calendar Year groups, should each group's renewal date be used, or should January 1 always be used regardless of whether or not the group's Plan Year begins at the start of the calendar year? • If the answer to the above question is "Use each group's renewal date as the starting date for TrOOP and Covered Drug Cost accumulation, "then what value of TrOOP is used to compare to such accumulations when the calendar year changes? For example, if a certain Non-calendar Year group's renewal date is September 1, 2007, is the TrOOP threshold for Drug Benefit Analysis reporting $3,580 through August 31, 2008, or does the TrOOP threshold for Drug Benefit Analysis reporting change to $4,050 on January 1, 2008?
	General	• Should enhanced alternative and OTC drug claims be excluded from reports as they were for 2007?

(4)

Medco Health Solutions Comments on CMS Draft 2008 Reporting Requirements

Section	Medco Question/Comment
Section I. Retail, Home Infusion and Long-Term Care Pharmacy Access	What month will the reference file for geo access reports be made available to current Part D sponsors, for the reporting time period January 1- March 31st?
Section III. Vaccine, Data Elements A-F	This section requires submission of the total number of vaccines for a given period (Data Element A), as well as the reporting of the number of vaccine claims processed through each listed method (Data Elements B-F). It should be noted the total of B-F may exceed the total listed in A, since a small number of beneficiaries may receive their vaccine at a pharmacy and then later have the vaccine administered in a physician's office. Additionally, this section refers to a "paper enhanced process, where the provider used or navigated a process that facilitated out-of-network access." Is this considered any process in which the provider, other than a network pharmacy, submits the claim to a Part D Sponsor for payment?
Section V. MTMP, Subsection I. J and Subsection II	CMS requires reporting of the number of beneficiaries whose participation status in the MTMP is pending during the specified time period above. We respectfully request clarification of the term "pending status." Does this refer to members who are eligible to participate in the program but did not contact the Part D Sponsor to opt in or opt out of the program?
Section VII. Home Infusion Utilization	This section requires reporting of home infusion drugs provided as part of a bundled service under a Part C supplemental benefit. Please confirm that this requirement applies only to MA-PDs, and not PDP Sponsors.
Section VIII. Grievances, Data Element M	In regards to the required submission of LIS grievances, please clarify the types of grievances that should be considered an LIS grievance. Does this pertain to situations where a member has a grievance regarding their LIS status, or does it apply to all situations where a grievance is filed by a member with LIS? Should a grievance concerning LIS status ,that is filed by a member who does not have LIS, be included in this category?
Section IX. Pharmacy & Therapeutics Committee/Provision of Part D Functions, Data Element B	Please provide a clarification regarding "organizations providing Part D functions." What organizations should be included in this category?
Section XVII. Drug Benefit Analyses, Data Elements B-E	For data elements B – E, please clarify the difference between the pre-initial coverage phase and the deductible phase of coverage. Is the pre-initial coverage phase considered the period between the deductible phase and the coverage gap?

PARTNERS Medicare

VIA FACSIMILIE

(6)

DATE: November 13, 2007
TO: **Carolyn Lovett**
COMPANY: OMB Human Resources and Housing Branch
RE: Comments on Draft 2008 Part D Reporting Requirements
FAX #: (202) 395-6974
FROM: Lisa Brown
PHONE#: (336) 201-4500
TOTAL OF PAGES: 1

Ms. Lovett:
In response to the e-mail of October 12, 2007, and on behalf of CMS contracts H3449, H3404 and S5540, I submit the following regarding Section V. of the draft 2008 Part D Reporting Requirements:

1. Please provide examples for element H- "The number of beneficiaries who discontinued participation from the MTMP for a reason not specified in data elements E-G during the specified time period above."

2. Please clarify the term "pending" as it relates to element J- "The number of beneficiaries whose participation status in the MTMP is pending during the specified time period above." Does this include members who have been contacted by the Plan for participation in the program but have not responded and/or members who have been identified but have not been contacted by the Plan to participate in the program?

Please feel free to contact me directly with any questions, via phone as listed above, or via e-mail at lisa.brown@partnershealth.com. Thank you for allowing review by our plans, and for considering our comments.

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HealthPartners

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(6)

November 9, 2007

OMB Human Resources and Housing Branch
Attn: Carolyn Lovett
New Executive Office Building, Room 10235
Washington, DC 20503

Subject: 2008 Part D Reporting Requirements

Dear Ms. Lovett:

Thank you for the opportunity to provide feedback on the 2008 Part D Reporting Requirements. Attached is a list of our comments and suggestions.

Please feel free to contact me at 952-967-5183 with questions regarding our comments.

Sincerely,

Tracy Pederson
Senior Medicare Programs Coordinator
HealthPartners

Hard copy sent by mail.

HealthPartners comments regarding
2008 Medicare Part D Reporting Requirements
November 5, 2007

Report	Comment
Section I – Retail, Home Infusion, and Long-Term Care Pharmacy Access	
Part D Sponsors should use the CMS reference file that provides counts of Medicare beneficiaries by State, region, and zip code.	Can CMS provide a link to this file?
For purposes of evaluating compliance with the LTC and home infusion pharmacy access standards, CMS will use data elements submitted by Part D Sponsors, as well as information from CMS reference files containing counts of nursing home beds and Medicare beneficiaries by State, region, and zip code.	Can this data be accessible to plans along with the formula for calculating adequate access?
A. Data elements to be entered into the HPMS at the Plan (PBP) level:	Does this include all PBP's i.e. individual and 800 series plans? Why is reporting at PBP level if contracted network is at contract or sponsor level?
1. The number of contracted retail pharmacies in a Plan's service area (State for PDPs and regional PPOs, and service area for local MA-PD plans) as of the last day of the reporting period specified above.	For 800 series plans, should we include eligible beneficiaries living outside of the service area since pharmacy count is service area. This makes a difference for PFFS where many beneficiaries may live outside the defined service area or should we just use "national" for the service area?
Section II – Access to Extended Day Supplies at Retail Pharmacies	
Reporting Period	Why is this measure biannual when the other access measures (Section I) are annual. We recommend changing to an annual reporting cycle.
Data elements	What is the value of a raw number with no relation to the number of beneficiaries, size of overall network/service area, etc? What is the criteria for success on this measure?

HealthPartners comments regarding
2008 Medicare Part D Reporting Requirements
November 5, 2007

	Can this be reported at the contract level instead of PBP level since the networks are the same and they're not tying back to PBP enrollment?
Section III – Vaccines	
	Please specify vaccines that should be included. What is the value to CMS of receiving this breakout? Could they just collect an aggregate number and include list of sources to be included in the instructions? We could keep break-out counts in our reporting documentation for audit.
Section VII. Home Infusion Utilization	
A. The number of Part D beneficiaries receiving Part D-covered home infusion drugs dispensed by any of its network providers as part of a bundled service under a Part C supplemental benefit in the time period specified above (if applicable).	Bundling language is confusing. Please clarify. MA-PDs may be able to report this data, but how would PDPs without access to medical claims know?
Section XVII. Drug benefit analysis	
	Please clarify source data should be plan enrollment data rather than CMS MMR data. Especially in light of previous enrollment and LIS discrepancies.

LTCPA

Long Term Care
Pharmacy Alliance

November 12, 2007

Carolyn Lovett
OMB Human Resources and Housing Branch
New Executive Office Building, Room 10235
725 17th Street NW
Washington, DC 20503

Re: Comments on Draft Medicare Part D Reporting Requirements for Contract Year 2008
Federal Register Notice, October 12, 2007, page 58096

Dear Ms. Lovett:

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. **In particular, I would like to bring to your attention our comments on Section XV, the reporting of long term care pharmacy rebates.**

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:

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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 from 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 # 5326 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).

[1] § 1860D-11(i)

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, 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(q)(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

[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).

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

We have carefully considered CMS' 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. 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 simply 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. 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"

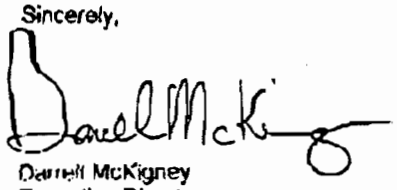
Of course, this burden is the estimate for the Part D plans to comply with the full Reporting Requirements. What is not taken into account in this estimate is that in the case of LTCP rebate reporting, for example, almost the entire regulatory burden falls on the LTCP, not the Part D plan. The cost of 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.

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

We note that since the previous draft of the reporting requirements, CMS has added an exemption for pharmacies with less than 5% of the beds in an area. We see this as an acknowledgement of the burden imposed by the rebate reporting requirement. While this exemption is a start in the right direction of lifting this burden, the real solution remains to lift the rebate reporting requirement entirely for all long term care pharmacies.

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 drop the LTC rebate reporting requirement entirely.

Sincerely,



Darrell McKigney
Executive Director
Long Term Care Pharmacy Alliance
1776 Massachusetts Avenue, Suite 410
Washington, D.C. 20036
(202) 386-7559

Fax transmittal

6

Date:	November 19, 2007
Attention:	Carolyn Lovell
Company name:	OMB Human Resources and Housing Branch
Fax number:	(202) 395-6974
From:	Dawn Mathson Al
Company name:	Blue Cross and Blue Shield of Minnesota and Blue Plus P.O. Box 64560 St. Paul, MN 55164-0560
Telephone number:	651 662-6861
Fax number:	651 662-6861
Pages to follow:	1
Message:	Enclosed pleased find our organization's comments on the draft 2008 Part D Reporting Requirements in response to the request in the Federal Register.

2008 Part D Reporting Requirements Section	Questions/Comments
GENERAL	Please clarify whether enhanced alternative and OTC drug claims be excluded from reports as they were for 2007?
Section I. Retail, Home Infusion, and Long-Term Care Pharmacy Access	Will CMS also be requesting GEO Access report supporting Data Elements A1-A3?
Section III. Vaccines	Please clarify the following. • Are plans to report the number of paper claims filed for vaccines specifically administered in a "clinic setting" or all paper claims filed for administration? • Are plans to report paper claims for administration, the vaccine, or both?
Section V. Medication Therapy Management Programs	Regarding the Beneficiaries Eligible for MTMP Record Layout, will CMS allow null values or blanks in the "Date MTMP enrollment" field? Per the requirements this is a DATE REQUIRED field. This field could/should be empty for eligible non-participants. There will be no enrollment date when a participant declines enrollment to MTM. Regarding the Beneficiaries Eligible for MTMP Record Layout, will CMS allow null values or blanks in the "Date MTMP participation was declined" field? Per the requirements this is a DATE REQUIRED field. This field could/should be empty for enrolled participants. Regarding the Beneficiaries Eligible for MTMP Record Layout, will CMS allow null values or blanks in the "Date MTMP participation discontinued MTMP" field? Per the requirements this is a DATE REQUIRED field. This field could/should be empty for enrolled participants. Regarding the Beneficiaries Eligible for MTMP Record Layout, will CMS allow null values or blanks in the "Reason participant discontinued MTMP" field? Per the requirements this is a TEXT REQUIRED field. This field could/should be empty for enrolled participants.
Section XIV. Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions	Please clarify what CMS' expectations are on the reporting of Prior Rebates when restating prior reporting periods?

WELLPOINT

9

November 13, 2007

OMB Human Resources and Housing Branch
Attention: Carolyn Lovett
New Executive Office Building, Room 10235
Washington, DC 20503
Fax Number: (202) 395-6974

Dear Carolyn:

With regards to the proposed information,

Title: 2008 Part D Reporting Requirements
Date: 10/12/07
Summary: In accordance with the Paperwork Reduction Act of 1995, today we are posting the draft 2008 Part D Reporting Requirements for public comment in the federal register http://cms.hhs.gov/PaperworkReductionActof1995/PRAL/list.asp?listpage=1. CMS welcomes comments from the public on all items set forth in these documents. To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on November 13, 2007.

Please find WellPoint's comments regarding the draft 2008 Part D Reporting Requirements below:

[illegible]	[illegible]	[illegible]
I. Retail, Home Infusion, and Long-Term Care Pharmacy Access	New section	• Need clarification from CMS if their definition of Medicare beneficiaries includes plan enrollees or is it all Medicare beneficiaries residing within the pharmacy network. • Do plan sponsors have to cross-reference the CMS reference files to enrollee data? If yes, then there may be constraints in providing pharmacy access data at the PBP level • Need clarification from CMS as to the threshold that CMS uses to determine if a PBM has met Long Term Care Pharmacy access requirements. Their current guidance (Chapter 5 Section 50: (http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDMChap5BeneProtections_03.09.07.pdf) states they use a formula of # of LTCPs divided by the number of eligible nursing home beds. What is the "passing" percentage?

III. Vaccines	New section	• Implementation of this new reporting requirement will not pose any challenges with the exception of Item D – Item D (The number of vaccines processed through a paper enhanced process, where the provider used or navigated a process that facilitated out-of-network access during the time period specified above) refers to physician paper claims (standardized claim form-CMS 1500 or Accredited Standards Committee (ASC) X12 electronic format) • Accredited Standard Committee (ASC) claims are currently not part of the PBM claims systems and it may not be possible to adjudicate such claims
VII. Home Infusion Utilization	New section	• Need clarification from CMS if this reporting section is limited to MA-PDs since Part C bundling for home infusion (HI) services is mentioned. However, the use of "Part D beneficiaries" within this element causes confusion if those under Part C are considered enrolled in a MA-PD and would not need to be in a separate category • Need clarification from CMS on the definition of Medicare beneficiaries within the reporting sections: "Part D beneficiaries" is used in this section and "enrollees" and "beneficiaries" are used in other sections • Part C claims are not adjudicated by WellPoint NextRx and therefore Part C HI bundled service claims would not be a PBM deliverable
IX. Pharmacy & Therapeutics (P&T) Committees/Performance of Part D Functions	Section was renamed to reflect incorporation of Performance of Part D Functions from subsection 4 of the Licensure & Solvency Data elements revised: A1-2 and B1-2 that drop-down box is no longer used.	• Need clarification from CMS as to what other entities, besides a Part D Sponsor, constitute an "organization" within this data element
XIII. Overpayment	No change	• CMS needs to clarify their current definition of an overpayment as provided in the CY07 Reporting Requirements FAQs. Further definition will allow for more accurate data collection and reporting

XVII. Drug benefit analyses	Section to be reported monthly Data elements added: • C. Number of LIS enrollees in the deductible phase as of the last day of the month. • D. Number of LIS enrollees in the pre-initial coverage limit phase as of the last day of the month • F. Number of non-LIS enrollees in the deductible phase as of the last day of the month. • G. Number of LIS enrollees in the coverage gap as of the last day of the month • I. Number of LIS enrollees in the catastrophic coverage level as of the last day of the month.	• Need clarification from CMS if WellPoint will also need to pull those members who are in a plan without a deductible, due to the fact they will still potentially be in the deductible phase even though their benefit may not have a deductible • Items C, D, G, and I- LICS members will need to be extracted which may present a difficult task for the PBM and must be lead by a significant effort

Sincerely,

Carolyn Haynes
Vice President of Compliance
Senior Business

National PACE Association

801 N. Fairfax Street, Suite 309
Alexandria, VA 22314
Phone: 703/535-1565 • Fax: 703/535-1566
Web site: www.npaonline.org

10

TO: Carolyn Lovett
FAX: 202-395-6974
PHONE:
RE: PACE Part D appl.

FROM: Chris VanRaemen
PHONE: (703) 535-1568
DATE: 11/13/07
OF PAGES (with cover): 2

Please see attached.

National PACE Association

November 11, 2007

OMB Human Resources and Housing Branch
Attention: Carolyn Lovett
New Executive Office Building, Room 10235
Washington, DC 20503
Fax Number: (202) 395-6974

In reviewing the Medicare Part D Application for New PACE Organizations for the 2009 Contract Year, the National PACE Association (NPA) would like to comment in regard to the attestations required of PACE organizations related to Claims Processing. In the 2007 version of the application, applicants attested to their ability to either:

a) Contract with a third party that agrees to develop and operate an on-line claims processing systems that operates in real time to ensure accurate and timely payment of all claims submitted by network pharmacies, OR

b) Have internal procedures in place to assure accurate and timely payment of all claims submitted by network pharmacies.

In the 2009 Part D application, option (b) is no longer listed.

We are concerned that omission of option (b) results in a requirement that PACE organizations must process claims in real time regardless of how they organize the provision of Part D drugs to their enrollees. Unlike typical Medicare beneficiaries, PACE enrollees, all of whom are certified eligible for nursing home level of care, generally do not acquire their drugs from local pharmacies. Rather, PACE organizations arrange for medications to be delivered to enrollees in the PACE center or in their homes. Also, under PACE regulatory requirements, PACE organizations are prohibited from charging their enrollees cost-sharing amounts so real time processing is not required at the point of sale. NPA is concerned that this new requirements will impose a very substantial burden on PACE organizations that is not warranted in order to insure the appropriate administration of the Part D benefit at the beneficiary level.

We are hopeful that CMS and others as appropriatewill engage NPA and its PACE provider members in a dialogue in order to fully understand the impact of a requirement for "an on-line claims processing system that operates in real time" before imposing such a substantial new requirement on PACE providers.

For questions and further follow-up, please contact Chris van Reenen at the NPA at (703) 535-1558 or chrisvr@npaonline.org.

KAISER PERMANENTE®

Kaiser Foundation Health Plan, Inc.
Legal Department
393 E. Walnut, 2nd Floor
Pasadena, CA 91188
626-405-5482 Direct
626-405-6726 Facsimile

Facsimile transmittal

Date:	November 12, 2007
To:	Carolyn Lovett, OMB Human Resources and Housing Branch
FAX:	(202) 395-6974
From:	Amy Hafey, Senior Counsel
Phone:	Direct Line 626-405-5494
Subject:	Comments to Proposed Part D Reporting Requirements
Pages to follow:	

☐ **Urgent**	☐ **For Review**	☐ **Please Comment**	☐ **Please Reply**

Comments:

Kaiser Foundation Health Plan, Inc.
Comments to CMS Draft 2008 Part D Reporting Requirements
Submitted November 12, 2007

1. Section I, Retail, Home Infusion, and Long-Term Care Pharmacy Access (Data Element A): CMS is proposing that Part D Sponsors provide information on the percentage of Medicare beneficiaries living within 2 miles of a retail network pharmacy in urban areas, 5 miles of a retail network pharmacy in suburban areas, and 15 miles of a retail network pharmacy in rural areas. However, this Data Element should not apply to plans that have a waiver of the convenient access standard for retail pharmacies. (All of the Kaiser Foundation Health Plans have such waiver). This is because Part D Sponsors with this waiver fill a majority of prescriptions in pharmacies they own or operate and convenience is imputed based on fact that pharmacies are generally co-located with medical facilities. Therefore, access is measured by a different metric, and the mileage information is not relevant.

2. Section I, Retail, Home Infusion, and Long-Term Care Pharmacy Access (Data Elements C and D): CMS is proposing that Part D Sponsors that have received a waiver of the any willing pharmacy requirement, and a waiver of the convenient access standards report, by Plan Benefit Package number, the number of prescriptions provided by all owned and operated pharmacies and all contracted pharmacies. (All but one of the Kaiser Foundation Health Plans have a waiver of the any willing pharmacy requirement). Part D Sponsors should also be given the opportunity to report this information on a contract wide basis, so that CMS can assess whether a Part D Sponsor's particular PBP that may not meet the standard is meaningful in the context of the Sponsor's actual pharmacy delivery system, rather than an anomaly of a very small enrollment PBP that has a higher proportion of nonplan pharmacy prescriptions. For example, one of the Kaiser Plans has a PBP with enrollment of 23 members; another Kaiser Plan has a PBP with enrollment of almost 141,000 members.

3. Section VII, Home Infusion Utilization: CMS is proposing that Part D Sponsors provide information on the number of Part D beneficiaries receiving Part D-covered home infusion drugs dispensed by any of its network providers as part of a bundled service under a Part C supplemental benefit, as well as the total number of associated claims. We are requesting clarification regarding whether this requirement applies to Cost Contractors that offer home infusion services as a medical benefit.

FACSIMILE TRANSMITTAL COVER SHEET

DEPARTMENT NAME | FAX NUMBER

Date 11/14/07 Time

To Carolyn Lovett At OMB Human Resources & Housing Branch

From Deb Swenson At Wisc. Physicians Service

Following this cover page, 1 page(s) will be transmitted. If problems occur in transmission, or all pages are not received, please contact us at:

(608) 226-2693 Ext. .

Operator: DS

Comments: Hello Carolyn. I am so sorry that we are a day late with getting our comments back to you on the 2008 Part D Reporting Requirements. Our Contract # is S5753. I hope you will still accept these. You can reach me at (608) 226-2693. Thank you,

WPS HEALTH INSURANCE
Wisconsin Physicians Service Insurance Corporation
1717 W. Broadway - Madison, WI 53713
(608) 221-4711
www.wpsic.com

THE EPIC LIFE INSURANCE COMPANY
P.O. Box 8430 - Madison, WI 53708

Wisconsin Physicians Service (WPS) Comments on CMS Draft 2008 Reporting Requirements

Section	WPS (Contract S5753) Question/Comment
Section I. Retail, Home Infusion and Long-Term Care Pharmacy Access	What month will the reference file for geo access reports be made available to current Part D sponsors, for the reporting time period January 1 - March 31st?
Section III. Vaccine, Data Elements A-F	This section requires submission of the total number of vaccines for a given period (Data Element A), as well as the reporting of the number of vaccine claims processed through each listed method (Data Elements B-F). It should be noted the total of B-F may exceed the total listed in A, since a small number of beneficiaries may receive their vaccine at a pharmacy and then later have the vaccine administered in a physician's office. Additionally, this section refers to a "paper enhanced process, where the provider used or navigated a process that facilitated out-of-network access." Is this considered any process in which the provider, other than a network pharmacy, submits the claim to a Part D Sponsor for payment?
Section V. MTMP, Subsection I. J and Subsection II	CMS requires reporting of the number of beneficiaries whose participation status in the MTMP is pending during the specified time period above. We respectfully request clarification of the term "pending status." Does this refer to members who are eligible to participate in the program but did not contact the Part D Sponsor to opt in or opt out of the program?
Section VII. Home Infusion Utilization	This section requires reporting of home infusion drugs provided as part of a bundled service under a Part C supplemental benefit. Please confirm that this requirement applies only to MA-PDs, and not PDP Sponsors.
Section VIII. Grievances, Data Element M	In regards to the required submission of LIS grievances, please clarify the types of grievances that should be considered an LIS grievance. Does this pertain to situations where a member has a grievance regarding their LIS status, or does it apply to all situations where a grievance is filed by a member with LIS? Should a grievance concerning LIS status ,that is filed by a member who does not have LIS, be included in this category?
Section IX, Pharmacy & Therapeutics Committee/Provision of Part D Functions, Data Element B	Please provide a clarification regarding "organizations providing Part D functions." What organizations should be included in this category?
Section XVII. Drug Benefit Analyses, Data Elements B-E	For data elements B – E, please clarify the difference between the pre-initial coverage phase and the deductible phase of coverage. Is the pre-initial coverage phase considered the period between the deductible phase and the coverage gap?

AMCP Academy of Managed Care Pharmacy

CELEBRATING AMCP'S 20th ANNUAL MEETING
APRIL 16-19, 2008 • MOSCONE WEST CONVENTION CENTER • SAN FRANCISCO, CA •

19

November 8, 2007

OMB Human Resources and Housing Branch
Attention: Carolyn Lovett
New Executive Office Building, Room 10235
Washington, DC 20503
Fax Number: (202) 395-6974

Subject: Medicare Part D Reporting Requirements

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide comments on the Centers for Medicare & Medicaid Services' (CMS') Medicare Part D Reporting Requirements for Contract Year 2008.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's 5,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

The Academy appreciates that the required data elements contained in the Medicare Part D Reporting Requirements for Contract Year 2008 are each individually important to provide the information that CMS could use to evaluate plan performance on required aspects of the Part D benefit. However, AMCP is concerned about the amount of time required by staff of a prescription drug plan or Medicare Advantage plan to complete these reporting requirements and the attendant costs to both the Program and beneficiaries. The Academy respectfully asks CMS to make absolutely certain that each data element requested is necessary to ensure proper oversight of Part D.

100 North Pitt Street
Suite 400
Alexandria, VA 22314
800 827 2627 / 703 683 8416
Fax 703 683 8417
www.amcp.org

If you have any questions regarding our comments or require any additional information, please do not hesitate to contact me at (703) 683-8416 or at jcahill@amcp.org.

Sincerely,

Judith A. Cahill
Executive Director

SecurityHealth Plan

Underwritten by
Security Health Plan of Wisconsin, Inc.

1515 Saint Joseph Avenue
P.O. Box 8000
Marshfield, WI 54449-8000

1-800-472-2363 *OR* 715-221-9555
FAX 715-221-9500

www.securityhealth.org

Fax Cover Sheet

Today's date: 11/12/07

No. of pages (including cover sheet): 2

To:	OMB Human Resources and Housing Branch, Attn: Carolyn Lovett	**Fax #:**	202-395-6974
From:	Contract No. H5211, Security Health Plan of Wisconsin, Inc.	**Phone #:**	800-472-2363

Comments:

Re: 2008 Part D Reporting Requirements - Comments

Per your request in an email from HPMS dated 10/12/07, attached is a list of comments for the proposed information collections on the draft 2008 Part D Reporting Requirements to be sent to you by 11/13/07. Thank you for your consideration.

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2008 Reporting Requirements – Comments

Section I. Retail, Home Infusion, and Long-Term Care Pharmacy Access

Are the data elements in Section A 1.-3. to be reported the same as we had to provide for the initial Pharmacy Access Analysis ? (ex. Urban = 2miles, Suburban = 5miles, Rural =15miles) ? We are a local MA-PD with a predominantly rural geographic area. On our initial geoNetworks report we had no counties that qualified as Urban so would we answer question #1 as ZERO?

Section VII. **Home Infusion Utilization**

Comment about following data elements :

A. The number of Part D beneficiaries receiving Part D-covered home infusion drugs dispensed by any of its network providers **as part of a bundled service under a Part C supplemental benefit** in the time period specified above (if applicable).
B. The total claims associated with Part D-covered home infusion drugs dispensed by any of its network providers **as part of a bundled service under a Part C supplemental benefit** in the time period specified above (if applicable).

Both elements mention bundled service under a Part C supplemental benefit. How do stand alone PDP's or MA-PD's that didn't specify these HI drugs to be covered under Part C list any home infusion drugs? Since plans had to designate these drugs either on their Part D formulary or list them as "bundled under Part C" during the bid process if these drugs are just covered under standard Part D do they need to be reported in this section?

Section XVII. **Drug benefit analyses**

Comment about the following data element:

C. The total number of LIS enrollees in the deductible phase as of the last day of the month. [List all LIS beneficiaries for all subsidy levels.]

Our plan does not have a deductible phase. Therefore, does this mean even for LICS III beneficiaries that technically would have the $56 deductible this should be reported as "zero" since claims for these members would be treated as if they were in our non LICS plan?