#9

Managed Health Care Associates, Inc.

August 15, 2006

Melissa Musotto
Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development—A
Room C4–26–05
7500 Security Boulevard
Baltimore, Maryland 21244–1850

Dear Ms. Musotto:

I am writing this letter to provide my comments on the draft PDP Call Letter issued by your office on February 21, 2006 and then subsequently released for a sixty-day public comment period on June 21, 2006.. I am currently the Chairman & CEO of Managed Health Care Associates, Inc. (MHA). MHA is the largest Group Purchasing Organization in the country for Long Term Care (LTC) Pharmacies. We also provide contracting services for our members with PDPs through the MHA Long Term Care Network. Currently, over 600 Independent LTC pharmacies use MHA to purchase products and obtain contracts and rebates from pharmaceutical manufacturers and to access PDPs for participation in their Part D networks.

MHA has worked closely with CMS on many LTC pharmacy issues over the past year, including the issue of rebates from pharmaceutical manufacturers to LTC pharmacies. We have been very open about our willingness to disclose rebates to PDPs and believe the new requirements outlined in your document are a step in the right direction towards insuring transparency of all activities. We believe this transparency will eventually benefit all concerned including our pharmacies and more importantly, the Beneficiary. We are in support of this new requirement and appreciate CMS' willingness to work with us as this has developed. Now CMS and plans must ensure that the provisions are implemented in a uniform, consistent manner that is administratively feasible for all parties. We understand that plans have expressed concern about the scope and administration of implementation.

In reviewing the requirements more closely since the original release and working with plans, additional concerns have arisen that must be considered prior to implementation of the rebate reporting requirements. These issues are listed below.

LTC pharmacies receive rebates based on aggregate purchases of drug products, not based on dispensed prescriptions and therefore MHA supports reporting based on purchases not dispensing. This creates several administrative issues that must be resolved prior to implementation. Credit for the rebate occurs in the same quarter as the drug is purchased but not necessarily dispensed if a pharmacy maintains inventory over several quarters. How does CMS intend to require rebate reporting by LTC pharmacies?

MHA and the other members of the NCPDP task force for rebate reporting agree that the unit reporting method is the most effective way to communicate rebate information. However, plans have expressed the need to receive this information at the NDC level. This is a difficult challenge for LTC pharmacies because rebates generally are paid based on a particular brand name and not by package size or strength. It would present a significant administrative challenge for LTC pharmacies to report this information and then LTC pharmacies and plans would risk incorrect reporting. The NCPDP task group is considering ways to resolve this issue but acknowledges that it presents great difficulty to implement.

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Earlier this year, CMS clarified to MHA that the rebate-reporting requirement does not include a requirement for non-Part D lines of business. An aggregate reporting system that does not differentiate between lines of business would violate some manufacturer contract agreements between LTC pharmacies and manufacturers. This means that LTC pharmacy reporting to plans will not be specific to contract and therefore, plans must extrapolate its share from the data submitted. MHA has learned from plans that this would be difficult and could substantially overstate rebates if the plan did not process a claim from a particular pharmacy. MHA encourages CMS to consider this issue and resolve it with plans before implementing the final rebate provisions. MHA will also continue to work with plans to resolve this issue but the situation is primarily an administrative issue for the plans with guidance from CMS.

Again, thank you for the opportunity to submit public comments on the reporting requirements. We affirm our support of disclosure and now want to ensure that prior to implementation, CMS and plans resolve the administrative issues presented. MHA will continue to work with plans through the NCPDP task force and will also continue to share information with CMS to ensure appropriate implementation.

Sincerely,

Douglas A. Present
Chairman & CEO

CC: Lawrence Kocot – Senior Policy Advisor, CMS
Vikki Oates, Director, Division of Clinical & Economic Performance, CMS

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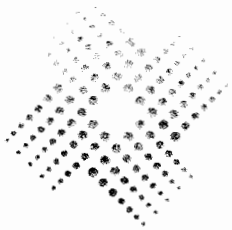

LTCPA

Long Term Care
Pharmacy Alliance

August 14, 2006

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Attention: Melissa Musotto,
Room C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Comments on 2007 Part D Reporting Requirements

Dear Dr. McClellan:

The Long Term Care Pharmacy Alliance (LTCPA) represents the leading providers of institutional pharmacy services for residents of long-term care facilities. Our members provide comprehensive pharmacy services to more than 60 percent of all long-term care residents in the United States.

We are pleased to have the opportunity to comment on the CMS draft Medicare Part D Reporting Requirements. Our comments will be organized by section, as they appear in the draft document.

Section I: Enrollment/Disenrollment

While CMS has proposed several categories of reporting requirements, for both LIS and non-LIS beneficiaries, we believe it is critically important for plans to report to CMS, and to the public, the number of beneficiaries enrolled and disenrolled who are residents of long-term care facilities. Plans will have access to this information, at a minimum, based on locator codes of beneficiaries for whom claims were submitted.

As you are aware, long-term care residents are the most medically fragile of all Medicare beneficiaries and it is vital that both CMS and the general public, are aware of the number of these beneficiaries managed by Part D sponsors at any given quarter.

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Recommendation: Require plans to indicate the number of long-term care LIS and non-LIS beneficiaries enrolled or disenrolled by each plan for each quarterly reporting period.

Section II: Reversals

As CMS is aware, Part D plan sponsors have inappropriately assigned co-pay responsibility for dually-eligible residents of nursing facilities who are exempt from co-pays. This error may have resulted from inaccurate data supplied by State Medicaid programs, but pharmacies have significant outstanding receivables from plans related to this issue. CMS has produced guidance to plans on several occasions instructing them to reimburse pharmacies for inappropriately-assigned co-pays. However, many plans have been unwilling to comply.

Recommendation: CMS should require plans to report the number of claim reversals related to inappropriately-assigned co-pays for residents of long-term care facilities.

Section III: Medication Therapy Management Programs

Given the specialized nature of long-term care, we believe CMS would profit from asking plans to report the number of beneficiaries in long-term care facilities enrolled in MTM programs.

Since beneficiaries residing in nursing facilities are subject to monthly chart review by a consultant pharmacist, and also by the volume of drug consumption will generally qualify for MTM participation, it will be instructive to determine what impact enrollment in MTMP may have on drug utilization, cost and health status of affected beneficiaries.

Recommendation: Require plans to report on MTM participation of beneficiaries residing in long-term care facilities.

Section IV: Generic Dispensing Rate

State Medicaid programs have noted a lower cost-per-script in the long-term care setting than in the retail environment[1]. This is arguably due to the higher rate of generic drug dispensing in the LTC environment.

It would be appropriate for CMS to request information from plans on the rate of generic dispensing in retail settings as well as in long-term care settings.

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[1] Massachusetts Executive Office of Health and Human Services, Division of Health Care Finance and Policy: *Report to the General Court: Payment for Prescribed Drugs*; April, 2004. Shows cost per script in LTC at $43.97 vs. $62.17 for retail.

Recommendation: Require plans to report the rate of generic drug dispensing in retail separately from the rate in institutional settings.

Section V: Grievances

Given our experience to date with plan performance in long-term care, it is important to collect grievance information related to plan performance in long-term care. This information would be very helpful for State Medicaid program use, especially as applied to dual eligibles. As you are aware, states share responsibility under the Medicaid program for funding medical care for nursing home residents. States' efforts to assure compliance with state and federal standards for nursing home care are directly impacted by the performance of individual plans with respect to quality of care and adherence to standards.

Recommendation: Capture grievance data for residents of LTC facilities and report these data as a discrete line item.

Section VI: Pharmacy and Therapeutics Committees

Although special qualification in geriatric medicine is not a requirement of P&T Committee membership, we continue to believe that this is a quality indicator for plans. We believe that CMS could require reporting, if not actually require credentialing, of the special qualifications of P&T Committee members as it relates to special geriatric certifications.

Recommendation: Solicit plans to require the identification of specialized geriatric certifications of P&T Committee membership.

Section VII: Transition

CMS has required plans to indicate their transition policy, not only for ambulatory beneficiaries, but for institutionalized beneficiaries as well. Therefore, it is possible that a plan may be compliant with a less generous transition period for ambulatory beneficiaries, but non-compliant with the long-term care population. Therefore, it is critically important that CMS insist that plans report long-term care specific transition data separately from the ambulatory data.

Recommendation: Require plans to report transition data for long-term care residents separately from ambulatory beneficiaries.

Section VIII: Prior Authorization, Step Edits, Non-Formulary Exceptions, and Tier Exceptions

Much of the increased administrative burden faced by long-term care pharmacies and nursing facilities relates directly to these issues. Given the persistent problems associated with plans that are not transparent related to formularies (e.g., plans that list many drugs as "formulary" drugs, yet require "fail first" and other prior authorization methods), we believe the plan's experience with utilization management techniques is an important indicator of a plan's compatibility with long-term care requirements.

Recommendation: CMS should insist that plans report the proposed data elements for both ambulatory populations and for institutionalized beneficiaries.

Section XIII: Pharmaceutical Access/Performance Rebates Received by LTC Pharmacies

The LTCPA strenuously objects to any requirement for the reporting of manufacturer rebates to any entity other than to CMS. Even then, we would only support reporting rebates if confidentiality were guaranteed.

Requiring pharmacies to report rebates to Part D plans marks the first, and only, instance where CMS would require a provider to disclose rebate information to anyone other than a federal agency. Under the provisions of OBRA'90, manufacturer Medicaid rebate information (with respect to best price and average manufacturer price) is reported only to HHS with explicit requirements for confidentiality.

CMS was aware of the existence of manufacturer rebates prior to issuance of final regulations for implementation of the MMA. In fact, preamble language discusses rebates at some length and speculates that rebates would disappear following the implementation of Part D. CMS could have regulated rebate disclosure in the final rule, had it so desired. Despite not making this a requirement under the formal rule, the agency has determined to regulate pharmacy rebates by sub-regulatory guidance.

On the substance of CMS' misgivings about the benefits of rebates, we point to the HHS report to Congress on the standards of practice of long term care pharmacy, delivered to Congress in October, 2005. In that document, CMS points out that rebates serve to allow for the provision of services to beneficiaries that would not be feasible under the common terms of reimbursement.

Further, CMS seems to believe that, absent pharmacy rebates, manufacturers would shift this new-found money to plans in the form of increased access or performance rebates. There is absolutely no reason to believe this will be the case.

Clearly, CMS is attempting to achieve an outcome through the process of expressing "concern" that they could have achieved through the formal rulemaking process. If successful, it is almost certain that the cost of Medicare Part D will increase, as pharmacies would be required to negotiate with plans without the expectation of supplemental income from manufacturer rebates.

Finally, it appears that CMS misunderstands the method by which pharmacies earn rebates. LTCPA members report that their therapeutic formularies are consistent with plan formularies in over 90 percent of cases. Pharmacies may have an opportunity to earn marginal revenue, not by recommending non-formulary drugs, but rather by encouraging the use of drugs consistent with the preferences of drug plans.

Recommendation: CMS, if it insists on pharmacy reporting of manufacturer rebates to LTC pharmacies, should strive to be consistent with existing requirements for reporting rebates and price concessions. We believe this consistency is achieved only by requiring pharmacies to submit rebate data directly to CMS, while providing assurance that this information is not disclosed to entities outside the federal government.

Aetna™

#11

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August 14, 2006

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RE: CMS 10185
Medicare Part D Reporting Requirements for Contract Year 2007

Dear Ms. Musotto:

Aetna welcomes and appreciates the opportunity to comment on the 2007 Part D Reporting Requirements. We have reviewed these requirements and have enclosed for your consideration our comments and recommendations.

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

Enclosure

#11

Aetna Comments and Recommendations to the Medicare Part D Reporting Requirements for Contract Year 2007

General Comments

- Four new reporting sections have been added to the Medicare Part D Reporting Requirements for Contract Year 2007 (hereafter referred to as the "Requirements"). In addition, new metrics were added to six other sections. Consistent with the current reporting requirements for CY2006, the majority of the new metrics in these Requirements are to be reported at the "plan level".

  Reporting at the plan level presents an additional administrative burden to those organizations offering multiple Medicare Advantage (MA-PD) and Medicare Prescription Drug (PDP) products in multiple regions. In addition, given that over 20% of plans have less than 10 members, as indicated in the Annual Report by Plan released 7/26/06, the usability of data reported at this level, and the degree to which it represents the population in question, may be diminished.

  For these reasons, we recommend that CMS reconsider which sections may be reported at a more aggregate level of reporting, thereby reducing the administrative burden on all plans, while maintaining the usefulness of the data provided. Alternatively, we suggest that CMS further explore opportunities for the automation of the data submission process, including the ability to upload files (e.g. flat files, Excel files) for other sections of the Requirements in lieu of manually entering data into HPMS.

Section I. Enrollment/Disenrollment

- In the Draft Requirements released earlier this year, two metrics were split out to require separate reporting for LIS versus non-LIS beneficiaries. In the current Requirements, all eight metrics were split in this fashion, effectively doubling the reporting requirement for this section. However, it is unclear why this additional level of detail is needed from the plans. We request that the requirement to report separate figures for LIS and non-LIS beneficiaries be removed from this section of the Requirements for 2007.

- If the requirement to report separate figures for LIS and non-LIS beneficiaries will remain, we recommend that the determination as to whether an enrollee was LIS or non-LIS be based upon the member's status as of the last day of the quarter, for both the enrollment and disenrollment metrics. For example, a member who was non-LIS as of 1/1/07, but then became LIS effective 3/1/07, should be reported as LIS for the 1Q2007 reporting period.

Section V. Grievances

- Item H indicates that quality of care grievances include "grievances received from beneficiaries or Quality Improvement Organizations (QIOs) regarding quality of care". We recommend that the issues received from the QIOs not be included in the data reported by plans. The QIOs already report this data to CMS, so plans should not be required to track and report this data for these Requirements. Plans should only report those issues initiated by members, or member representatives, as received by the plan's Grievance and Appeals units.

- Item I indicates that plans are to "provide the number of transition grievances received related to Part D" and that "examples include, but are not limited to, issues related to pharmacies not included in network, and formulary issues not related to exceptions or appeals. " It appears that this element pertains to grievances regarding the transition of care policy. If so, it is unclear how "issues related to pharmacies not included in network" would be relevant to this category, and request additional clarification from CMS on this point.

Section IX. Appeals

- Item Q instructs plans to report the "average number of hours for the Plan to complete **standard** redeterminations". Since the regulation and CMS guidance indicate that standard redeterminations must be resolved within 7 calendar days, we recommend that CMS change this requirement to indicate that plans must report the "average number of **days** for the Plan to complete standard redeterminations".

Section X. Call Center Measures: Beneficiary Service line and Pharmacy Support line

- In the *Response to Public Comments on the Draft Reporting Requirements Document* issued in 2005, CMS noted that "these reporting requirements were designed to provide flexibility around each Part D Sponsor's call center structure. CMS requests data is submitted at the most detailed level available...." The same language is also found in the *Medicare Part D Reporting Requirements*, updated 1/25/06, which also noted that "Data elements must be entered into HPMS at the Part D Sponsor level....."

  However, the *CY2006 Part D Reporting Requirements: Frequently Asked Questions*, last updated on 5/16/2006, indicated that "...provisions were granted for call center reporting to be at the contract level." Up to this point, "Part D Sponsor" was interpreted to mean the "parent organization"; however through conversations with CMS staff, we have since learned it was always CMS' intention to have this data reported at the Contract level. Still, this apparent change in reporting level, from "Sponsor level or Plan level" to "Contract level or

Plan level", has a significant impact to those MA-PD and PDP Sponsors which have multiple H, R and S contract numbers.

Specifically, contractors like Aetna, who have membership in multiple CMS contract numbers, afford members the convenience of one central toll-free number for customer service. This call center structure is not designed to segregate calls based upon CMS contract number or PBP. For example, Aetna MA-PD member calls are received by Aetna Medicare Member Services, at 1-800-282-5366. These include calls from all Aetna Medicare members enrolled in one of the 25 Aetna MA-PD contract numbers (H numbers), as well as those members enrolled in our Regional PPO contract number (R5595).

Aetna Medicare Customer Service Representatives (CSRs) are trained to take calls from all members, regardless of contract number. In addition, all member materials reflect this one central number for Member Services. This improves the level of service we provide our Medicare beneficiaries, while allowing us to maximize operating efficiencies.

To segregate calls based upon CMS contract number or PBP will require significant system enhancements. Organizations with multiple CMS contract numbers, like Aetna, will be required to establish front-end identification mechanisms including, but not limited to, establishing unique toll-free numbers for each contract number, or creating prompts on the central toll-free number to identify and separate calls by contract number before they are answered by a CSR. However, doing so will create unnecessary and cumbersome steps for the beneficiary, or the potentially confusing scenario where members would need to dial different toll-free numbers dependent upon which CMS contract number they are enrolled in. Further, current members would likely need to receive updated materials, reflective of the toll-free number that is applicable to the contract number they are enrolled in. In addition, new materials may need to be provided to those members who move their residence, when that move causes a change in contract number. Unfortunately, these members would also still have their old materials with the toll-free number associated with the prior contract number. Last, given that all calls would be received by the same customer service group staffing the same toll-free number, it's highly unlikely that any difference in the contract-specific call data would be statistically significant.

Because the Medicare Part D Reporting Requirements for Contract Year 2007 continues to indicate that the permissible level of reporting for the Call Center Measures is at the "Contract level or Plan level", we are requesting that CMS accept reporting at the Sponsor level (e.g. parent organization level). This is consistent with how these calls are managed and tracked by organizations holding multiple contract numbers. Again, we do not see any benefit it gathering the Call Center data at a more granular level than the Sponsor level and believe that attempting to track and report call center data at the contract level may adversely affect the level of service provided to our beneficiaries, yet not increase the

overall utility of the data provided.

- Items I and J indicate that plans must report "the number of calls....completed with issue resolved and not requiring a call back." While we would appreciate further clarification on the definition of "not requiring a call back", we recommend that these be limited to cases where the plan's customer service representative was required to perform the call back.

Section XIII. Pharmaceutical Manufacturer Access/Performance Rebates Received by LTC Pharmacies

- Rebates received by LTC pharmacies may apply to multiple lines of business, and are often not specific to a particular segment or product. We have confirmed with a large LTC group purchasing organization (GPO) that they collect this information, however the GPO does so for their entire book-of-business, and cannot break-out the data specific to Medicare beneficiaries. In light of this information, we recommend reconsideration of this reporting requirement.

- In contrast to section XII, the requirements for this section indicate that the level of reporting is "at the CMS Part D Contract level". Through recent conversations with some LTC pharmacies and intermediaries, we have confirmed that they cannot report the data required by this section at the Contract level. As a result, for any data that will be reported for this section, we strongly recommend that CMS change the level of reporting to the "CMS Part D Sponsor level", so organizations holding multiple contract numbers may submit one combined data file.

  We further recommend that CMS extend the submission deadline for any required reporting. Pharmacies will need adequate time to reconcile and invoice manufacturers, receive payment from the manufacturers, and report the data to all contracted plans. Plans would then need time to validate and combine the data for submission to CMS.

Section XV. Drug benefit analyses

- The reporting requirements in this section are duplicative of existing plan reporting requirements. Specifically, CMS has access to this data for all plans from the monthly PDE data submissions. We recommend that CMS eliminate this reporting section from the Requirements and instead extract this data from the current PDE data reporting. Doing so will eliminate the additional burden on plans, while helping to ensure consistency of the data.

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#12

Passionate for the Appropriate Use of Medication

August 15, 2006

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Room C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Attention: Melissa Musotto

Re: Comments on Part D Reporting Requirements Relating to Medication Therapy Management, Contract year 2007

Dear Ms. Musotto:

Thank you for the opportunity to comment on the proposed reporting requirements for Part D plans for contract year 2007. Our comments focus solely on the reporting requirements relating to the Medication Therapy Management Program (MTMP) authorized under the Medicare Modernization Act (MMA) and its implementing regulations at 42 C.F.R. § 423.153(d).

excelleRx, Inc., is a rapidly growing, technology-based, prospective medication therapy management company, based in Philadelphia, Pennsylvania. We service over 100,000 patients per month and most of these are Medicare beneficiaries who reside in 49 states and Guam. We are dedicated to helping physicians migrate from preference-based medication choices to pharmacotherapy decisions that are rooted in medication-related outcomes evidence. Using a) pharmacist-staffed call centers that operate 24/7; b) patient-specific clinical data that is maintained in an electronic medical record; and c) comprehensive, proprietary pharmacotherapy guidelines, excelleRx intervenes in real time to provide clinicians with patient-specific, medication care plans. We then monitor patient response, measuring both clinical endpoints and quality of life outcomes. Through this approach, we are able to ensure appropriate use of medication, improve patient quality and safety and demonstrate cost savings for our clients

Given our background and experience, we were pleased to see that the MMA contained a requirement that every Medicare Part D plan include MTMP to ensure cost-effective and optimal pharmacotherapy. Understandably, in the roll out of Medicare Part D, the Centers for Medicare and Medicaid Services (CMS) was reluctant to mandate MTMP program requirements in the final Part D implementing regulation due to the lack of consensus around what constitutes MTMP best practices. In the preamble to the final regulation, CMS expressed a concern that requiring a set of minimum services and service levels, without fully understanding how they could effectively be implemented on a much larger platform, could result in MTMPs becoming perfunctory services offered just to satisfy regulatory requirements, as opposed to patient focused services aimed at improving therapeutic outcomes. However, CMS did state that "MTMP must evolve and become the cornerstone of the Medicare

Prescription Drug benefit."[1] Under the final rule implementing Part D, CMS only requires MTMPs to meet two basic requirements: (1) improve medication use that optimizes therapeutic outcomes and (2) reduce risk of adverse events, but provides no guidance as to how these goals can be accomplished.

Lacking a regulatory framework, Medicare Part D plan sponsors have created an array of MTMP approaches. While every plan has posted descriptive information about its program, quantitative and qualitative data is not readily available. CMS has stated that it prefers to let the market operate to generate a variety of approaches. However, the only way to know which approaches are working and which might be viewed as 'best practice' models is to collect data elements including program design elements, patient demographics, clinical indicators, medication history and health outcomes.

Unfortunately, CMS' proposed data reporting requirements for MTMP programs focus almost entirely on process measures and enrollment numbers that will provide little, if any, useful information about the effect current MTMP programs have on beneficiaries or program costs. For example, CMS proposes that plans report the method for beneficiary enrollment, the number of eligible beneficiaries, the number of participating beneficiaries, the number of drop outs due to death, disenrollment from the plan or by request, the number who declined to participate, the total cost of medications for each participating beneficiary, and the average number of covered drugs per beneficiary per month. None of these data elements will help to advance our understanding of the characteristics of the beneficiaries who are enrolled in MTMP and how they have benefited from participation.

Recommendation: Given the critical need to understand how MTMP can be leveraged to reduce costly medication errors, improve health care quality, and reduce overall health care costs, CMS should require plans to report a more robust data set that will allow CMS to monitor MTMP outcomes over time. Specifically, data should be collected concerning the following domains:

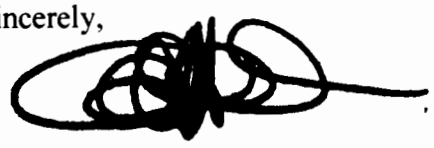
1. Program design including criteria for inclusion and exclusion.
2. Population level summaries of beneficiary demographics, including age, race, sex, and living situation.
3. Population level summaries of beneficiary's medical and medications history, including primary diagnoses.
4. Population level summaries of medication risk assessments including how medication risks are identified, what are the types of medication related problems identified (e.g. adverse or potential adverse reaction, inappropriate medication, duplicative therapy, untreated indication), and frequency/ distribution of medication related problems detected.
5. Average beneficiary medication costs and number of medications at program enrollment and at every subsequent reporting period.
6. Actual occurrence of adverse events and medication errors among the MTMP inclusion group.
7. Actual reductions in treatment costs (based upon medical claims data during the reporting period) among the MTMP inclusion group.

[1] 70 Fed. Reg. 4280 (January 28, 2005) (Preamble to the Final Rules Implementing the Medicare Prescription Drug Benefit)

Conclusion: As recently noted in the Institute of Medicine Report, "*Preventing Medication Errors*," the frequency of medication errors and preventable adverse events (ADEs) is a very serious cause for concern. Among outpatient Medicare patients alone, the IOM report cites a study that projected, conservatively, 530,000 preventable ADEs.[2] The IOM recommends that regulatory authorities and payors use their authority and payment mechanisms to motivate the adoption of practices and technologies that can reduce medication errors and to ensure that professionals have the competencies required to deliver medications safely. Specifically, IOM recommends that CMS "evaluate a variety of strategies for delivering medication therapy management."[3]

Our own experience tells us that MTMP reduces medication errors, improves quality of life and reduces health care costs. However, unless CMS is serious about collecting adequate data from plans (or alternatively, conducting a national demonstration with a strong, evaluative component), it is unlikely that we will succeed in reducing medication errors in the nation's largest, government-funded, prescription drug program. Accordingly, we urge CMS to assert leadership and adopt a more proactive role in helping to identify and evaluate best practice models for MTMP in Medicare Part D.

Sincerely,



Calvin H. Knowlton, MDiv, RPh, PhD.
President and CEO

[2] "Preventing Medication Errors," Institute of Medicine, 2006 (hereinafter IOM Study) at 3. In our own study of 142 frail, elderly patients enrolled in a Medicaid home and community-based care waiver, we found 287 potential MRPs, of which the most prevalent was an actual or potential adverse drug reaction (56.3%). Bain K, Weschules D, Tillotson, P. "Prevalence and Predictors of Medication-related Problems," Medicare Patient Management, January/February 2006.

[3] IOM Study at 17.

#13

PhRMA

Lori M. Reilly, Esq.
Vice President for Policy

August 15, 2006

Melissa Musotto
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development-A
Room C4-26-05
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Baltimore, Maryland 21244-1850

Re: 2007 Medicare Part D Reporting Requirements

Dear Ms. Musotto:

PhRMA is pleased to submit comments on CMS's 2007 Medicare Part D Reporting Requirements. We specifically address the Medication Therapy Management Program (MTMP) elements found in Section III of the Part D Reporting Requirements and support the reporting of metrics which would enable CMS to evaluate the effectiveness of successful MTMPs and enhance plan accountability.

A. Medication Therapy Management Programs (MTMPs)

Current MTMP reporting requirements appear to focus almost exclusively on administrative and procedural aspects of the MTM program (e.g. the method used to enroll beneficiaries into the MTMP). This set of reporting elements will provide little to no ability to evaluate whether the MTM program is achieving the goals set forth in the final Part D rule (appropriate use of medicines and a reduction in adverse events such as drug interactions)[1]. It also will not give CMS the ability to evaluate basic aspects of MTMP to determine which features are more or less effective in achieving these desired outcomes. We therefore recommend that CMS broaden the scope of MTMP reporting requirements to begin to move toward these goals. In particular, reporting should include some of the basic indicators of clinical quality improvement in these areas that are

[1] 70 *Fed. Reg.* at 4279 (January 28th, 2005)

reportable based on an analysis of pharmacy claims data, such as avoidance of clinically inappropriate medications and drug-drug interaction and patient adherence with prescribed therapy. The Ambulatory Quality Alliance (AQA) starter set of measures, for example, includes measures of acute- and continuation-phase treatment adherence. CMS should incorporate measures of treatment adherence and persistence in MTM reporting requirements, and should base these measures on existing methods of evaluating adherence and persistence.

Improving patient adherence and persistence to prescribed therapy would yield dramatic health and economic benefits.[2] Numerous studies highlight the large gap in adherence—which results in avoidable outcomes such as heart attacks, strokes, and kidney failure.

Measuring improved adherence would help assure CMS that it is getting value for the MTMP fees it is paying as part of plans' administrative fees. A recent study by Sokol et al. showed that a high level of medication adherence in diabetes, hypertension, and hyperlipidemia treatment resulted in lower disease-related medical costs.[3] "For diabetes, the average incremental drug cost for a 20% increase in drug utilization is $177 and the associated disease related medical cost reduction is $1251, for a net savings of $1074 per patient (an average ROI of 7.1:1). For cardiovascular conditions, the average ROI for a 20% increase in drug utilization is 4.0:1 (hypertension) and 5.1:1 (hypercholesterolemia)." The study concludes that while medicines represent a "small fraction of total healthcare costs for these conditions, they have high leverage – a small increase in drugs costs (associated with improved adherence) can produce a much larger reduction in medical costs."[4] Balkrishnan cites estimates that noncompliance costs the U.S. health system $300 billion per year.[5]

CMS also should consider adding reporting elements to assess improvements in patient safety, such as reduction in the use of contraindicated drugs and duplicate therapies. These measures must, of course, be understood in a context of the need to individualize a patient's treatment regimen.

The report released by the Institute of Medicine on July 20, 2006, *Preventing Medication Errors*, underscores the importance of reducing preventable medication errors such as those described above. The IOM reports cites estimates that in the ambulatory care setting, the annual total cost of preventable adverse drug events for Medicare enrollees is $887 million.[6]

CMS also should begin incorporating elements to evaluate structural measures to identify and encourage the use of MTM approaches that are more effective in achieving the goals of improved quality and patient safety. For example, Krueger et al. identify a range of

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[2] M.C. Sokol, K.A. McGuigan, R.R. Verbrugge, R.S. Epstein., "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," Medical Care 43 (June 2005): 6, 521-530.
[3] Ibid.
[4] Ibid.
[5] Rajesh Balkrishnan, Ph.D, "The Importance of Medication Adherence in Improving Chronic-Disease Related Outcomes," Medicare Care 43 (June 2005): 6, 517-520.
[6] Philip Aspden et al., *Preventing Medication Errors: Quality Chasm Series*, Institute of Medicine, 2007

interventions at the pharmacy and pharmacist level thought to have varying efficacy in improving adherence to prescribed therapy (e.g., adherence devices, telephone or postal reminders alone, education or counseling, and comprehensive management).[7]

We suggest that CMS evaluate established metrics of appropriate use such as those found in the starter set of the AQA for inclusion in future Part D reporting requirements.

We thank you for this opportunity to comment and look forward to continuing to work with CMS. If you have any questions, please feel free to call Lori Reilly at 202-835-3400.

Sincerely,

Lori M. Reilly

[7] Kem Krueger et al., "Improving Adherence and Persistence: A Review and Assessment of Interventions and Description of Steps Toward a National Adherence Initiative," Journal of the American Pharmacists Association, Vol. 43, No.6 (November/December 2003)

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August 15, 2006

CMS Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development—A
Attention: Melissa Musotto, Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Federal Express Overnight Delivery

RE: 2007 Proposed Medicare Part D Reporting Requirements and Supporting Regulations under 42 CFR 423.505

To Whom It May Concern:

The following comments are offered in response to the Federal Register posting of June 16, 2006 requesting industry comments regarding Medicare Part D Reporting Requirements for Contract Year 2007, more specifically Section X regarding Call Center Measures.

Security Health Plan of Wisconsin, Inc. is a rural health maintenance organization (HMO) serving 28 counties in central, northern, and western Wisconsin. The health plan is owned by Marshfield Clinic, a respected regional Medical Center in central Wisconsin. Security Health Plan first contracted with the Centers for Medicare and Medicaid (CMS) in August 2002 offering M+C services through our Advocare product. And now, as a local Medicare Advantage Prescription Drug (MA-PD) plan, we are serving over 10,200 Medicare Advantage members, of which approximately 3,800 are Part D members.

As we transitioned to become a MA-PD plan, we determined that we would continue to maintain our commitment to providing our members the most affordable health-coverage possible. Security Health Plan is pleased with our successful implementation of the Part D benefit, and also is particularly proud of the very positive member and provider testimonial comments concerning our very responsive beneficiary and pharmacy customer service call centers.

Thus, while Security Health Plan applauds efforts to ensure that the needs of all Part D enrollees are being met, we are concerned that small local health plans, like Security Health Plan, are being burdened disproportionately to the larger national MA-PDs and PDPs. The inclusion of data elements for the pharmacy call center (technical help desk) will require equipment that is far more sophisticated than we now have given our track record of excellent customer and provider service, with very few complaints. Security Health Plan has two separate call centers (Beneficiary and Pharmacy) that would need

to be equipped with the necessary mechanisms to separately track the required Part D data elements for a relatively low volume of Part D calls.

Since Security Health Plan strives to provide high quality customer service to all of its members, commercial or government contract, we have set consistently high standards for our call centers, and have not felt the need to equip our systems to track metrics on calls for separate categories of members, like Part D. While we appreciate the effort on the part of CMS to standardize the reporting requirements for both MA-PD and PDP plans to allow for comparability, the requirements are overly burdensome to small local MA-PD plans.

We request that CMS continue to allow MA-PD plans to report only beneficiary call center data as clarified in the *CY2006 Part D Reporting Requirements Frequently Asked Questions* - 5/16/06 Update (Page 13, FAQ #6). We understand that plans are still required to meet standards regarding the pharmacy technical help desk, but retro-fitting or replacing an existing phone system to separately report call center data is extremely burdensome for smaller MA-PD plans.

Thank you for your consideration of our comments concerning the proposed changes to the Medicare Part D Reporting Requirements regarding the Call Center Measures for contract year 2007.

Sincerely,

Sylvia L. Wagner

Sylvia L. Wagner
Government Programs Manager
E-mail: wagner.sylvia@marshfieldclinic.org
Telephone : 715-221-9852

#15

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development-A,
Attention: Melissa Musotto, Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Comments on CMS-1085
Medicare Part D Reporting Requirements and Supporting Regulations under 42 CFR section 423.505

The Medicare Rights Center appreciates this opportunity to comment on the **Contract Year 2007 Part D Reporting Requirements**. Over the last seven months, the Medicare Rights Center has helped thousands of people with Medicare who encountered problems under Part D. Through this work, it has become clear that there are substantial differences in how Part D plans are complying with requirements established by the CMS, in particular with regard to transition policies, timelines for exceptions and appeals and formulary requirements.

We appreciated the oversight challenges CMS faces given the number of Part D plans and the difficulty in capturing sufficient performance data without overburdening Part D sponsors or CMS officials with unwieldy reporting data. In that spirit, the Medicare Rights Center makes the following suggestions for amendments to the 2007 Part D Reporting Requirements with the understanding CMS' greater expertise with the Health Plan Management System may modify these proposals to better capture the performance data necessary for adequate oversight:

Section VIII. Transition

As CMS has emphasized to Part D plans, the purpose of mandatory transition policies is ensure people with Medicare do not go without needed medicines when they are confronted with formulary exclusions or restrictions. At the end of the transitional period, plan members should have either used the exceptions process to obtain coverage for a drug or had their physician prescribe an appropriate alternative that the plan will cover. For the transition to be effective, Part D plans must communicate well with plan members and their physicians and run an efficient and fair exceptions process. Unfortunately, plan performance in these areas has been uneven. CMS could obtain information on the effectiveness of plan transition polices by adding the following reporting requirements to Section VII:

- Number of enrollees who received one or more prescriptions via transition policy that had claims denied by the plan after the end of the transitional period. This will serve as a proxy for the number of plan members that did not effectively transition to a covered drug or obtain coverage through the exceptions process.
- Number of enrollees who received one or more prescriptions via transition policy who filed an exception/prior authorization seeking coverage. This number indicates how well the plan informs members of their ability to seek an exception.
- Number of these exceptions/prior authorizations granted before the end of the transitional period.

- Number of these exceptions/prior authorization denied before the end of the transitional period. The above two numbers may indicate whether the exceptions process is run efficiently or whether the transitional period is of sufficient duration.
- Number of enrollees who received one or more prescriptions via transition policy who subsequently filed a claim for a covered medicine within the same class.

Besides informing CMS on the effectiveness of plan transition policies, requiring the reporting of this data will ensure that Part D plans are adequately monitoring the how plan formularies are affecting their members access to medicines. This level of care coordination should be required of all Part D plans.

Section VII. Prior Authorization, Step Edits, No-Formulary Exceptions, and Tier Exceptions

Many of the appeals cases handled by MRC center on quantity limits, particularly on mental health drugs. While some quantity limits are medically appropriate, others seem to be motivated purely by cost considerations. The data set proposed by CMS fails to capture the impact of quantity limits or to alert the agency to whether the quantity limits employed by individual plans are the subject of a high number of appeals, which might indicate a medically inappropriate limit. The following data set would capture this information:

- Number of pharmacy transactions rejected due to quantity limits in the specified time period.
- Number of exceptions requested for quantity limits.
- Number of exceptions approved for quantity limits.

Section IX. Appeals

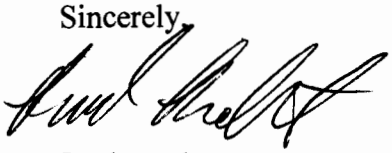
Our experience handling exceptions and appeals, Part D plans fail to meet mandatory timeframes at least half the time but do not submit the case to the Independent Review Entity for reconsideration as required. As a result cases that should be resolved within a couple of weeks can drag on for over a month. In addition, in a number of instances, plans have reversed negative coverage redeterminations only after review has been sought from the IRE, effectively "mooting out" the case. Whatever the motivation, these practices result in plans appearing to perform well on the data set collected by CMS even though they are flouting basic requirements. For example, these plans will have lower numbers of cases referred to the IRE for failure to meet timeframes and a lower number of reversals by the IRE. CMS could capture this practice by adding the following data sets:

- Number of standard coverage determinations made after the appropriate timeframe has elapsed (and not referred to the IRE).
- Number of expedited coverage determinations made after the appropriate timeframe has elapsed (and not referred to the IRE).
- Number of standard coverage redeterminations made after the appropriate timeframe has elapsed (and not referred to the IRE).
- Number of expedited coverage redeterminations made after the appropriate timeframe has elapsed (and not referred to the IRE).

Since from the plan member's point of view, adverse coverage determinations made after the timeframe has elapsed are more serious, CMS may want to plans to provide data on both negative and positive decisions made after the timeframe has elapsed. Plans should also be required to keep logbooks showing when exceptions/appeals were filed and when the decisions were made. These should be available to CMS auditors.

Thank you very much for considering these comments as you finalize the Part D reporting requirements for contract year 2007. If you seek clarification on these suggestions, please contact Paul Precht at 202-589-1316.

Sincerely,



Paul Precht
Policy Coordinator
Medicare Rights Center
Suite 250
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202-589-1316

#14

Consumers Union®

NONPROFIT PUBLISHER OF CONSUMER REPORTS

August 14, 2007

CMS, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development-A
Attention: Melissa Musotto, Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-10185, Medicare Part D Reporting Requirements

Dear CMS:

Thank you for the opportunity for Consumers Union, the independent, non-profit publisher of *Consumer Reports*, to comment on Medicare Part D 2007 Reporting Requirements.

As we indicated in our initial comment letter on April 3 (attached), we congratulate CMS for requiring a great deal more detail in reporting in 2007, and we especially appreciate the reporting which may help us see whether low income subsidy (LIS) individuals are receiving good care under the program. We also appreciate the reporting requirements on P&T committees and their potential conflict of interest. We appreciate the fact that this final proposed regulation has not appear to have been substantially weakened or diminished as a result of the initial comment period.

The key issue that is still unclear, however, is whether and when the consumer quality reporting data required under this regulation will actually be made public so that consumers can select the best plans and avoid the worst plans. We urge that you make it clear in the final document that key information on generic dispense rate, enrollment and dis-enrollment, grievances and appeals and their resolution, and quality of service in telephone call centers be made public within a month or two of its quarterly receipt by CMS.

Consumers Union

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We further urge that the data collected this year on those issues be made public prior to this fall's open enrollment season.

On the reporting of the conflict of interest status of P&T Committee members, it will be important to clarify (perhaps in the anti-fraud call letter to plans) that a mis-statement on this provision will have consequences. We raise this point because of the many recent reports of cases where individuals—even distinguished medical faculty at prestigious universities--have 'forgotten' to disclose conflicts. Undisclosed conflicts of interest in a P&T Committee could result in the steering of millions of dollars of business to a drug which may not be the safest, most effective, or most economical for consumers.

Thank you for your consideration of these comments.

Sincerely,

William Vaughan
Senior Policy Analyst (Health)

April 3, 2006

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
PartDplanreporting@cms.hhs.gov
Washington, DC

Dear Dr. McClellan:

Thank you for the opportunity to comment on the *Draft Medicare Part D Reporting Requirements for Contract Year 2007,* Updated 02/23/2006.

The key to all of these reporting requirements, of course, is that they be made public both quarterly and annually so that Medicare beneficiaries can have the latest information on the relative quality of the different Plans and Sponsors so they can make informed enrollment decisions. As per our letter of January 5, we continue to hope that as much information as possible will be made public before this fall's open enrollment season. All the reporting in the world will do no good, if it just sits buried in CMS files.

Congratulations on the Draft for 2007.

It provides some major increases in the 'granularity' or detail of the 2006 data, and will help the public and advocates understand better how the low income and most vulnerable are being served in the various Plans. It will require important information on how well Plans deal with transition formulary issues (clearly a major problem this winter). The increased information about possible conflicts of interest in the plan Pharmacy and Therapeutics (P&T) Committees is important and will help ensure 'good-for-patient formularies'—not just 'good for Plan-profits' formularies.

The addition of information on the 'number of pharmacy transactions rejected due to need for prior authorization' will be especially helpful to consumers in understanding which Plans require the least hassle—and which Plans to avoid.

The additional reporting requirements for Plan Call Centers are excellent. The failure of Plan call centers is a major source of frustration, and Consumers Union has received a number of complaints about unbelievably poor service at these centers. Attached is one example sent to us from a Humana enrollee. Enrollees in other Plans have reported similar problems.

We suspect that you will receive comments from Plans opposing these expanded reporting requirements. We hope you will stand firm with your Draft proposal: far too many Plans have woefully failed to prepare for and staff for the new benefit and they have contributed mightily to the rocky start of this important program. They have not earned the consumers' trust and therefore expanded reporting requirements are totally in order.

Thank you for your consideration of these comments.

Sincerely,

William Vaughan
Senior Policy Analyst

Attachment example:

I signed on with HUMANA in November 2005 and opted to have the premiums deducted from my Social Security check. I received a letter of acknowledgement dated 12/01/05. I received a card later in December.

On January 27, 2006 I received a coupon book for payments. I tried for several HOURS to talk with someone at Humana as I had signed up for payments to be deducted from my Social Security check. When I finally got someone they left me on hold for 20 minutes saying that they would check it out. They never came back on the line and I ended up hanging up. I then wrote them a letter explaining everything and enclosing a check for the January and February payments.

On February 11 (2 weeks later)I received a RECORDED MESSAGE from Humana saying that Humana had made an error and that January. February and March payments would be deducted from my March check.

I tried calling again to no avail and ended up writing another letter dated 2/13/06.

On 3/15/06 I received a letter from Social Security saying that the January, February and March payments would be deducted from my March Social Security check that I would receive in April. On 3/15/06 I called Humana and did get through to someone who told me that "what I was saying did not agree with what was on their computer screen." It was a frustrating conversation and I hung up afterwards and wrote still another letter. I requested an acknowledgement of receipt on the letter and a refund on my overpayments. To date I have heard NOTHING from Humana.

The point of all of this is that it has been impossible to #1 get anyone at Humana on the telephone. #2, Even if you get someone they are of no help. #3 Humana deals in mass communication with its policy holders - I have yet to receive a letter addressed to me regarding any of the letters I have sent to them. #4 Their efforts are directed at signing on as many as possible. #5 They are not concerned about

dealing with individual problems that they have created. #6 Staff is poorly trained and probably overwhelmed.

#17

OVATIONS
A UnitedHealth Group Company

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Minneapolis MN 55440-9472

To: CMS, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development – A
Attention: Melissa Musotto, Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850
Sent via overnight mail August 14, 2006

From: Teena Ballard Keiser, Director of Regulatory Affairs

Date: August 14, 2006

Re: Draft 2007 Part D Reporting Requirements

We have reviewed the Draft 2007 Part D Reporting Requirements and provide the following attached comments. These comments are provided on behalf of Ovations and other UnitedHealth Group affiliates that manage Medicare Advantage and Part D business (collectively "United"). Please note that, for the purposes of this letter, "United" includes the Ovations business units that manage the combined PacifiCare and Ovations legacy Part D business.

We greatly appreciate the opportunity to comment, and we look forward to continuing to work with CMS to develop successful products and services for Medicare beneficiaries. If you have any questions or concerns on our comments, please contact me at 507/663-1844 or via email teena_keiser@uhc.com.

Draft 2007 Part D Reporting Requirements

Comments Submitted by
UnitedHealth Group/Ovations
August 14, 2006

1. General Comment

Issue: Concern with requirement to report at the plan or contract level.

Recommendation: We recommend that CMS reconsider the requirement to report at the plan or contract level for some categories of reporting elements.

Rationale:

Some data is not available at the plan or contract level, but is available at the sponsor or organizational level. The following outlines some examples:

- Call Center Elements, Section X - The reporting requirements state that this information must be reported at the contract level. Our data is only available at the organizational/sponsor level since we do not maintain separate phone lines for each contract or plan.
- Drug Benefit Analyses, Section XV – The reporting requirements state that this information must be reported at the Plan level. Our data is not available at the plan level. We collect this data at the sponsor/organizational level.

For this type of data, we are unclear as to the benefit of tracking the data specific to a plan or even a contract. Unless there is a specific reason that CMS needs the data at the plan or contract level, we think a Part D Sponsor should be provided the option to report at the organization/sponsor level and indicate the contracts to which the data applies.

2. **Subject: Section I. Enrollment/Disenrollment.**

Issue: The new data elements for this category require Part D sponsors to break out totals based on LIS versus non-LIS membership. This new requirement is burdensome and may not result in accurate information.

Recommendation: We recommend CMS reconsider requesting these new categories of reporting.

Rationale: These additional data elements will require substantial system enhancements to capture. In addition, we question whether this additional reporting will be useful due to the high volumes of LIS discrepancies presently found when comparing full membership files with full LIS files. Until there is greater data integrity around LIS, we think CMS should hold off on requiring these additional data elements.

3. **Subject: Section III. Medication Therapy Management Programs.**

Issue: Concern with tracking and reporting additional detailed categories related to discontinued participation from the Medication Therapy Management Program (MTMP). Our specific concern is related to the two additional elements E and F: discontinued participation due to death and discontinued participation due to disenrollment from the plan.

Recommendation: We recommend that CMS reconsider requesting these new categories for reporting.

Rationale: These new categories for discontinued participation will be difficult to obtain since our enrollment systems are not linked to our MTMP system. This data request would require a system enhancement or manual process to obtain this data. In addition, we are not clear how this information is beneficial to CMS since discontinuing participation from MTMP due to death or disenrollment from the plan are not indicative of problems with MTMP. If this additional information is not crucial, we would question whether the administrative burden required to obtain this data is worth the additional cost to the Plan sponsors.

4. **Subject: Section III. Medication Therapy Management Programs.**

   Issue: Additional guidance is needed related to Element J. This element was added to the Draft 2007 Reporting requirements requesting the number of beneficiaries participating in the MTMP as of the last day of the reporting period specified.

   Recommendation: We would like CMS to provide a formula for this calculation, as CMS did for Element I. in the Draft 2007 Reporting requirements.

   Rationale: A formula will ensure that all Plans calculate this number in a consistent manner.

5. Subject: Section VI - Pharmacy & Therapeutics Committee

Issue: The requirement to report the Pharmacy & Therapeutics (P&T) committee membership through the HPMS upload process is of concern to us.

Recommendation: We urge CMS to revise the reporting requirement to require hard copy submissions in place of the HPMS process.

Rationale: Due to the importance of maintaining confidentiality of the P& T Committee membership, we recommend that CMS not require that this information be uploaded and maintained on HPMS. Instead, we recommend that the 2007 reporting requirements provide instructions for submitting changes (if there are any) to the P&T committee to CMS via a hard copy submission.

6. **Subject: Section X. Call Center Metrics.**

Issue: Concern with providing the data related to the draft element J. that requires that we report the number of calls to the Pharmacy Support line completed with issue resolved and not requiring.a call back.

Recommendation: We recommend that this type of data only be required for the Beneficiary Service line, but not the Pharmacy Support Line.

Rationale: This data will be difficult to capture for Pharmacy Support Lines due to the fact that contact with our pharmacies often involve information related to multiple beneficiaries. For example, we may receive a call from a pharmacy involving three different beneficiaries and we might resolve the issues related to two beneficiaries on the initial contact, but one beneficiary issue requires a call back. How would this be call be categorized? If this reporting requirement required us to track the data specific to the individual instead of related to each pharmacy call, the data collection would be administratively difficult and would require manual tracking. We would like CMS to reconsider requiring reporting of this type of data element for the Pharmacy Support line due to the significant administrative cost of obtaining this data and that the data would likely not be meaningful.

7. **Subject: Section XIII. Pharmaceutical Manufacturer Access/Performance Rebates Received by LTC Pharmacies.**

Issue: The frequency of reporting this rebate information is unnecessarily burdensome and might reduce accuracy of data.

Recommendation: We recommend reducing the frequency of the reporting time. Ideally, we would recommend reporting annually following 60-90 days after the close of the calendar year.

Rationale: The rationale for this recommendation is two-fold.

- First, we expect the collection of this information to be time-consuming for the Part D Sponsors as well as the LTC pharmacies, particularly for smaller independent pharmacies. We think that reducing the frequency of the reporting to annual will allow more time for the Sponsors to work with the pharmacies in getting the appropriate data.

- Secondly, data will be more accurate if viewed over a longer period of time due to purchasing practices in the long term care pharmacy industry. Rebates are based on purchases and purchases are not necessary made by long term care pharmacies evenly throughout the year. Due to these purchasing patterns, an annual view of the data would be more meaningful and accurate for CMS to review.

For both of these reasons, we recommend an annual submission of this reporting category.

8. **Subject: Section XIV. Licensure and Solvency, Business Transactions and Financial Requirements.**

Issue: PDP Sponsors are required to report annually, within 120 days of the end of our fiscal year significant business transactions by parties in interest. Currently the method of submission related to this reporting requirement is not included in the Part D reporting requirements document or elsewhere in writing. The requirement to report is stated in 42 CFR 423.514 (b) .

Recommendation: Define the requirements for reporting significant business transactions within this section of the reporting requirements. Further, specify whether or not MAPDs are exempt from this particular reporting requirement.

Rationale: To help ensure all reporting requirements are met, providing more specificity concerning the topics to be reported, method of reporting (e.g., HPMS, spreadsheet, etc.) along with the appropriate contact for this submission is needed.

9. Subject: Section XV. Drug Benefit Analysis.

Issue: Requiring reporting of elements that can be derived from other Sponsor data submissions seems redundant.

Recommendation: We recommend that CMS remove this proposed category.

Rationale: The data requested is available through other Plan data submissions (Prescription Drug Event data) and removal of this additional reporting requirement will assist in meeting the core criteria outlined in the reporting requirements introduction for selecting reporting criteria; *minimal administrative burden on Part D Sponsors* and *validity, reliability and utility of data elements requested*. The Prescription Drug Event records contain the data elements in this proposed section and will be submitted to CMS on a monthly basis. Removal of this additional submission would greatly alleviate the administrative burden associated with Plans that have numerous plan benefit packages.