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June 11, 2012

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4157–FC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS–4157–FC; Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes; Final Rule with Comment Period

Dear Sir or Madam:

Thank you for the opportunity to submit our comments on independence of long-term care (LTC) consultant pharmacists. As CMS solicits further comment to frame a comprehensive solution regarding medication management and quality in the LTC setting, the National Community Pharmacists Association (NCPA®) appreciates the opportunity to share our perspectives.

NCPA represents the interests of America's community pharmacists, including the owners of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together they represent a $93 billion health-care marketplace, have more than 315,000 employees including 62,400 pharmacists, and dispense over 41% of all retail prescriptions. In addition, 34% of our members serve an LTC facility and 48% serve an Assisted Daily Living facility. In sum, approximately 40% of the long-term care market is serviced by an independent community pharmacy.

NCPA members are the primary providers of drugs and pharmaceutical supplies to millions of Americans. Focusing on the Medicare Part C and D programs, NCPA members are a primary access point for prescription medications for millions of Part C and D beneficiaries in both outpatient and long-term care settings, and NCPA members comprise a critical piece of the Part C and D prescription drug distribution system.

NCPA agrees that consultant pharmacist decisions should be objective, unbiased, and in the best interest of nursing home residents. To support initiatives in this area, NCPA has agreed to participate in a multi-stakeholder Long-Term Care Pharmacy Workgroup formed by the Pharmacy Quality Alliance (PQA). NCPA will work with other members of this group to find viable ways to implement changes to address the problem of overuse and misuse of medications frequently used in long-term care settings.

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The workgroup will begin developing a framework of performance measures that can help ascertain the effectiveness and appropriateness of consultant pharmacists' recommendations. We believe the outcomes of this workgroup will allay the concerns of CMS related to the independence and effectiveness of LTC consultant pharmacists.

NCPA submits the following comments to CMS's solicitation in the Final 2013 Part D rule on the following topics:

Enhancing Medication Management and the Effectiveness of Medication Review

NCPA believes there is great value to the consultant pharmacist drug regimen review process. A study published in the Archives of Internal Medicine found that drug regimen review services by consultant pharmacists in the long-term care setting improve therapeutic outcomes by 43% and save $3.6 billion annually in costs associated with medication-related problems.[1] Drug regimen reviews by consultant pharmacists do yield the intended outcomes and provide protections to the beneficiaries without the requirement of independence.

While it is not in pharmacy's purview to comment on actions to be taken by prescribers or nursing home staff, we offer suggestions from pharmacy's perspective for consideration. There are actions that can be taken to strengthen attending physician (and other prescribers) medication management and prescribing practices to ensure the best quality of care for the nursing home resident. For example, NCPA suggests a dashboard report for each prescriber at the home that compares the prescribing habits of the practitioner to those of their peers highlighting how the prescriber compares locally as well as regionally.

Another suggestion is to track and better understand the origination of prescriptions, particularly antipsychotics prescribed to patients with dementia. To do this, we suggest that CMS surveyors look at medications initiated within the facility and those that are initiated outside, such as in the hospital. Systems are in place to identify new orders at any level and location. Therefore, those initiated at the nursing home can be identified as an LTC-specific event and tracked appropriately.

From a pharmacy perspective, the role of the medical director in overseeing the attending physician (or other prescribers) medication management activities is outside our scope of reference. However, if there is an opportunity for educating prescribers who practice outside the LTC environment and may not be familiar with its nuances, consultant pharmacists could have a role in helping to educate these practitioners as it relates to clinical rationale and nursing home regulations.

NCPA believes that the medical directors should have some responsibility and accountability within the facility to oversee medication management activities. For instance, if a consultant makes a recommendation to try a dose reduction and the attending prescriber responds by saying that the patient is stable, the medical director is an appropriate position to act as a liaison to discuss with the attending prescriber, peer-to-peer, the LTC clinical rationale for trying a dose reduction.

[1] Bootman J.L., Harrison D.L., Cox E. The Health Care Cost of Drug-Related Morbidity and Mortality in Nursing Facilities. Arch Int Med 1997;157:2089–96.

If attending physicians (or other prescribers) fail to engage in appropriate/adequate medication management activities for long-term care residents, the medical director should be encouraged to act as a liaison and provide the appropriate follow-up (education or discussion) with the attending prescriber.

Regarding actions/steps which could be undertaken to establish and ensure the independence of a consultant pharmacist in conducting their medication reviews on behalf of nursing home residents, we support disclosure by the consultant pharmacist of any affiliations that would pose a potential conflict of interest, including notation of the employer of the consultant pharmacist and the execution of an integrity agreement by the consultant pharmacist. If the consultant pharmacist feels he or she is under pressure by their employer to act in unlawful or unethical ways, there are already processes in place the employee can take to address this issue from a legal perspective.

As to actions/steps which could be undertaken to establish and ensure the effectiveness of a consultant pharmacist, we believe the product of the PQA LTC Workgroup will best address this question. The workgroup initially plans to develop performance measure concepts that assess the impact and uptake of consultant pharmacists' recommendations, provide testing recommendations for how these metrics can be validated and a plan for pilot testing, and develop an initial assessment of a measure for appropriate use of atypical antipsychotic use in the nursing home setting.

In addition, we would also like to note that reports authored by consultant pharmacists currently require a response by the prescriber. Enforcement of the response process would be helpful to consultant pharmacists to be more effective in their capacity. One suggestion is to have a central point of data collection and review at the facility. For example, someone, such as the medical director, should review the consultant pharmacist report and its recommendations, the response by the prescriber to the recommendation, and the patient outcome. If the consultant pharmacist recommendation does not have a response by the prescriber, this needs to be noted and followed-up accordingly.

Data Collection and Use

NCPA appreciates the interest by CMS to better define this issue with consultant pharmacists and formulate a more appropriate approach to address it. Regarding the data needed to enable and support the Medicare and Medicaid programs and others in monitoring the appropriateness and adequacy of medication management activities, including the use of antipsychotics drugs, we recommend that the monitored data should be tied to quality measures and the resident care plan; monitoring cannot simply be the tracking of the number of medications.

As noted in our comments above, consultant pharmacists are required to make recommendations and prescribers are required to respond, but sometimes they do not and there is no enforcement mechanism if the prescriber chooses not to respond. Furthermore, the responses of the prescribers that do respond are not tracked. We understand that the capability of software systems to tie consultant pharmacist recommendations to outcomes exists but needs to be further developed and could potentially allow a trace back from consultant pharmacist recommendations to prescriber actions. The development of this type of software upgrade could help to monitor the appropriateness of medication management activities.

We also want to recognize that sometimes no prescriber action is an appropriate response so the monitoring system should not be limited to having to act on the recommendation other than perhaps a note of recognition of the recommendation.

To enable CMS to study the effectiveness of consultant pharmacist medication reviews, the recommendations of the PQA LTC Workgroup will be useful. NCPA also believes the necessary data should include patient outcomes to demonstrate the effectiveness of the care provided, not the process. Effectiveness cannot be measured with any validity until a system is put into place which promotes a response by the prescriber, and such information is tracked and compiled for review.

NCPA does not believe that there are data available currently that can help create public performance metrics regarding the independence of consultant pharmacists and prescribers from pharmacies and drug manufacturers/distributors. We question what such performance metrics would do for the public and how they would understand them. Furthermore, since recommendations made by the consultant pharmacist are not tracked with the responses by the prescribers, it seems inappropriate to create public performance metrics at this juncture. If CMS proceeds in the manner, consideration should be made to include metrics for all licensed healthcare providers (e.g. registered dieticians and relationships with medical food manufacturers, etc.).

Data are available on the number and type of interventions recommended by consultant pharmacists, but the outcomes of the recommendations are not tracked. It would be helpful to have the outcomes of the recommendations tracked as stated above. Such data should be used for internal purposes only (within the facility) at monthly or quarterly meetings to discuss the individual resident plans of care and global medication recommendations within the facility.

Increasing Transparency

The question related to what specific details regarding the financial (and other) arrangements between LTC facilities, consultant pharmacists, and LTC pharmacies providing consulting and/or dispensing services should be disclosed, and to whom should this information be available, has limited answers that would lead to increased transparency without revealing proprietary information. Due to the sensitive nature of contractual agreements and proprietary information disclosed therein, financial disclosure is not appropriate. Consultants can sign integrity agreements that specify potential conflicts of interest and integrity agreements between a dispensing pharmacy and consultant pharmacist can be made available to anyone if asked, including family members. Some pharmacists are already adding disclosure statements to their consultant recommendation reports.

Although the public cannot be informed about financial arrangements between parties due to proprietary information in business practice, they could be informed that a contract is in place between the name of the pharmacy, the name of the consultant pharmacist and the name of the facility. NCPA encourages complete transparency in this regard, including a requirement that all licensed healthcare providers in the facility be required to disclose such information.

Regarding the information needed to assess the independence and adequacy of physician (and other prescriber) medication management and oversight on behalf of nursing home patients and metrics that could be used to assess the adequacy and appropriateness of prescriber response to consultant pharmacist recommendations, NCPA does not have insights to the actions of prescribers.

As mentioned above, software enhancements to track consultant recommendations and prescriber responses would be helpful in this scenario. We believe consultant pharmacists and prescribers may serve patients better if prescribers were more accountable to respond to consultant pharmacist recommendations.

There are a number of metrics that could be used to describe the adequacy and appropriateness of an LTC facility's medication management program. One suggestion is to monitor for trends at the facility and conduct education in the facility based on the trends occurring in that particular nursing home. Education can include things not necessarily related to the medication regimen review, but that perhaps have an indirect impact. As mentioned above, it would be useful to track the consultant pharmacist recommendations and the prescriber response to such recommendations. There are a number of quality measures in place currently, including the Nursing Home Quality Measures, and we suggest any additional metrics be reviewed with these in mind and incorporated into current measure processes.

Overall, it is worth noting that the focus of the metrics should concentrate on the quality of patient care; evaluate the whole patient and what the treatment goals are, not just the cost of medications. Consultant pharmacists are in a unique position to identify broad system issues and help update policies and procedures, conduct patient outcomes-based educational programs such as falls risk assessment programs or monitoring for hypoglycemia in patients with diabetes, and are a resource for the facility staff.

Conclusion

NCPA remains opposed to any requirement that LTC facilities employ or directly or indirectly contract the services of a licensed pharmacist who is independent of any affiliations with said LTC facilities' LTC pharmacies, pharmaceutical manufacturers and distributors, or any affiliates of these entities. We do not dispute that this practice was conducted by a small group of individuals; however, the entire industry should not be punished or completely changed for the actions of a few. It is our understanding that the influence that existed primarily affected the choice of which drug was used, rather than whether a drug was used at all.

We encourage CMS to enforce current regulations already in place and let the industry further address this issue by adopting the suggested changes to increase transparency and through its work with PQA. The vast majority of LTC consultant pharmacists strive to be objective, unbiased, and work with the best interest of nursing home residents in mind.

Lastly, as stewards of the healthcare dollar we as a group must be careful not to silo the cost of medications and tie this cost directly to overutilization. The prudent use of medications can decrease the total cost of patient care by properly managing disease states and thus avoiding costly procedures and inpatient stays.

It is also important not to assume that all use of atypical antipsychotics is inappropriate in dementia residents. In certain cases, short term use in some patients is appropriate. We must consider the overall care of patients and their wellbeing across all treatment modalities.

We appreciate the opportunity to share our concerns and recommendations with you.

Sincerely,

Ronna B. Hauser, PharmD
Vice President, Policy & Regulatory Affairs