creates an unnecessary tension in the doctor-patient relationship. Some commenters requested that CMS prohibit physicians or other prescribers who file IRE appeals on behalf of enrollees, from charging enrollees any fee for assistance unless an enrollee has agreed to the fee in writing. Other commenters requested that CMS issue guidance related to reasonable fees. A number of commenters also noted that CMS rules related to appointment of representatives include a provision that a physician representative may waive a fee for representing a beneficiary.

Response: Subpart M does not address fees charged by physicians or other prescribers; therefore, we believe these comments are outside the scope of the proposed regulation.

As stated previously, we are finalizing the proposed changes without modification. However, we are, changing the effective date of this provision from 60 days after the publication of this rule to January 1, 2013, to clarify that prescribers may not begin requesting reconsiderations on behalf of the beneficiary until the 2013 plan year.

5. Independence of LTC Consultant Pharmacists (§483.60)

In our October 11, 2011 proposed rule (76 FR 63038), we noted that under sections 1819(b)(4) and 1919(b)(4) of the Act, long term care (LTC) facilities must provide, either directly or under arrangements with others, for the provision of pharmaceutical services to meet the needs of each resident. This requirement is codified in regulations at §483.60, which require LTC facilities to employ or obtain the services of a licensed pharmacist to provide consultation on all aspects of the provision of pharmacy

services in the facility, including a drug regimen review at least once a month for each facility resident. We explained that, as a result of their role in LTC facilities, LTC consultant pharmacists may exercise significant influence over the drugs that LTC facility residents receive.

We noted that nursing homes commonly contract with a single LTC pharmacy for prescription drugs for facility residents. Very often the same LTC pharmacy then also contracts with the facility to provide consultant pharmacists for required consultation on all aspects of the provision of pharmacy services in the facility, including the monthly resident drug regimen reviews. We indicated that, in verbal conversations with industry representatives, we had been informed that some LTC pharmacies provide the consultant pharmacists to nursing homes at rates that may be below the LTC pharmacy's cost and below fair market value.

We expressed our concern with the potential effect on patient safety and quality of care for nursing home residents regarding the various contractual arrangements involving LTC facilities, LTC pharmacies, pharmaceutical manufacturers and/or distributors, and the LTC consultant pharmacists that may be provided through LTC pharmacies directly or indirectly to LTC facilities. We noted these arrangements may take many forms and mentioned the practice of LTC pharmacies' providing consultant pharmacists to nursing homes at below cost or fair market value as one such type of arrangement. We noted also that any such arrangements have the potential to directly or indirectly influence consultant pharmacist drug regimen recommendations. We indicated our concern that the lack of independence of the consultant pharmacist from the interests

of the LTC pharmacy or other LTC pharmacy-related organization may lead to recommendations that steer nursing homes to recommend or use certain drugs for their residents. We noted this could result in the overprescribing of medications, the prescribing of drugs that may be inappropriate for LTC or geriatric residents, or the use of unnecessary or inappropriate therapeutic substitutions. We remarked that such potential outcomes could pose serious health-related consequences to some nursing home residents' health and safety.

In our October 11, 2011 proposed rule (76 FR 63039), we referenced the claims brought by qui tam relators under the False Claims Act and cited research findings, HHS Office of Inspector General review findings, and nursing home survey and certification data to demonstrate that our concerns were not merely theoretical. We acknowledged that our findings did not directly connect LTC pharmacy relationships with consultant pharmacists to the research findings and survey results; however, we believed it was reasonable to presume that the incentives present in the relationships among some consultant pharmacists, LTC pharmacies, and drug manufacturers could influence the prescribing practices reflected in the data. As a result, we expressed our belief that requiring the independence of consultant pharmacists was necessary and appropriate and were considering making such a change. We solicited comments on our understanding in this matter.

In our October 11, 2011 proposed rule (76 FR 63040), we stated that we believed severing the relationship between the consultant pharmacist and the LTC pharmacy, pharmaceutical manufacturers and distributors, and any affiliated entities would further

protect the safety of LTC residents because it would ensure that financial arrangements would not influence the consultant pharmacist's clinical decision making to the detriment of LTC residents. Therefore, we indicated that we were considering requiring that LTC consultant pharmacists be independent of any affiliations with the LTC facilities' LTC pharmacies, pharmaceutical manufacturers and distributors, or any affiliates of these entities and believed such a requirement would be necessary to ensure that consultant pharmacist decisions were objective, unbiased, and in the best interest of nursing home residents. LTC facilities would use a qualified professional pharmacist to conduct drug regimen reviews and make medication recommendations based on the best interests of the resident. We expressed our belief that this could be achieved only if the consultant pharmacist were working without the influence of conflicting financial interests that might otherwise encourage overprescribing and overutilization, which creates health and safety risks for residents.

We noted the changes we were considering would use the authority available under sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act to require that LTC consultant pharmacists be independent. The cited statutory provision gives the Secretary authority to establish "such other requirements relating to the health, safety, and well-being of residents…." We stated we were considering requiring that LTC facilities employ or directly or indirectly contract the services of a licensed pharmacist who is independent. We also noted we were considering including a definition of the term "independence" to mean that the licensed pharmacist must not be employed, under contract, or otherwise affiliated with the facility's pharmacy, a pharmaceutical manufacturer or distributor, or

any affiliate of these entities.

Finally, we noted our understanding that some LTC consultant pharmacists may perform approximately 60 drug regimen reviews in a day. We indicated we suspect that this rate may be too high, given our expectation that independent consultant pharmacists would conduct more thorough drug regimen reviews, monitoring for drug side effects and efficacy. Therefore, although we did not propose to codify changes to the drug regimen review requirements, we solicited public comment on best practices related to the conduct of drug regimen reviews and stated we would use these comments to inform possible future rulemaking regarding the drug regimen review requirements.

Comment: CMS received many responses to our request for comment on our understanding of the problems associated with conflict of interest involving LTC consultant pharmacists. A significant number of commenters who identified themselves as current or former consultant pharmacists either acknowledged they had experienced conflict of interest in the past or confirmed our understanding that conflict of interest were an on-going problem. Several of these commenters claimed that conflicts of interest have been widespread and alleged that patient care suffers because of it. A number of these commenters wrote anonymously stating they feared retribution from their pharmacy employers. A commenter asserted that the rules LTC pharmacies placed on their employee consultant pharmacists strongly influenced utilization. This, they note, often resulted in a higher number of medications per resident and use of inappropriate drugs. Commenters who had witnessed or experienced conflict of interest described practices associated with it that included the following:

- Several commenters indicated their LTC pharmacy gave consultant pharmacists a list of "preferred" drugs; that is, drugs for which the LTC pharmacy receives preferred pricing or higher rebates from the pharmaceutical manufacturer, to be used for making their medication recommendations.

- A few commenters described their LTC pharmacy's therapeutic interchange program, which involves the consultant pharmacist recommending a change from a prescribed non-preferred drug to one of the pharmacy's preferred drugs. A commenter characterized therapeutic interchange to rebated drugs as "big business" for the pharmacy. Another commenter explained that, once a change recommendation was made by the consultant pharmacist, the LTC pharmacy automatically generated a fax notice to the prescriber requesting the he or she sign the notice to approve the therapeutic interchange. An additional commenter indicated that the consultant pharmacists' medication change recommendations were communicated in the form of letters to the prescriber prepared by the corporate clinical department of the pharmacy.

- Several commenters explained that consultant pharmacists' performance evaluations and bonuses were based on the market share of particular brand name drugs in the LTC facility. Thus, as the commenters noted, consultant pharmacists had financial incentives to make medication recommendations that enabled the facility market-share targets to be met.

- Many commenters stated that they had first-hand knowledge that LTC pharmacies continue to charge below-market rates for the LTC consultant services as a means of acquiring the LTC facility's pharmacy business, noting that this remains a

common practice. Some of these commenters charged that the pharmacies recovered their costs for the consultant pharmacist services by requiring the consultant pharmacists to recommend drugs that generated the highest profit for the pharmacy.

- Many commenters charged that the consultant pharmacists' drug regimen review quotas were so high that sufficient time was not available to perform a thorough review of the residents' medication regimens and make good recommendations. One commenter cited a minimum drug regimen review quota of 1,500 reviews per month. Another commenter reported that, when a large LTC pharmacy organization acquired the pharmacy at which the commenter had been employed, the new management required that the commenter perform the same number of drug regimen reviews as the commenter had been performing previously, but also that the commenter spend 2 days per week dispensing. As a result, the time available for the commenter to perform the same number of medication reviews was decreased by 40 percent.

- Some commenters asserted that by limiting the time available to conduct them, the drug regimen reviews were perfunctory. Others described how the drug regimen review requirements were subverted. For example, a commenter contended that the consultant pharmacists employed by an LTC pharmacy were performing the medication reviews at the pharmacy rather than the facility and, thus, had no access to medication administration records, physician and nursing assessment notes, lab results, or other information available in the residents' medical records. Another asserted that an LTC pharmacy organization had its consultant pharmacists review the residents' medication administration records, not the entire medical record, thus missing lab values and other

assessments and notes.

- Many commenters agreed that consultant pharmacists should be free from conflict of interest and their medication recommendations should be based solely on the residents' best interests. Finally, however, many other commenters stated that they never experienced any pressure in the conduct of their consultant pharmacist activities, nor had they seen others pressured, and thus they believed that conflict of interest is not an issue for consultant pharmacists.

Response: We appreciate the confirmation of our understanding that conflict of interest may be a problem for many LTC consultant pharmacists. We recognize that a significant number of commenters disagreed with our understanding and, thus, the problem may not be universal. We believe the comments suggest that the problem has been addressed in some places and not in others, is more widespread in some places and therefore more evident, or is associated with a particular LTC pharmacy or pharmacies, particular LTC facilities or chains or pharmaceutical manufacturers or manufacturer representatives.

However, the reports of conflict of interest are sufficient to indicate it continues to exist and our concerns regarding its impact on the quality of care in LTC facilities are well-founded. We believe that this demonstrates that change is necessary to ensure that all LTC consultant pharmacists are free from conflicts of interest, are able to base their professional medication recommendations on the best interest and clinical needs of LTC facility residents, and are able to advocate for the Medicare beneficiary.

Comment: CMS received a large number of comments from advocates and

advocacy organizations, long term care ombudsmen, LTC consultant pharmacists, and others supporting a requirement for LTC consultant pharmacists to be independent and noting that such a policy was needed and long overdue. These commenters asserted that independence is essential to ensure that drug regimen reviews are impartial and the consultant pharmacist is able to act as an advocate for the resident without fear of financial repercussions. A commenter agreed with an independence requirement, noting that removing the financial incentives between the consultant pharmacists and the LTC pharmacy would increase transparency.

CMS also received many comments opposing a requirement that would separate LTC pharmacy consulting from dispensing services. Many of these commenters claimed the requirement would be seriously disruptive, asserting that communication and collaboration between the dispensing pharmacy and the consultant pharmacist would be diminished, consultant pharmacists would be deprived of access to proprietary LTC pharmacy systems, data and other resources critical to the performance of consultant pharmacists' activities. Opposing commenters noted the requirement would also deprive consultant pharmacists of the significant advantages derived from pharmacy employment, including health, retirement and other benefits, and would increase costs to both the LTC facilities and consultant pharmacists. A significant number of these commenters expressed concern that independence would decrease the quality of patient care accordingly.

Many commenters requested that we finalize the requirement and not yield to those who argued against it. CMS received several comments from independent

consultant pharmacists noting that, although others have argued otherwise, working independently has neither hindered access to residents' prescription or medical information, nor diminished the residents' quality of care.

Response: We appreciate these comments, as well as the concerns expressed by those commenters opposed to the requirement for independent consultant pharmacists. The comments supporting the independence requirement have sustained our concerns about conflict of interest and its impact on the quality of long term care. Also, the significant advantages associated with employment described in the opposing comments serve to highlight the strong influence such financial ties can exert on pharmacy-employed consultant pharmacists and reinforce the importance of an independence requirement to ensure unbiased medication reviews. As a result, we remain convinced of the need for changes to ensure that the consultant pharmacists' recommendations are based solely on the residents' best interests and clinical needs. However, we acknowledge that an independence requirement could be highly disruptive to the industry overall, including the LTC facilities and those consultant pharmacists with current industry affiliations, and would result in higher costs to the facilities and consultant pharmacists.

Comment: A few commenters claimed we do not have the statutory authority to impose an independence requirement. These commenters asserted that we cannot use the Secretary's authority under sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act, because consultant pharmacist independence has no direct relationship to resident health and safety. Therefore, for us to require consultant pharmacists to be independent would

require Congressional authorization.

Response: We disagree. We believe that the conflict of interest inherent in the employment relationship between a consultant pharmacist and an LTC facility's pharmacy undermines the ability of the consultant pharmacist to make unbiased medication recommendations that are solely in the best interests of the residents. Many of the comments previously discussed corroborate our belief. Recommendations made on other bases, such as those reflecting the financial interests of the consultant pharmacist or the consultant pharmacist's employer, pose health and safety risks for the residents. Even in those situations in which the consultant pharmacist is able to make unbiased medication recommendations because there are no pressures to do otherwise, if the drug regimen review quota established by the consultant pharmacist's employer is so high as to permit the consultant pharmacist to perform only the most perfunctory medication reviews, then resident health and safety are at risk.

Comment: Many commenters agreed with the definition of "independence" we indicated we were considering. Some commenters disagreed with the definition, indicating that consultant pharmacists should not be permitted to be employees of the LTC facility in order to avoid the potential conflict of interest inherent in an employment relationship. Other commenters requested that consultant pharmacists be permitted to affiliate with pharmaceutical manufacturers and distributors. These commenters argued that affiliations with these entities permit the exchange of scientific and educational information on topics, such as medications and product benefits and risks, and much of this exchange occurs at educational programs supported by the industry at professional

meetings and trade shows. They noted that consultant pharmacists frequently serve on industry advisory boards and are engaged as speakers and researchers with industry financial support and contended that HHS Office of Inspector General guidance for pharmaceutical manufacturers and industry guidelines related to the healthcare professionals' decision-making provide sufficient oversight. One other commenter requested that we define the terms "affiliates" and "affiliated."

Response: We acknowledge that there may be potential conflicts of interest in an employment relationship between consultant pharmacists and LTC facilities, but note that both the LTC facility and its residents have a common interest in the facility meeting CMS standards for unnecessary drug use in the facility. We do not agree with the commenters who advocated that we allow consultant pharmacist relationships with pharmaceutical manufacturers and distributors. The relationships that these commenters describe cause us substantial concern, as we believe they represent a basis for the conflicts of interest that we seek to eliminate. We believe that consultant pharmacists who receive remuneration from pharmaceutical manufacturers/distributors for activities, such as research and speaking engagements or for serving on advisory boards, may be influenced by these relationships in the performance of their consultant pharmacist activities. Thus, if the consultant pharmacists' recommendations are to be based solely on the LTC residents' best interests, these affiliations should be prohibited.

Comment: We received many comments from those supporting the independence requirement for LTC consultant pharmacists as well as from those opposing it, noting that consultant pharmacist independence would not solve the entire problem of conflict of

interest, because other agents contribute to drug overutilization and inappropriate drug use in LTC facilities. Contributors specifically cited by commenters were LTC facility medical directors, nurse practitioners and physician assistants and the residents' attending physicians. A few commenters noted that family members, influenced by pharmaceutical advertisements, could request antipsychotics as adjuncts for depression and the prescriber could accede to these requests. Other commenters noted the LTC facilities' role citing serious understaffing, high staff turnover, and the lack of specialized staff trained in meeting the needs of dementia patients as factors contributing to inappropriate drug use in LTC facilities. Another commenter observed that others also play a contributing role, noting that a considerable number of residents admitted into LTC facilities from their homes, hospitals, and assisted living facilities are already on potentially unnecessary drugs.

Many commenters pointed out that the ultimate decision regarding what medications to prescribe and whether to accept or reject a consultant pharmacist's recommendation lies with the physician. Therefore, the commenters asserted prescribers, not consultant pharmacists, should be held accountable for overuse or inappropriate use of drugs in LTC facilities. Commenters claimed LTC residents' physicians, as well as the facility's medical director, rarely see or examine the residents and medications are reordered without the physician reviewing the residents' condition. According to another commenter, if a resident's behavior problem escalates, such as in the case of a resident with dementia, facility staff would call the physician to increase the medication dosage, and the physician would commonly comply without seeing the resident. Several others

commenters noted that prescribers, aware of potential bias, ignore the consultant pharmacists' recommendations due to uncertainty that the recommendations are in the residents' best interests.

Many of the commenters in opposition to the consultant pharmacist independence requirement noted that conflicts of interest pervade the LTC industry, affecting the facility (which imposes its own formulary requirement to contain costs for the drugs it covers), facility staff (who can encourage the use of chemical restraints to manage residents with behavioral problems), and the residents' physicians and LTC facility-based prescribers (who may have their own financial ties to the pharmaceutical industry). For these reasons, the commenters objected to a requirement that would single out only one group of actors that contribute to this problem. Several commenters recommended that we require that all clinicians in an LTC facility be independent, or that we at least consider the role of the physicians who prescribe medications when determining how best to solve the problem. Other commenters agreed with the independence requirement, but indicated that it was only a partial solution and a more comprehensive approach would be necessary to respond effectively to the whole problem.

Response: We appreciate the many comments noting that others in the LTC industry, including facility staff and residents' attending physicians, contribute significantly to overutilization. Commenters not only implicated others as contributing to overuse of drugs in LTC facilities, but also described other factors that contribute to the problem. Therefore, we recognize that requiring consultant pharmacists to be independent will not solve the entire problem. As a result of these comments, we are

better aware that the independence requirement we specifically described in the October 11, 2011 proposed rule would disproportionately target consultant pharmacists and leave the other actors to continue to operate as they do currently. This suggests that, unless the industry on its own implements steps to curtail overutilization and inappropriate drug use in LTC facilities, we must consider requiring broader changes than independence only for consultant pharmacists and propose those changes in future notice and comment rulemaking.

Comment: Several commenters mentioned the recent investigations of nursing homes conducted by the California Department of Public Health which found that LTC consultant pharmacists failed to identify and report the misuse of antipsychotic medications in 90 percent of the cases identified by investigators as involving inappropriate and potentially lethal doses of these drugs. We also received comments from an LTC pharmacy reporting that over the past 5 years its consultant pharmacists' have made over 700,000 recommendations to prescribers regarding antipsychotic drug use and that more than 99 percent were recommendations to reduce dosage, discontinue or question use or recommend monitoring for side effects. (We note this commenter did not provide information on whether these recommendations were followed.) Citing these data from the LTC pharmacy, another commenter noted that, if (as the level of antipsychotic drug use suggests) prescribers are ignoring the consultant pharmacist recommendations, it raises the question of the effectiveness of the drug regimen reviews. A commenter suggested that, over time, conflict of interest can diminish prescribers' confidence in the consultant pharmacists, eroding their effectiveness. This suggestion was

supported in the comments of another who claimed that prescribers who have been practicing in LTC facilities are sensitive to the ethical conflicts faced by consultant pharmacists and are skeptical of their recommendations because of the prescribers' uncertainty as to whether the recommendations are in the residents' best interests.

Response: These comments and the data reported by the commenters suggest that the required monthly drug regimen reviews are not yielding the intended outcomes nor are they providing the expected beneficiary protections. If perceived conflict of interest has potentially eroded confidence in the recommendations of the consultant pharmacists that prescribers are ignoring them and the reviews have become merely perfunctory exercises, then we may consider changing the requirements in §483.60(c) and explore alternative requirements and approaches. In determining whether a regulatory change is necessary, we will continue to evaluate the number of deficiency citations for unnecessary medication use and will monitor two new performance measures on the use of antipsychotics in LTC facilities. These new performance measures, based on resident assessment information reported in the Minimum Data Set (MDS 3.0), will reflect antipsychotic drug use by short-term stay and by long-term stay facility residents and will be available later in 2012 on the CMS nursing home compare Web site at http://www.medicare.gov/NHcompare/home.asp.

Comment: We received extensive comments expressing serious concerns about the level of overuse and inappropriate use of antipsychotic drugs in LTC facilities. A commenter stated that, "On any given day, over 350,000 nursing home residents receive powerful antipsychotics, despite FDA warnings that the drugs increase the risk of death

and studies that show the drugs do not work and have terrible side effects." Many commenters noted the vast majority of those receiving these drugs are residents with dementia who are being chemically restrained when there are safe, effective, and less expensive nonpharmacological methods to care for these residents. Another commenter stated that studies show that compassionate, person-centered care can minimize anxiety and depression and minimize the need for psychotropic medications.

Response: We share the grave concerns expressed by the commenters concerning the level of antipsychotic drug use in LTC facilities. We believe these comments also call into question the effectiveness of the consultant pharmacists' drug regimen reviews in curtailing the use and misuse of antipsychotics drugs, regardless of whether the ineffectiveness is caused by inadequate medication reviews by consultant pharmacists or prescribing physicians ignoring the recommended changes. As we indicated previously, we agree that consultant pharmacist independence will not solve the whole problem. Therefore, we challenge the entire LTC industry to do what is in the best interests of our most vulnerable beneficiaries and implement the necessary and appropriate changes to address this serious situation.

We expect that through the implementation of changes, such as placement of greater emphasis on the use of nonpharmacological methods of care as an alternative to pharmacological treatment for the behaviors associated with dementia, the industry will achieve substantial improvement in the appropriate use of these medications. Although not all non-pharmacological treatments are appropriate for all patients, some nonpharmacological interventions may have potential benefits for residents with the

behavior symptoms associated with dementia, such as agitation or aggression, wandering and sleeping disturbances. These interventions include, for example, music therapy, massage therapy, behavior management techniques, and animal-assisted therapy.

Comment: A number of commenters offered recommendations for increasing transparency in order to address conflicts of interest issues in LTC facilities. Some commenters recommended that we require LTC facilities to separate contracts for LTC consulting services from contracts for other services, including drug dispensing, and require LTC facilities pay a fair market rate for consultant pharmacist services. Some commenters suggested either that we require consultant pharmacists to disclose to the facility any affiliations that would pose a potential conflict of interest or require consultant pharmacists to sign an integrity agreement. Several commenters recommended that LTC pharmacies ensure that consultant pharmacists are empowered to make independent judgments and affirm this in a statement to the facility. One commenter suggested that, should the implementation of a requirement for consultant pharmacists to be independent be delayed, we require consultant pharmacists to disclose their affiliations and potential conflicts of interest.

Response: We continue to believe that requiring independent consultant pharmacists is part of the right approach to address our concerns regarding conflict of interest and quality of care in LTC facilities. It is an approach that was strongly supported by some consultant pharmacists who confirmed our belief that LTC pharmacies do exert pressure on the consultant pharmacists in their employ to influence the medication recommendations. It was also supported by individual commenters,

advocates and advocacy organizations, Part D plan sponsors and PBMs, and consultant pharmacist organizations. However, we acknowledge that others in the industry, including LTC facility staff and prescribers, are likewise implicated in the problem of overprescribing and inappropriate drug use. Thus, an independence requirement solely for consultant pharmacists would not solve overutilization and would single out one party, but leave the others to continue unaffected. We agree with commenters that the requirement would be highly disruptive to both LTC facilities and consultant pharmacists with current industry affiliations. Because the proposed requirement does not address the role of facility staff and prescribers in driving overutilization and inappropriate use, it is unlikely to result in substantially reducing these problems that would, in our view, outweigh the costs of industry disruption.

Comment: We received several comments that noted the lack of empirical evidence linking overutilization of drugs in LTC facilities to consultant pharmacists' possible conflicts of interest. Numerous commenters suggested that we study the recommendations, drug utilization and outcomes data for independent and pharmacy employed consultant pharmacists and many of these commenters also recommended that we consult with stakeholders to better define and scope the problem and formulate a more appropriate approach for addressing it.

Response: If, as suggested by other commenters, consultant pharmacist recommendations are rarely acted upon, this calls into question the very purpose of the consultant pharmacists' medication reviews. We expect the industry to demonstrate the value of these reviews to the LTC residents' quality of care. Therefore, we believe the

industry should collect data on the number and type of interventions recommended by the consultant pharmacists and on the outcomes of those recommendations. We expect some, if not all, of these data are already being collected and we recommend the industry work with such entities as the Pharmacy Quality Alliance (PQA) and other consensus gathering organizations, to develop performance measures to assess consultant pharmacist effectiveness. Further, since the consultant pharmacists are not the only group with responsibility for the ensuring the safety and efficacy of care in the LTC facility, we expect the LTC provider and medical industry to also implement changes to address the problem of overuse and misuse of medications in LTC so that we will see inappropriate prescribing of all medications, but particularly antipsychotics, decrease. Should marked improvement not occur, we will use future notice and comment rulemaking to propose requirements to address our concerns. In determining whether marked improvement has been made, we will continue to evaluate the number of deficiency citations for unnecessary medication use and will monitor the two new performance measures on the use of antipsychotics in LTC facilities.

Comment: We received comments recommending that LTC pharmacies be required to disclose their rebates and several other comments recommending the elimination of manufacturer rebates to LTC pharmacies based on utilization.

Response: Although we agree that market-share-moving rebates may provide incentives that are not in the LTC residents' best interests, we believe that these suggestions are beyond the scope of this proposal, and we are not in a position to respond to these recommendations at this time.

Comment: Several commenters recommended a requirement that facilities use qualified professional consultant pharmacists for LTC consulting services and strictly enforce compliance with that requirement. Another commenter suggested that, as an alternative, we establish an audit or other oversight process to review and evaluate all medication changes recommended by LTC consultant pharmacists and all contractual agreements that pose potential conflict of interest risk.

Response: We appreciate these comments and will consider the recommendations in the process of future rulemaking on this issue. However, as noted above, we believe the LTC industry should collect data on the number and type of interventions recommended by the consultant pharmacists and on the outcomes of those recommendations and we recommend the industry work with such entities as the PQA and other consensus gathering groups, to develop performance measures to assess consultant pharmacist effectiveness. Since the consultant pharmacists are not the only group with responsibility for the ensuring the safety and efficacy of care in the LTC facility, we expect the LTC provider and medical industry to also implement changes to address the problem of overuse and misuse of medications in LTC so that we will see inappropriate prescribing of all medication.

Comment: Many commenters responded to our request for comment on permitting exceptions for unique situations involving minimal conflict of interest risk or waiving the independence requirement to permit other alternate approaches. Some commenters recommended that we grant no waivers or exceptions, arguing that there should be a level playing field and that no employment relationship was free from

conflicts of interest. Other commenters agreed with allowing exceptions or waivers for alternate approaches for IHS/Tribal facilities and facilities in rural or other "hardship areas". Several commenters suggested we monitor the exception and waiver processes to ensure they are fair and equitable. Other commenters requested either exceptions or alternate approaches for facilities with in-house pharmacies, VA, and State Veterans nursing homes, and various other situations.

Response: We appreciate these comments and will consider them in the process of future rulemaking on this issue.

Comment: Several commenters recommended either coordination between consultant pharmacists' drug regimen reviews and medication therapy management (MTM) services in order to eliminate overlap/duplication between the two reviews.

Response: We agree that the potential overlap between the drug regimen reviews required in LTC and Part D MTM reviews could possibly result in conflicting reviews. As a result, in the provision on MTM in LTC facilities discussed elsewhere in this rule, we encourage plan sponsors to consider making arrangements that include the LTC consultant pharmacist in conducting Part D MTM services for targeted beneficiaries in LTC facilities. We note such arrangements could include direct contracts between the sponsor and consultant pharmacists (or their intermediaries), or indirect contracts between the sponsor's MTM vendor or PBM and consultant pharmacists (or their intermediaries).

Comment: Several commenters recommended we establish a January 1, 2013 effective date, and other commenters requested either a delay in implementation or

suggested a later effective date. Commenters provided recommendations for phasing in the requirement and for implementing the requirement initially as a demonstration program. Commenters also noted that these latter approaches would enable us to benefit from lessons learned and identify best practices for future implementation.

Response: We appreciate these comments, but, as discussed further later in this section, we are not finalizing this provision at this time.

Comment: We received numerous comments in response to our request for information concerning best practices in the conduct of drug regimen reviews. A few commenters suggested that we require consultant pharmacists be afforded adequate time for the monthly drug regimen reviews. Another suggested that we refer to the American Society of Consultant Pharmacists "Guidelines for Assessing the Quality of Drug Regimen Review in Long Term Care Facilities" which the commenter noted provides standards to evaluate the quality of the drug regimen review and to improve the process. Several other commenters asserted that establishing a specific rate would be inappropriate because the facility's case-mix could affect the rate. However, other commenters specified what they believed would be the optimal rate per day; the suggested rates varied from a low of 20 to a high of 64 per day.

Response: We appreciate the comments and suggestions and will use them to inform possible future rulemaking regarding the drug regimen review requirements.

Comment: Many commenters noted that the services performed by LTC consultant pharmacists are more extensive than the drug regimen reviews and include activities, such as destroying unused medications, checking storage areas, conducting exit

conferences, providing in-service education to nursing staff, observing medication distribution, and attending meetings. Commenters stated all the full range of consultant pharmacist services need to be considered in evaluating the impact of any new requirements.

Response: We appreciate these comments and, as we indicated in the October 11, 2011 proposed rule, we will use them to inform possible future rulemaking regarding the LTC consultant pharmacist requirements.

As a result of considering the comments we received on this issue, we now believe a more targeted and less disruptive approach, at least initially, is warranted. We considered the possibility of finalizing several of the requirements recommended by these commenters to increase transparency around current contractual arrangements and incentives. We agree with the recommendation that LTC facilities pay a fair market rate for consultant pharmacist services; we note that the OIG has stated that provision of consultant pharmacists' services by LTC pharmacies at below market rates "present[s] a heightened risk of fraud and abuse" (*OIG Supplemental Guidance Program for Nursing Facilities*, 73 FR 56832, 56838, note 53, September 30, 2008). However, we do not believe it is within our statutory authority to require provision of such services at market rates. We also considered requiring that LTC facilities separately contract for consultant pharmacist services from other pharmacy services and that consultant pharmacists disclose to the LTC facility, the medical director, ombudsmen, and residents upon request any affiliations that would pose a potential conflict-of-interest risk.

However, due to the notice and comment provisions of the Administrative

Procedure Act (5 U.S.C. 553) and section 1871(a)(4) of the Act, and their respective requirements that a final rule be the logical outgrowth of a proposed rule, we believe that any such requirements cannot be finalized in this final rule with comment period, since we did not propose them initially. As a result, since a requirement for independent consultant pharmacists will not solve the entire problem, but would be significantly disruptive for much of the LTC industry, we are not finalizing this provision at this time. Instead, we are soliciting additional comments to help us determine a more comprehensive approach to eliminate overprescribing and the use of chemical restraints in LTC.

In the meantime, given our continuing conflict of interest concerns, we strongly encourage the LTC industry in general to voluntarily adopt the following changes to increase transparency: separate contracting for LTC consulting services from dispensing and other pharmacy services; payment by LTC facilities of a fair market rate for consultant pharmacist services; and disclosure by the consultant pharmacists to the LTC facility of any affiliations that would pose a potential conflicts of interest; or the execution by the consultant pharmacists of an integrity agreement. We expect the industry to use this opportunity to collect data on the number and type of interventions recommended by the consultant pharmacists and on the outcomes of those recommendations. We believe that LTC pharmacies may already collect some, if not all, of these data and would be able to work with such entities as the Pharmacy Quality Alliance (PQA) and other consensus gathering organizations, to develop performance measures to assess consultant pharmacist effectiveness.

Until the next opportunity for us to propose a regulatory change, we will closely evaluate the number of deficiency citations for unnecessary drug use and will monitor the two new performance measures to track the use of antipsychotics in LTC facilities and expect to see significant improvement. We will also continue to participate in a Department of Health and Human Services (DHHS) initiative focused on the use of antipsychotics for persons with Alzheimer's disease. As part of this effort, we are seeking to eliminate the inappropriate use of antipsychotic drugs in LTC facilities for residents with Alzheimer's disease through updated guidance on the use of these medications and stricter enforcement of current requirements. In partnership with the Alzheimer's Disease Education and Referral Center, we will work to better educate LTC facilities, prescribers and the resident's families. We believe that effort focused on eliminating the use of inappropriate chemical restraints for LTC facility residents with Alzheimer's disease may also serve to improve the quality of care for the LTC facility residents with the behavior symptoms associated with dementia.

Our expectation is that the industry will implement changes to address the problem and we will see inappropriate prescribing decrease. Should marked improvement in inappropriate utilization not occur, we will use future notice and comment rulemaking to propose requirements to address these concerns. After considering the public comments received, we are not finalizing this provision. However, we are soliciting further comment to assist us to better define the problem and frame a more comprehensive solution to address our concerns regarding medication management and quality in LTC. Specifically, we solicit comment related to the

following three issues:

- Enhancing medication management and the effectiveness of medication review.

We noted in the previous comment summary and responses that many commenters pointed out that besides consultant pharmacists, other parties and factors contribute to overprescribing and inappropriate drug use in LTC facilities. These commenters charged that prescribers, including facility medical directors, nurse practitioners and physician assistants as well as the residents' attending physicians, are major contributors. Others described how pharmaceutical representatives and advertising, family members, and the LTC facility's understaffing, high staff turnover, and lack of specialized staff trained in meeting the needs of dementia patients contribute to the problem. We noted, too, that commenters questioned the effectiveness of the consultant pharmacists' medication reviews, charging that drug regimen review quotas were so high that the reviews had become perfunctory and that others had described how the review requirements were subverted. Other commenters suggested that the consultant pharmacists' recommendations were being ignored by prescribers due to their lack of confidence that the recommendations were in the best interests of the residents. As a result of these comments, we are not only aware that requiring consultant pharmacists to be independent will not solve the entire problem, but also that the drug regimen reviews may not be yielding the intended outcomes or providing the expected beneficiary protections, Therefore, we seek comment in response to the following questions:

++ What actions/steps should 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?

++ What is and should be the role of nursing home medical director in overseeing the attending physician (or other prescribers) medication management activities?

++ What actions, if any, should the medical director take when attending physicians (or other prescribers) fail to engage in appropriate/adequate medication management activities?

++ What actions/steps could be undertaken to establish and ensure the independence and effectiveness of a consultant pharmacist in conducting their medication reviews on behalf of nursing home residents?

++ What training and best practice models would assist all nursing home staff to better understand behavior signs and symptoms and respond appropriately and effectively in assisting and caring for nursing home residents?

• Data collection and use.

As we indicated previously, in commenting on this provision, several commenters noted the lack of empirical evidence linking overuse and inappropriate use of drugs in LTC facilities to consultant conflict of interest. Numerous commenters recommended CMS conduct further study and consult with stakeholders to better define the problem and formulate a more appropriate approach for addressing it. As a result, we solicit comment in response to the following questions:

++ What data are 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?

++ What data are needed to enable CMS to study the effectiveness of consultant pharmacist medication reviews?

++ What data are needed to create public performance metrics regarding the independence of consultant pharmacists and prescribers from pharmacies and drug manufacturers/distributors?

++ Are data needed on the number and type of interventions recommended by consultant pharmacists and on the outcomes of those recommendations? If so, how could such data be used and by whom?

- Increasing transparency.

Finally, as noted previously, a number of commenters offered recommendations for increasing transparency in order to address conflict of interest in LTC. Many commenters on this provision charged that conflict of interest was pervasive in LTC, affecting the facility which imposed its own formulary requirements to contain costs for the drugs it covered, facility staff who encouraged the use of chemical restraints to manage residents with behavioral problems, and residents' attending physicians and facility prescribers who may have had their own ties to the pharmaceutical industry. We expressed our interest in several of the recommendations, but due to the notice and comment provisions of the Administrative Procedure Act and section 1871(a)(4) of the Act, and their respective requirements regarding logical outgrowth, we believe that any such requirements cannot be finalized in this rule. Thus, we solicit comment in response to the following questions:

++ 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?

++ Should the public be informed of the financial and other arrangements between LTC facilities, consultant pharmacists, and LTC pharmacies providing consulting and/or dispensing services? If so, what metrics could be used?

++ What information is needed to assess the independence and adequacy of physician (and other prescriber) medication management and oversight on behalf of nursing home patients? What metrics could be used to assess the adequacy and appropriateness of prescriber response to consultant pharmacist recommendations?

++ What metrics could be used to describe the adequacy and appropriateness of a LTC facility's medication management program?

++ Describe the incentives and other arrangements that create the conflict of interest in LTC that contributes to overutilization and inappropriate drug use in LTC facilities. How can the conflict of interest stemming from these incentives and arrangements be contained or eliminated?