independent review of their cases which creates the potential for delays in prescription drug access. Furthermore, given a prescribers' ability to act on behalf of an enrollee in requesting Part D plan level appeals, prescribers frequently express dissatisfaction with not being able to also assist patients with IRE level appeals and the perceived burden associated with becoming the enrollee's appointed representative. Clearly, this proposal would significantly reduce the number of requests for review that the Part D IRE dismisses due to the lack of an AOR form. In addition, because the IRE will no longer have to seek an AOR form, it will be able to immediately initiate substantive review of these cases. Thus, we believe this change would enhance beneficiary access to the appeals process and better ensure prompt IRE decisions on whether requested drugs should be covered under Part D.

Under this proposal, the regulations would continue to require a Part D enrollee, or a prescriber acting on his/her behalf, to request an IRE review; adverse redeterminations would not be automatically forwarded to the IRE. We have considered requiring auto-forwarding of adverse redetermination requests under the Part D program, but we continue to believe that the statute supports the position that in order to obtain IRE review the enrollee (or someone acting on the enrollee's behalf) must request such review. (See the January 28, 2005 final rule (70 FR 4193) for a discussion of this issue.) Although section 1860D–4(h) of the Act states that only the Part D eligible individual shall be entitled to bring an appeal to the IRE, we do not interpret this language as precluding a prescriber from acting on a Part D enrollee's behalf in requesting IRE review. As required by section 1860D–4(h) of the Act, this proposed change makes the MA and prescription drug benefit programs' appeals processes more similar, by giving Part D prescribers a mechanism to assist enrollees in accessing IRE review. In the MA program, the regulatory requirement that adverse plan reconsiderations be auto-forwarded to the IRE essentially gives physicians acting on behalf of enrollees direct access to the IRE reconsideration process. Also, as explained in our January 2009 final rule, allowing prescribers to request IRE appeals on behalf of enrollees does not present a conflict of interest because Part D prescribers are generally not entitled to payment from the enrollee, pharmacy, or plan for the prescribed drug, and therefore, do not have a financial interest in the outcome of appeals in the same manner as physicians requesting appeals under the MA program. Furthermore, we believe that an enrollee's prescriber has already been selected by the enrollee and occupies a position of trust. A prescriber is in a good position to know whether an independent review is warranted and is in the best interest of his or her patient.

This proposal should reduce administrative burdens under the IRE appeal process by eliminating the need for prescribers to routinely obtain AOR forms from enrollees and permitting prescribers to assist their patients in the appeals process without taking on the added responsibilities attendant to being an appointed representative. In contrast to the ongoing authority of appointed representatives, this proposal would allow a prescriber to act on an enrollee's behalf on an as-needed, case-by-case basis. A completed AOR form is not necessary or advisable for prescribers who are only seeking to assist Part D enrollees in exercising their own appeal rights under the statute. Prescribers will not have the same authority as an appointed representative, such as the right to bring appeals at any level, the right to obtain information on appeals, etc. Instead, we envision that from the time of the initial IRE appeal request, the prescriber's role will remain what it has been—providing a supporting statement or the clinical information necessary to approve coverage, if appropriate. Accordingly, we believe that this proposal will promote enrollee access to the Part D appeals process, reduce the burden on the prescriber community, and allow a more efficient use of appeals resources.

We are proposing a corresponding change to § 423.602(a) to specify that the IRE is responsible for notifying the prescriber of its decision when the prescriber makes the request on behalf of the enrollee. The enrollee will receive a written decision notice from the IRE, ensuring that enrollees are fully informed about the review process and able to participate if they choose to do so. We intend to issue additional manual guidance regarding the specifics of prescriber notice requirements.

As in § 422.582 and § 423.580, we are proposing that prescribers must notify enrollees whenever they request IRE review on their behalf, and we intend to issue additional operational guidance with respect to how this requirement may be satisfied. Finally, we want to make clear that this proposal addresses only the right of a prescriber to file an appeal on behalf of an enrollee at the IRE level. Other individuals who wish to act on behalf of an enrollee in filing an appeal must continue to do so as the enrollee's representative.

5. Independence of LTC Consultant Pharmacists (§ 483.60)

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.

In the process of performing the drug regimen reviews, if the consultant pharmacist recommends a modification of a resident's drug treatment regimen, he/she notates the resident's medical record with the recommendation to the prescribing physician. The prescribing physician must respond to the recommendation and, based on our experience, the physician generally follows it because the consultant pharmacist is considered to be an unbiased expert of pharmacology in the LTC setting. As a result of their role in LTC facilities, LTC consultant pharmacists have significant influence over the drugs that LTC facility residents receive.

In accordance with section 1860D–4(b)(1) of the Act, as codified in our regulations at § 423.120(a)(5), Part D sponsors are required to provide LTC facility residents who are plan enrollees convenient access to LTC pharmacies. We expect that each LTC facility would select one, or possibly more than one, eligible network LTC pharmacy to provide Medicare drug benefits to its residents. We have specified minimum performance and service criteria in the Medicare Prescription Drug Benefit Manual, Chapter 5 (''Benefits and Beneficiary Protections''), section 50.5.2 (available on the CMS Web site at: *http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter5.pdf).*

Commonly, nursing homes 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. In verbal conversations with industry representatives, we have been informed

that LTC pharmacies typically provide the consultant pharmacists to nursing homes at rates that are well below the LTC pharmacy's cost and below fair market value.

We have been concerned with the potential effect on patient safety and quality of care of various contractual arrangements involving LTC facilities, LTC pharmacies, the LTC consultant pharmacists these pharmacies provide to LTC facilities, and pharmaceutical manufacturers and/or distributors. These arrangements may take many forms. The practice of LTC pharmacies' providing consultant pharmacists to nursing homes at below cost or fair market value is one such type of arrangement. We are concerned that these arrangements may be used to entice nursing homes to enter into contracts with the LTC pharmacy for pharmacy dispensing services and the purchase of prescription drugs. We are greatly concerned with financial arrangements that involve payments from pharmaceutical manufacturers directly or indirectly to LTC pharmacies and LTC consultant pharmacists for encouraging physicians to prescribe the manufacturer's drug(s) for residents. The impact of these financial incentives is heightened when, as permitted under State law or by the State Pharmacy Board, LTC facilities sign agreements with LTC pharmacies permitting the consultant pharmacists to make medication switches. These types of arrangements may result in incentives for the LTC consultant pharmacist to make recommendations that conflict with the best interests of nursing home residents, as well as with Part D sponsors' formularies and/or drug utilization management (DUM) programs. Any such arrangements have the potential to directly or indirectly influence consultant pharmacist drug regimen recommendations. As a result, the arrangements bring into question the ability of the LTC consultant pharmacists to provide impartial reviews of the residents' drug regimens, which in turn raises concerns regarding the quality of those reviews and potential impact on resident health and safety.

Industry estimates indicate that three LTC pharmacy organizations have 90 percent of the market. Based on these estimates, the LTC pharmacy industry is highly concentrated, and we believe, therefore, these arrangements are widespread. As a result, we are concerned 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 home residents to certain drugs. This steering could result in the overprescribing of medications, the prescribing of drugs that are inappropriate for LTC residents, or the use of unnecessary or inappropriate therapeutic substitutions. Such potential outcomes can pose serious jeopardy to nursing home residents' health and safety. Although we have no evidence directly linking these arrangements to adverse outcomes, we believe a requirement under consideration that LTC consulting pharmacists be independent would be appropriate and prudent because it would ensure that financial arrangements did not influence the consultant pharmacist's clinical decision making to the detriment of LTC residents. Our concerns are not merely theoretical. We are aware of claims brought by qui tam relators under the False Claims Act alleging that, for instance, an LTC pharmacy received quarterly payments styled as rebates from the pharmaceutical manufacturer to engage in an active intervention program to convince physicians to prescribe a manufacturer's antipsychotic agent to the physicians' nursing home patients and to authorize all competitive products only after the failure of the manufacturer's product. In 2005, the Food and Drug Administration (FDA) issued warnings of the increasing death rate associated with the use of antipsychotic agents for behavioral symptoms for older persons with dementia. In reporting the results of 17 clinical trials, FDA noted an approximately 1.6 to 1.7 fold increase in mortality, compared to placebo-treated patients, in these studies.[1] Thus, any financial arrangements that encourage consultant pharmacists to prescribe these drugs to older LTC residents with dementia contrary to FDA warnings may detrimentally affect those residents' health and safety.

Recent research suggests the use of antipsychotic drugs in nursing homes remains high—higher, in fact, than the percentage of residents diagnosed with psychoses. Despite the serious safety concerns, researchers reported nearly 1 in 3 nursing home residents in the U.S. received antipsychotic drugs in 2007.[2] Prior research examining potentially inappropriate prescription drugs among nursing home residents found half of the almost 3,400 study residents were prescribed a potentially inappropriate prescription medication. Forty percent of these residents had medication that was identified as both inappropriate and generally to be avoided among older LTC residents; a third of these medications posed a potential for severe harm. The therapeutic class most prevalent was antipsychotic agents.[3]

More recently, a review by the HHS Office of Inspector General of Medicare Part D claims for atypical antipsychotics for elderly nursing home residents in the first half of 2007 found that 22 percent of those drugs were not administered in accordance with CMS standards for unnecessary drug use in nursing homes. The OIG also found a very high incidence of atypical antipsychotic prescribing for elderly nursing home patients with dementia despite the presence of an FDA black box warning that such prescribing is associated with increased mortality.

In addition to research findings, nursing home survey and certification data reported in the CMS online survey and certification reporting system indicate unnecessary drug use in nursing homes continues to be a problem. In 2006, we issued updated guidance for LTC survey and certification reviews of the use of potentially unnecessary medications.[4] The guidance, providing specific information on medications that are problematic to the nursing home population, was implemented in December 2006. In the 7 years prior to the implementation, the percent of surveys with a citation for unnecessary drug use ranged from 12.6 to 14.0 percent. Since implementation, however, the percent of surveys with these citations has increased yearly from 18.2 percent in 2007 to 19.4 percent in 2009.

The research and our survey and certification data indicate that the use of unnecessary medications, particularly antipsychotics, is problematic in LTC facilities. Although our findings do not directly connect LTC pharmacy relationships with consultant pharmacists to these research findings and survey results, we believe it is reasonable to presume that the

[1] FDA, Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances, April 2005. Accessed online at *http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/UCM053171* on May 26, 2010.

[2] Chen, Y, Briesacher, BA, Field, TS Tjia, J Lau, DT, Gurwitz, JH. Unexplained Variation across US Nursing Homes in Antipsychotic Prescribing Rates. *Archives of Internal Medicine.* 2010:170(11):89–95.

[3] Lau, DT, Kasper, JD, Potter, DE and Lyles, A. Potentially Inappropriate Medication Prescriptions among Elderly Nursing Home Residents: Their Scope and Associated Resident and Facility Characteristics. *Health Services Research.* 2004:39(5):1257–1276.

[4] CMS, Guidance for Unnecessary Drugs § 483.25(l), September 2006. Accessed online at *http://cms.gov/manuals/Downloads/som107ap_pp_guidelines_ltcf.pdf* on June 3, 2010.

incentives present in the relationships among consultant pharmacist, LTC pharmacies and drug manufacturers can influence the prescribing practices reflected in these data.

As a result, we believe requiring the independence of consultant pharmacists is necessary and appropriate and are considering making such a change. We solicit comments on our understanding in this matter, as well as on our changes under consideration discussed in this section.

We note further that, although Federal regulations at § 483.25(l) require LTC facilities to avoid unnecessary drugs, our experience indicates that this responsibility generally is delegated to the consultant pharmacist who is, for the most part, provided by the facility's contracted LTC pharmacy. According to a June 2008 report of a study by the HHS Office of Inspector General (OIG) regarding Part D drugs and LTC facility residents, about 80 percent of the 128 nursing home administrators interviewed for the study indicated the consultant pharmacists performing their facility's drug regimen reviews were employed by the nursing home's LTC pharmacy.[5] Further, this report states that 54 percent of the 79 pharmacy directors interviewed for the study reported that their pharmacy receives rebates from pharmaceutical manufacturers that are frequently based on market share or volume. However, only three of the pharmacy directors reported providing rebate information to the LTC facility. Thus, in delegating responsibility for avoiding use of unnecessary drugs to consultant pharmacists, nursing homes generally are unaware of any financial interests that can bias the pharmacist's drug recommendations.

Consultant pharmacists perform monthly drug regimen reviews for all LTC facility residents. During this review, the consultant pharmacist may recommend a medication change. In making a decision whether to accept the recommended change, prescribing physicians are likewise generally unaware of the LTC pharmacy rebate arrangements with pharmaceutical manufacturers that may influence the recommendation. In the previously cited report, the OIG noted that when a consultant pharmacist recommended a medication change during the drug regimen review, the recommendation was accepted by the prescribing physician about 74 percent of the time.[6] We believe 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 will ensure that financial arrangements do not influence the consultant pharmacist's clinical decision making to the detriment of LTC residents.

Therefore, we are 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. For the reasons described in this section, we believe such a requirement is necessary to ensure that consultant pharmacist decisions are objective and unbiased. That is, LTC facilities must use a qualified professional pharmacist to conduct drug regimen reviews and make medication recommendations based solely on what is in the best interests of the resident. We believe this can be achieved only if the consultant pharmacist is working without the influence of conflicting financial interests that might otherwise encourage overprescribing and overutilization, which creates health and safety risks for residents. We note that some arrangements we are addressing here may also implicate the fraud and abuse laws for which the HHS OIG and the Department of Justice (DOJ) have jurisdiction.

The changes we are 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 are considering requiring that long term care facilities employ or directly or indirectly contract the services of a licensed pharmacist who is independent. We also are 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. Our changes would also prohibit nursing homes from contracting for the provision of consultant pharmacy services with entities (such as a subsidiary of an LTC pharmacy) that have been created for the purpose of providing reorganized consultant pharmacist services.

We do not believe it necessary to define the terms ''affiliate'' or ''affiliated'' as we believe the meaning should be broadly interpreted to cover all relationships that incent overprescribing and inappropriate prescribing in LTC facilities. We do not intend, however, for any of the changes under consideration to prohibit any relationships that would be inherently free of conflict of interest. Thus, we solicit comment on the specific relationships that should be permitted.

We are aware that some Indian Tribes and Tribal organizations own LTC facilities that serve their members and that the Tribe may also own the pharmacy that serves the facility. We believe that the Tribal-owned LTC facility may employ the services of a pharmacist to provide consultation and perform drug regimen reviews who is also employed by the facility's pharmacy without violating the independence requirement. In these instances, because the LTC facility and pharmacy are commonly owned by the Tribe, the consultant pharmacist's incentives for prescribing are aligned with the best interests of not only the Tribal members who are LTC residents, but also the Tribe. We believe a similar alignment of interests would exist in Indian Health Services (IHS) owned facilities and Tribal facilities that are serviced by IHS pharmacies. We expect there are other LTC providers or systems in which the incentives for prescribing are similarly aligned to sufficiently limit the risk of conflicts of interest and ensure the best interests of the LTC residents are served. Therefore, we are thinking of including an exception for Tribal owned LTC facilities and pharmacies. We also solicit comment from the public on our interpretation that in these unique situations independence is not an issue because the risk of conflicts of interest is sufficiently limited.

We anticipate that if we were to require that LTC facilities engage independent consultant pharmacists, this would cause consultant pharmacists to reorganize to achieve independence from the parties (facility pharmacies, pharmaceutical manufacturers and distributors, and affiliated entities) with which the consultant pharmacists are currently affiliated. That is, we believe the consultant pharmacists currently assigned to LTC facilities would seek to

[5] HHS, Office of Inspector General, ''Availability of Medicare Part D Drugs to Dual-Eligible Nursing Home Residents,'' June 2008. Available online at *http://oig.hhs.gov/oei/reports/oei-02-06-00190.pdf.* Accessed on June 28, 2010.

[6] HHS, Office of Inspector General, ''Availability of Medicare Part D Drugs to Dual-Eligible Nursing Home Residents,'' June 2008. Available online at *http://oig.hhs.gov/oei/reports/oei-02-06-00190.pdf.* Accessed on June 28, 2010.

retain relationships with those facilities, either through direct employment or by banding together with other consultant pharmacists, for instance, in professional corporations. We believe that if the changes under consideration were to take effect beginning January 2013, such a time frame would provide sufficient time for implementation of the requirement. However, we recognize that there may be some areas where certain conditions or extenuating circumstances might argue for a longer implementation period. Specifically, we anticipate that LTC facilities in rural areas would face the greatest challenges in recruiting qualified consultant pharmacists, particularly if the consultant pharmacists currently serving the rural facilities do not reorganize in order to continue to provide services. Therefore, the requirements under consideration may need to be modified to assist these facilities. One way to assist would be to extend the time period for implementation. Thus, we are soliciting comment on whether to provide for a later effective date for rural facilities as opposed to other LTC facilities or to make other accommodations for the unique circumstances in which rural facilities operate. While we do not believe that any consultant pharmacist should have a conflict of interest, we are also soliciting comments on whether it would make sense to waive the independence requirement to permit alternative approaches. In describing these other approaches, comments should address the protections that would be implemented to reduce the risk of conflict of interest due to the lack of independence of the consultant pharmacists.

It is our understanding that LTC consultant pharmacists commonly perform approximately 60 drug regimen reviews in a day. 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 are not proposing in this rule to codify changes to the drug regimen review requirements, we are soliciting public comment on best practices related to the conduct of drug regimen reviews. We will use these comments to inform possible future rulemaking regarding the drug regimen review requirements.

C. Excluding Poor Performers

This section includes three proposals designed to strengthen our ability to remove poor performers. We believe we could protect beneficiaries through the proposal that would enable us to terminate health care prepayment plans (HCPPs) whose administration does not meet specified financial, reporting, and access requirements.

A second proposal would enable us to look at the plan rating system, which we developed to provide beneficiaries with information about the quality and performance of health and drug plans to assist in plan selection during the open enrollment period. The plan ratings include process measures that focus on whether good medical care or drug care was provided, outcome measures that address the result of that care, and measures that relate to administrative processes that support and direct the provision of care. It is our view that the star rating system not only provides beneficiaries/consumers with easy-to-understand information critical for making choices among sponsors, but provides a powerful tracking tool that enables us to continue to administer the Part C and D programs with the best interests of the beneficiaries in mind.

We propose to give CMS the authority to terminate MAOs and Part D sponsors that have failed to provide, over a course of 3-years, service meriting at least 3-star ratings. A second proposal would give CMS the authority to deny applications submitted by MAOs and Part D sponsors that have performed poorly in the past. We anticipate that this proposal would directly enable us to protect beneficiaries from poor care. Both these provisions, in our opinion, would give entities that want to administer benefits to Medicare beneficiaries a strong incentive to pay attention to the star rating criteria and provide for better quality health care if they wish to stay in or join the program. See Table 3 for details of these proposals.

TABLE 3—PROVISIONS TO EXCLUDE POOR PERFORMERS

Preamble section	Provision	Part 417		Part 422		Part 423	
		Subpart	Section	Subpart	Section	Subpart	Section
II.C.1	CMS Termination of Health Care Prepayment Plans.	Subpart U	§ 417.801	N/A	N/A	N/A	N/A.
II.C.2	Plan Performance Ratings as a Measure of Administrative and Management Arrangements and as a Basis for Termination or Non-Renewal of a Medicare Contract.	N/A	N/A	Subpart K	§ 422.504 § 422.510	Subpart K	§ 423.505. § 423.509.