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Medicare Part D Update

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With the implementation of Medicare Part D in January, 2006, Medicare rather than Medicaid will become the most important payor for prescription drugs in nursing homes. In addition to restructuring of their existing relationships with long term care pharmacies, nursing homes face several operational challenges to ensure continued quality of care for their residents. These changes under Part D will increase both administrative costs and risk of citations for noncompliance with the federal Require-

ments for Participation for Medicare and Medicaid certified nursing homes. Some of the changes, such as massive enrollment issues and physician education efforts, are short-term because they are related to the initial transition to Part D. Other changes, like developing implementation information systems to manage multiple drug plans with different formularies, and coverage and appeals processes, will persist into the future as the Part D program continues to evolve. Despite complexity, confusion and costs, it is clear that nursing homes will be held accountable for ultimately ensuring that the appropriate drugs are administered timely to all residents.

Some of the operational issues stem from the fact that Part D was not enacted or implemented with nursing home residents in mind. Rather, the Medicare prescription drug plans (PDPs) that won contracts for the Medicare Part D benefit planned their Part D benefit with the community based ambulatory beneficiary in mind. The PDPs are not familiar with the nursing home regulatory environment and beneficiaries who are cognitively impaired and depend on others for their decision support. Further, CMS has acknowledged that there are inconsis-

tencies between the nursing home regulations and Part D. Therefore, it will be up to nursing facilities to implement the new benefit in a way that ensures compliance with the OBRA survey regulations.

CMS and state agencies that monitor nursing home quality through the long term care survey process must ensure that the changes resulting from Medicare Part D do not undermine quality of care or patient safety. In November 2005, CMS conducted surveyor training that emphasized particular risk areas in nursing home operations as a result of Part D. As emphasized in this training, surveyors are not responsible for pro-

viding education on Medicare drug coverage but rather are to survey for compliance with the pharmacy, residents' rights and quality of care regulations that are intended to provide a safe and effective medication system in nursing homes. This article will summarize some of the compliance points for nursing homes to consider as they develop and implement systems for Medicare Part D.

Background

Starting January 1, 2006, all Medicare beneficiaries will be eligible for prescription drug coverage under Medicare Part D. Although there is no change for residents on a Medicare Part A covered stay, as of that date, Medicare Part D will replace prescription drug coverage currently provided by state Medicaid programs to those who are covered by both Medicaid and Medicare (Full Benefit Dual Eligibles, or FBDEs). Because two-thirds of the FBDEs are nursing home residents who have spent down to qualify for Medicaid, Part D implementation is an important issue for nursing homes.

All FBDEs must enroll in a PDP by December 31, 2005 to ensure continuation of their prescription drug coverage with no gaps in coverage. If a beneficiary has not enrolled in a PDP by that time, CMS will auto enroll him or her in a PDP randomly selected from those offering the basic Part D benefit in the nursing home's PDP region. At the end of October 2005, the Centers for Medicare and Medicaid Services ("CMS") mailed letters to all FBDEs, including those living in nursing homes, explaining the auto-enrollment process and providing the name and contact information for the plan in which Medicare will enroll them. Although CMS's goal is to ensure that the long term care population has a seamless transition to Part D, this random selection process does not take into account or measure individual drug regimes, plan utilization management techniques, or nursing home placement. As a result, CMS may auto-enroll a FBDE into a PDP that does not match his or her medication needs or best interests. After the initial enrollment period ending on May 15, 2006, FBDEs have access to a Special Enrollment Process (SEP) that allows a change of plans for any reason, including changes in medication regime or level of care. As a practical matter, however, the SEP take effect on the first day of the month following the election leaving the potential of up to 30 days of enrollment in a plan that does not fit and/or is not contracted with the nursing home's long term care pharmacy (LTCP).

Private contractors will administer the Part D benefit. PDPs must contract with pharmacies, including LTCPs, to

create a pharmacy network that meets Medicare's access standards. Some LTCPs will not have a contract with all PDPs in a Part D region. If a resident is enrolled in a PDP that has not included the nursing home's contracted LTCP in its network, the nursing home will have to obtain that resident's drugs from another LTCP that is part of that PDP's network or absorb the cost of the drugs. Although CMS has acknowledged the importance of the traditional 1:1 nursing home/LTCP relationship for optimal quality of care and compliance with the Requirements of Participation, the agency also acknowledged that the Part D regulations are not always consistent with the federal nursing home Requirements of Participation.

Moreover, CMS has taken the consistent position in a number of policy documents that beneficiaries should have free choice of all PDPs available in their region and that PDPs should have an equal opportunity to enroll beneficiaries throughout a region. CMS has based its policy against "steering" on legitimate concerns, including potential conflicts of interest due to financial gains or other conflicting incentives, lack of knowledge of all available plans and benefits, and the possibility of beneficiary confusion. CMS's efforts are intended to ensure that plan selection is always in the best interest of the beneficiary.

Operational Challenges and Survey Compliance

However, nursing homes may encounter operational challenges if faced with the need to contract with more than one long term care pharmacy in order to provide the plan of choice for nursing home residents. Surveyors may view limitations on the number of PDPs "recommended" by a nursing home as a restriction on the resident's right to free choice of provider. Nursing home staff should provide objective, factual information about Part D in general and the available PDPs specifically so that residents and/or their legal representatives can make an informed choice of plan selection while in the facility. CMS had developed materials for this purpose that are easily accessible on its website. To the extent possible, reliance on CMS materials is highly recommended. For purposes of survey compliance, documentation of such discussions is advisable.

Beyond the initial enrollment decisions, facility staff must be aware that residents may experience adverse drug reactions if, due to PDP formulary requirements, their drug regime must be altered or they have to request an exception from the PDP to obtain a noncovered drug. Careful monitoring and prompt responses, including physician notification, are necessary to ensure that the resi-

dent's quality of care is maintained. Surveyors will look into whether staff recognized changes in condition and whether they took appropriate steps to investigate the root cause of the problem.

All PDPs have utilization management tools designed to control their costs and will use a less expensive drug whenever possible. There are also tools like prior authorization, step therapy and quantity limits that impose barriers to a pharmacist dispensing ordered drugs. Nursing home staff must understand these tools and their management or risk having no drug in the drug cart at 4:00 PM on a Saturday afternoon to give the resident. Access to ordered drugs may be problematic if the doctor orders drugs that are not on a resident's PDP formulary. Staff nurses on all shifts must know how to respond if the pharmacy calls and informs them that a certain drug is not covered. The facility, in conjunction with the Medical Director, must develop and communicate to the attending doctors policies about generic substitution and, where legal, therapeutic interchange. Care will need to be taken to ensure that the Medication Administration Records (MARs) are current and include the drugs actually being provided.

The variations in PDP formularies and their management tools may make an error free Med Pass Observation more difficult to achieve during survey because the opportunities for error dramatically increase under Part D. Ways to bolster compliance here include staff education and training, collaboration and effective timely communication with the facility long term care pharmacy, a clear allocation of tasks between the pharmacy and the nursing home (i.e., who is going to call the doctor?) and additional consulting pharmacy time to conduct med pass observations and trouble shoot potential compliance issues.

Surveyors will not accept lack of knowledge about Medicare Part D as an excuse for failing to comply with the nursing home Requirements of Participation. Facilities are still responsible for timely pharmacy services including medication delivery, labeling and storage, even if there is more than one long term care pharmacy in the building. Staff must also know the Part D exceptions and appeals process if a resident's medication regime is changed to include a nonformulary drug. Even though there is an expedited process for these initial

exception determinations, it may take 24 hours at best to obtain a determination. The prescribed drugs must be administered to the resident even if the nursing home must bear the risk of payment if the exception is denied. The facility's duty to provide all care and services necessary to obtain or maintain the highest practicable physical mental or psychosocial well-being is not suspended during the exceptions and appeals process.

Conclusion

In summary, the nursing home's responsibilities under the federal survey regulations do not change in January when Medicare Part D is implemented. Surveyors have been instructed of the need for increased vigilance on their part to identify potential drug errors or adverse consequences due to formulary mandated changes. Facilities must develop and implement systems to ensure that staff, residents and/or their families or legal representatives have accurate information about the Medicare drug benefit. There must be clear communication channels to address formulary changes and respond to problems as they arise. Contracts between the nursing homes and their long term care pharmacies need to be clear and specific about the duties and responsibilities of both parties to resolve issues and ensure that residents get prescribed drugs in a timely manner. There should be no duplicative or inappropriate drugs or doses. Physicians and nurses need to be aware of prescribing cascades that occur when another drug is prescribed to treat an adverse drug reaction instead of assessing the root cause of the symptoms and changing the original drug.

On January 1, 2006 when Medicare Part D begins, the delivery of pharmacy services in the nursing home will change. Medication delivery to residents nevertheless must continue without causing residents any discomfort or danger to health or safety, and the right drug must be given to the right resident in the right dosage at the right time and through the right route. Surveyors will continue to monitor facility performance under residents' rights, pharmacy services, professional standards and quality of care to ensure ongoing compliance. The Medicare drug benefit does not preclude compliance with the applicable regulations to ensure quality of care.