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MEDICARE PART D AND LONG TERM CARE: THE REIMBURSEMENT AND OPERATING ISSUES

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Effective January 1, 2006, Medicare coverage for prescription drugs under the new Medicare Part D becomes effective. At that time, Medicare will become the predominant purchaser of prescription drugs in this country. Because nursing home residents have some of the highest rates of prescription drug utilization among the elderly population with a mean monthly average of eight prescription drugs,[1] this change will have significant effects on the long term care (LTC) community. For beneficiaries whose care is covered by Medicare Part A, all drug costs will continue to be bundled into the Prospective Payment System (PPS) rate because Part D covers only those drugs for which no other credible drug coverage is available under Medicare or any other plan. However, the majority of nursing home residents who have "spent down" their assets for medical care and are dually eligible for both Medicare and Medicaid benefits will see vast changes in their prescription drug coverage.

Full benefit dual eligibles currently receive prescription drug coverage through the state Medicaid programs. A LTC pharmacy typically provides the drugs and a number of other items and services under contract with the nursing home and bills the state Medicaid program directly for residents who qualify for such benefits. With some exceptions, the state Medicaid programs offer unrestricted access to all prescription and other drugs deemed medically necessary and ordered by a physician or other appropriate prescriber under state law. As of January 1, 2006, Medicaid reimbursement and coverage of most prescription and all "over-the-counter" (OTC) drugs for nursing home residents will cease when all dually eligible nursing home residents will migrate "cold turkey" to Medicare Part D coverage. For the reasons discussed below, this change will result in significant operational and potential reimbursement issues for every nursing home in the country.

The Medicare Part D Benefit

Medicare Part D is a market-based model under which competition is intended to ensure that beneficiaries receive low prices for prescription drugs. Drug coverage will be provided by private stand-alone prescription drug plans (PDPs) or through Medicare Advantage (formerly, Medicare +Choice) plans with prescription drug coverage (MA-PDPs). Low-income beneficiaries also are eligible for government subsidies to defray their costs further.[2] To implement Part D, as required under of the Medicare Mod-

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[1] *See Stefanacci, R.G., The Cost of Being Excluded: Impact of Excluded Medications under Medicare Part D on Dually Eligible Nursing Home Residents, USIP (Feb. 16, 2005).*

[2] *Current information about eligibility and application for Low Income Subsidies ca n be accessed at www.cms.hhs.gov/medicarereform/lir.asp .*

ernization Act, CMS announced the establishment of 26 MA regions and 34 PDP regions.[3] Some plans submitted bids to operate nationally while others will be regional or local. CMS reports extremely high interest by potential Part D sponsors and has predicted that there may be up to 30 plans available in some regions. The autoenrollment process for dual eligibles will randomly distribute nursing home residents evenly in the PDP plans available in a given region.

The plans submitted bids to the Centers for Medicare & Medicaid Services (CMS) on or before June 6, 2005, and CMS expects to award contracts in September 2005. CMS will evaluate many factors to determine the adequacy of the drug benefit offered by the plans. Of particular concern to CMS are the following:

- Formulary structure (evidence-based decision making; cost considerations based on total health costs not just drug costs; a balance of clinical and cost considerations);
- Utilization review methods (prior authorization, step therapy, generic substitution, quantity limits);
- Exceptions process (more favorable cost-sharing, access to non-formulary drugs), and
- Appeals process.

CMS anticipates that, to be commercially viable and to make a profit, the PDPs will negotiate favorable price concessions with both drug manufacturers and their network pharmacies. PDPs also can use drug formularies to control costs. Part D formularies must meet certain minimum requirements in the law and regulations, but they will vary by PDP and by the type of plans offered within each PDP. A formulary need not include all drugs that could be covered under Part D - the minimum number is, wherever possible, two drugs per therapeutic class and category. PDPs also may use cost management techniques such as prior authorization, step therapy, and quantity limitations.

Auto-enrollment of Dual Eligibles

In recognition of the issues presented by the vulnerable long term care population and in an effort to ensure the continuation of prescription drug coverage on and after January 1, 2006, all dually eligible beneficiaries who live in nursing homes or ICF/MRs will be automatically enrolled by CMS into a basic PDP beginning in October 2005. As institutionalized dual eligibles, these beneficiaries will incur no out-of-pocket costs for deductibles or co-payments and no gaps in coverage related to the so-called "donut hole" that is part of the standard Part D benefit. In contrast, other subsidy-eligible beneficiaries living in the community, including those in assisted living facilities, will be subject to these out-of-pocket costs on a somewhat sliding scale.

If the assigned PDP is not acceptable to the resident or his or her legal representative (e.g., the plan does not cover a sufficient number of the resident's drugs or the formulary or utilization management programs make it too restrictive), he or she can change plans during the special enrollment period (SEP), assuming that another basic plan is available in that region and the facility contracts with an accessible LTC pharmacy in the plan network. Also, newly admitted residents who qualify for or are enrolled in Part D can elect a new plan at the time of admission to ensure network pharmacy access. This ability to change plans at any time while institutionalized is important because the resident can only access Part D drugs covered by his or her plan through a pharmacy that participates with that PDP. No out-of-network pharmacy access is permitted under the Part D regulations. CMS has established specific protections for beneficiaries who live in nursing homes and get their drugs from LTC pharmacies. For example, every approved plan must, as a condition of participation, provide coverage to all of its enrollees who live in any nursing home in its region. They must also have a transition process to account for any issues associated with filling the first prescription of a non-formulary drug. PDPs must also ensure that the LTC pharmacies in their respective networks cooperate with the nursing homes to provide for a smooth transition. Nursing homes will have to take an active role in learning which plans are approved in their regions and in seeking specific procedural information from each plan about its transition policies and procedures.

One can envision the operational issues that will come up at admission as admissions staff who are knowledgeable about the Part D program requirements diligently query and evaluate the source of prescription drug coverage for each new resident and advise him or her and the legal representative about the possible need to enroll in another plan that includes an accessible LTC pharmacy and appropriate coverage of the resident's prescriptions.

[3] *Links to maps and fact sheets on the regions can be accessed at* *www.cms.hhs.gov/medicarereform/mmaregions*

If a prospective resident decides to use the SEP option to change plans, nursing home staff in close coordination with the contracted LTC pharmacy must ensure the availability of prescription drugs until the resident's change in enrollment becomes effective, and drugs are delivered from the new plan. CMS has addressed this timing issue in subregulatory transition guidance to ensure that no gaps in coverage occur. For example, plans may need to provide a temporary "first-fill" supply order for a limited amount of a prescribed medication that is not part of a plan's formulary, a therapeutically equivalent drug, or a formulary exception if the drug is medically necessary. Each of these three options requires knowledge of each plan's policies and procedures and an informed evaluation of the best alternative for an individual beneficiary. Close coordination of nursing home, pharmacy and physician efforts as well as reliable, effective and timely communication will be necessary. Clarification is still needed on whether the nursing home can include an authorization to switch plans in its admissions agreement or whether the facility can otherwise "steer" residents to its preferred PDPs. CMS has also left open the issue of who bears the cost for transition drugs although, in very recent guidance, has stated that if a beneficiary appeal is not successful, the nursing home must pay for the noncovered drugs.

Contract Issues

All contracts between nursing homes and their LTC pharmacies will require renegotiation and revision before January 1, 2006. Facilities that are accustomed to contracting with a single specialized LTC pharmacy are likely to find themselves dealing with several pharmacies that participate in the Part D plans available in their respective CMS Part D regions. Multi-facility chains that have a single national or regional pharmacy contract in place may find that this arrangement is no longer feasible. Moreover, many of the items and services typically found in a contract between a nursing home and its LTC pharmacy are not covered under Part D. For example, Part D does not cover drug carts, consultant pharmacy services, emergency boxes, stat and off-hour deliveries, fax machines, medication administration records and other forms, med-pass observations, attendance at quality assurance and care plan meetings, and participation during surveys. To negotiate effectively, nursing homes must know precisely what is covered under the dispensing fee paid by the PDP to the LTC pharmacy so as not to pay for such costs. On March 16, 2005 CMS issued its Long Term Care Guidance which defined the performance, access, formulary, beneficiary protections and service criteria for LTC pharmacies that will participate and contract with the PDPs as part of their network pharmacies.[4] Dispensing fees between the PDP and the LTC pharmacies must include acceptable unit dose packaging and dosage forms; IV medications; alternative forms of drug composition; on-call pharmacist services; minimum delivery requirements (7days/week, 3 times/day) including automatic restocking and delivery to medication carts; emergency boxes; log books; and miscellaneous reports, forms, and ordering supplies. Nursing homes must review contracts carefully to ensure that they are not charged for these items and services. Other items and services that are now typically bundled into LTC pharmacy contracts but not included in the dispensing fee are specifically not covered by the Part D benefit and therefore must be priced and paid for separately by the nursing home. CMS sees benefit in the increased competition among LTC pharmacies, resulting cost transparency, and competition to offer noncovered services, but such benefits may not outweigh the fact that there is, at this time, no obvious source of third-party reimbursement for any noncovered costs.

The Medicare statute and final regulations implementing Part D do require Part D plans to have a medication therapy management program ("MTMP") for beneficiaries that incur high drug costs, and the design of the MTMP is up to each Part D plan. These programs may satisfy the requirement for monthly drug regime reviews that is included in the nursing home Requirements of Participation, but only some residents would qualify because MTMPs are limited by the MMA to beneficiaries with certain conditions. Some drug utilization review services are included within the role of the dispensing pharmacist but these are not necessarily the same functions as those of the consulting pharmacist to meet nursing home regulations. This area is yet another where care in contracting is needed and where additional guidance from CMS likely will be forthcoming.

The final Part D regulations require PDPs to contract with any willing LTC pharmacy as long as the pharmacy is prepared to meet the performance and ser-

[4] The Long Term Care Guidance (March 16, 2005) can be accessed at www.cms.hhs.gov/pdps/LTC_guidance.pdf, the Strategy for Transitioning Dual Eligibles from Medicaid to Medicare Prescription Drug Coverage (May 2, 2005) can be accessed at www.cms.hhs.gov/medicarereform/strategyforduals.pdf.

vice criteria described in the Long Term Care Guidance. Modeled on LTC pharmacy best practice standards, these criteria are a required feature of contracts between PDPs and LTC pharmacies. Because nursing homes are not a party to these contracts, nursing homes must remain alert to CMS guidance about what is to be covered by the PDP when contracting for LTC pharmacy services. Hospital-based skilled nursing facilities (SNFs) serving only Medicare Part A residents will see little, if any change, as a result of Part D's implementation because, as mentioned above, prescription drug coverage will remain bundled into the Part A PPS rate. However, if the unit has a long term resident population or if the facility is part of a hospital-based system, obtaining prescription drugs from the hospital pharmacy may not be an option unless the hospital pharmacy contracts with all PDPs in the region or CMS issues a policy on this issue before Part D implementation in 2006.

Resident Support and Assistance

Nursing homes will need to assist residents who cannot choose or evaluate the merits of one or more PDPs on their own behalf. The cognitive and physical impairments of this population will complicate this already complex choice for residents and their legal representatives, particularly if a number of PDPs are approved to operate in a region. In particular, physician consultation may be necessary to evaluate the therapeutic adequacy of a formulary for a particular resident. CMS is counting on the provider community to assist in the education of beneficiaries. For dually eligible nursing home residents, this task will begin in Fall 2005 when CMS sends enrollment information to the beneficiaries and/or their legal representatives. With 6.4 million dual eligibles in the country, the likelihood that someone will fall through the cracks is very real so nursing homes should monitor the automatic enrollment process to ensure that all residents have their prescription drugs available on and after January 1, 2006.

Availability of Drugs and Formulary Issues

Availability of appropriate prescription drugs will depend in large part on the formulary structures chosen by each PDP. A LTC pharmacy will be subject to the formulary of each PDP with which it contracts and the ability of either the nursing home or the LTC pharmacy to steer residents into a "preferred" plan is doubtful as of this writing but subject to clarification by CMS in the future. Nursing homes should educate their medical directors and community-based attending physicians about the formulary issues for each of their patients and the available PDPs in their region well in advance of January 1, 2006. In the initial automatic enrollment phase, time will be of the essence because CMS does not expect to award the PDP contracts until September. If a drug is not on a PDP's formulary or is otherwise not covered by Part D (as described below), the physician must order an acceptable substitute from the preferred list, if one is available. Otherwise, the nursing home may well bear the cost of nonformulary drugs ordered for their residents.

The LTC community should be aware that many types of medications that are commonly prescribed for nursing home residents are excluded from coverage under Part D. Such classes of drugs include:

- Drugs for anorexia, weight loss, or weight gain (e.g., Megace®);
- Drugs prescribed for cosmetic reasons or hair loss;
- Drugs for the symptomatic relief of coughs and colds;
- Prescription vitamins and mineral supplements;
- Non-prescription (i.e., over-the-counter) drugs (e.g., Tylenol® or other pain relievers, as well as commonly prescribed drugs for constipation, indigestion, and others);
- Barbiturates (e.g., Phenobarbital); and
- Benzodiazepines (e.g., Klonopin®, Ativan®, Xanax®, Restoril®).

Medicaid coverage for these drugs is currently available in many states. In a June 3, 2005 letter to State Medicaid Directors, CMS clarified that, to the extent that state Medicaid programs cover the excluded drugs for Medicaid recipients who are not full benefit dual eligibles, they are required to cover these drugs for the dual eligible population including those in nursing homes. If gaps in coverage occur, nursing homes may have to absorb the costs. Abrupt therapeutic disruptions can cause adverse clinical outcomes, and residents could be at significant risk. Nursing homes will have to manage these issues diligently to avoid quality of care and potential survey problems. Ironically, necessary therapeutic substitution for more expensive drugs that may be included in PDP formularies actually could increase drug costs unnecessarily. For a number of reasons, residents who are enrolled in or elect to join a Medicare Advantage (managed care or "MA") plan may find that these plans provide more generous coverage for prescription drugs because the MA plans must manage overall health care costs rather than just the cost of covered drugs. How-

ever, these coverage issues will be a significant change from the open Medicaid formularies most states now have in place.

Part D includes an exceptions process for requesting coverage of noncovered Part D drugs, but only beneficiaries, their legal representatives, and attending physicians may use it. The Long Term Care Guidance explicitly stated that an enrollee may choose an agent of the LTC facility (for example, a registered nurse, social worker, or case manager) to act as his or her appointed representative. No mention was made of permitting a consulting or dispensing pharmacist from the network LTC pharmacy to act in this capacity, and there are some significant but unresolved conflict of interest issues inherent for pharmacists who are employed or contracted by the LTC pharmacies.

Even in its expedited form, the time to pursue the exceptions and appeals process may result in temporary gaps in coverage, and there is no guarantee that a request for an exception will be successful. Plans have some obligation to provide a temporary supply of drugs while an exception request is pending, but, ultimately, nursing homes will be charged for the cost of these drugs if the appeal is unsuccessful.

The long term care community should be aware that nursing home residents, particularly those with cognitive and physical impairments, and their legal representatives likely will look to facility staff for assistance. The exceptions process imposes, among other requirements, a written or oral certification from the prescribing physician that all choices on a plan formulary are clinically unacceptable and a statement of the reasons why. The plan may then require a more detailed written statement from the physician. Most physicians are not inclined or do not have sufficient time to participate in this type of exceptions process.

More important to nursing home operators, attending physicians will have to rewrite most if not all medication orders for submission to the new PDP plans to ensure that covered drugs will be available on January 1, 2006. This project alone will require a significant effort by all nursing homes, their medical directors, and community-based attending physicians. An accurate working knowledge of the contents of CMS's Long Term Care Guidance will be very important to nursing homes that must manage these changes and their costs while ensuring continued availability of drugs for their residents.

Recommendations and Conclusions

Managing the changes that will occur with the implementation of Medicare Part D will require education, preparation, and collaboration by facilities, physicians, other care providers, pharmacists, residents, and their legal representatives. Nursing facilities have a high duty to provide all the care and services necessary to attain or maintain the highest practicable physical, mental, and psychosocial well-being for all residents. This duty may well override the gaps in coverage under Part D resulting in new activity costs and unreimbursed costs for all facilities. As mentioned, CMS will continue to issue additional regulatory and subregulatory guidance issued in the coming months, and these issuances should be monitored carefully for new developments. Further, legislative changes are possible in the 109th Congress to address some of the issues emerging under the MMA. Nursing homes should consult knowledgeable long term care counsel to minimize reimbursement and compliance risks in this new operating environment and to assume an advocacy position on behalf of their residents as implementation of Medicare Part D continues to unfold.

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