California HealthCare Foundation

The Medicare Drug Benefit:
Impact on Nursing Facilities

ISSUE BRIEF

October 2005

Introduction

Medicare beneficiaries who receive long-term care in California nursing facilities will face significant changes in coverage and access when the Medicare prescription drug benefit begins in 2006. This is particularly true for dual-eligible beneficiaries because numerous Medicare prescription drug plans will replace Medi-Cal as the predominant payer for drugs in nursing facilities. Long-term care residents disproportionately suffer from physical and cognitive impairments and tend to be high users of prescription drugs. Therefore, it will be especially important for nursing facilities, state lawmakers, and the federal government to take action to ensure that the more than 105,000 nursing facility residents in California are protected during the transition to, and by the coverage under, the new Medicare Part D benefit.

This issue brief, the third in a series on the implementation of the new Medicare drug benefit in California, provides an overview of the current mechanisms for the delivery and financing of prescription drugs in nursing facilities; examines the likely impact of the new Medicare drug benefit on nursing facilities and their residents; and provides recommendations for federal and state officials, nursing facility operators, and consumer advocates to help ensure that the transition to the new drug benefit is successful.

Among the key findings and recommendations:

- Nursing facility residents will experience changes in their drug regimens as drug plans establish their particular drug formularies. Many residents, particularly those with cognitive impairments, will require assistance to navigate changes in their drug coverage, including selecting a drug plan.
- Nursing facility providers face several challenges, including the restructuring of existing relationships with long-term care pharmacies designed to ensure quality and patient safety. Among the actions required, nursing facilities must: establish relationships with multiple drug plans; help their residents choose drug plans; identify which current residents require off-formulary drugs; and develop systems to manage different rules for coverage, dispensing, and appeals among dozens of drug plans, in order to ensure that appropriate drugs are provided in a timely manner. These new requirements will increase administrative costs for nursing facilities.
- Federal Medicare officials must ensure that changes do not erode the quality of care or patient safety. They should monitor patient access to medications as limited by the plans' new utilization management tools and exceptions and appeals processes. Officials should ensure that nursing facility residents receive the assistance they need, nursing facility staff are provided with adequate training, and nursing facilities are supplied with accessible drug coverage information for their residents. They should also develop systems to ensure that nursing facilities have accurate information

on plan structure and premium levels, along with systems to monitor quality of care and quickly address problems as they arise.

- State officials should also monitor changes in quality of care for nursing facility residents over time, as well as the impact of changes in drug financing and delivery on Medi-Cal spending for nursing facility care. They should update state requirements, as needed, to ensure that nursing facilities have the authority to assist residents with Part D, especially during the initial transition period.

The Situation Today

California has some 1,300 certified nursing facilities which serve over 105,000 individuals.[1] These facilities provide 24-hour care, including rehabilitation and medical services, and assistance with activities of daily living, such as bathing and eating. Nursing facility residents tend to be the frail and elderly, but also include non-elderly people with physical disabilities and mental impairments. Nursing facilities also provide short-term, post-acute care which is covered under Medicare Part A, and which will not be affected by the new Medicare Part D drug benefit.[2]

Facts About Nursing Facility Residents

- 75 percent are age 75 or older
- 70 percent are female
- 71 percent have a cognitive impairment (16 percent have a severe or very severe cognitive impairment)
- Typically have 3 to 5 medical diagnoses
- Use an average of 9 medications
- Average length of stay is 29 months

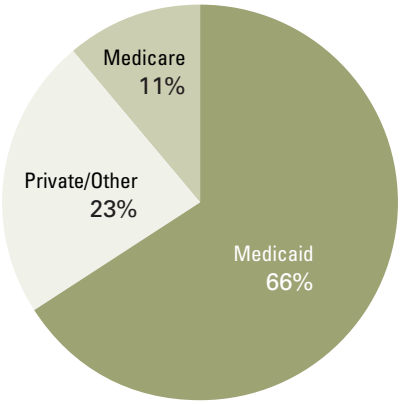
Source: Long Term Care Pharmacy Alliance. White Paper: Description of Long Term Care Pharmacy Services. Available at www.ltcpa.org; Nursing Home Data Compendium, 2001.

Current Coverage and Financing

Medi-Cal is the predominant payer in California for nursing facility care, including prescription drugs (see Figure 1). In 2003, Medi-Cal was the primary source of coverage for 66 percent of nursing facility residents, the majority of whom were "dual eligibles" with both Medi-Cal and Medicare coverage. Medi-Cal pays nursing facilities a fixed per-diem, which is capped based on the average spending of other similar facilities in the area and adjusted based on a resident's relative resource needs. Medi-Cal pays long-term care pharmacies on a fee-for-service basis for drug costs and associated dispensing fees for drugs delivered to nursing facility residents.

Medicare, which provides coverage under Part A for up to 100 days of post-acute, skilled nursing care, pays for approximately 11 percent of California's nursing facility population. Medicare bundles reimbursement for services and drugs in a single per-diem payment to nursing facilities. The remaining 23 percent of people in nursing facilities pay for their care through some type of private resource, such as their own health insurance, long-term care insurance, or personal funds.

Figure 1. Primary Payer for California's Nursing Facility Population, June 2005



Note: Private/Other includes private health insurance (generally for post-acute stays), private LTC insurance, and individuals who pay for their care out of their own pockets.

Source: CMS OSCAR Data Current Surveys, June 2005.

The Role of Long-Term Care Pharmacies

Most nursing facilities contract with a single pharmacy provider, called a long-term care (LTC) pharmacy, to serve their residents.[3] The relationship between nursing facilities and LTC pharmacies has been shaped, in part, by federal and state regulations designed to ensure the safe and effective delivery of prescription drugs.[4] These regulations require nursing facilities to reduce medication errors, complete drug regimen reviews at least once a month, and monitor adverse events. Nursing facilities typically contract with LTC pharmacies to perform services necessary to meet these requirements.

When an LTC pharmacy receives a prescription order from a nursing facility, the on-staff pharmacist performs an initial drug regimen review to check for adverse drug interactions. The pharmacist then fills the order for delivery in specially packaged, single doses to ensure that a facility staff nurse provides the resident with the correct dosage. Consultant pharmacists employed by the LTC pharmacy conduct such drug regimen reviews on at least a monthly basis. LTC pharmacies also ensure timely access to drugs by making regularly scheduled and emergency deliveries to their nursing facility customers, and by providing on-site emergency drug kits stocked with small quantities of urgent care drugs. LTC pharmacies provide many of these additional services free of charge or at a reduced rate in exchange for nearly exclusive access to contracted-facility residents.

LTC pharmacies also play an active role in determining which drugs are dispensed. Many LTC pharmacies have developed guidelines that contain information about drug effectiveness and contraindications for the elderly population. Similar to formularies, these guidelines encourage prescribing doctors and consultant pharmacists to choose the most appropriate drugs for nursing facility residents. Consistent with the business practices prevalent in the non-institutional pharmacy benefit management (PBM) industry, LTC pharmacies have also developed rebate relationships with pharmaceutical manufacturers, which provide a source of revenue for the pharmacies. These rebates are paid to LTC pharmacies in recognition of their ability to influence medication regimens.[5]

Consumer Decision Making

Federal and state laws and regulations provide multiple rights and protections to nursing facility residents. Among these is the right to their own medical records and the information necessary to make their own care decisions. When residents are unable to advocate for themselves, nursing facility staff often work with family members to implement a care plan in the resident's best interests. For an incapacitated resident without sufficient family support, California law grants the facility the right to make decisions on behalf of the resident; in these cases, the facility acts as the resident's authorized representative to ensure that the resident's care plan is being complied with.

Quality Monitoring and Oversight

The Centers for Medicare and Medicaid Services (CMS) is responsible for monitoring whether nursing facilities that accept Medicare and Medicaid funding meet over 150 regulatory standards, including those for resident care processes, interactions between residents and staff, and facility environment. Regulations mandate that nursing facilities properly order, store, and administer medications; decrease medication errors and adverse drug events; and monitor over-medication and under-medication. CMS contracts with the California Department of Health Services (DHS) to conduct onsite inspections to determine whether a facility is meeting the Medicare and Medicaid quality and performance standards.

DHS is responsible for licensing and certifying nursing facilities and monitoring compliance with state regulations. As such, DHS is the entity most responsible for ensuring resident safety, including the safe provision of

drugs.[6] To do so, DHS conducts on-site visits to nursing facilities to certify their eligibility under Medicare and Medicaid; investigates complaints; identifies cases in which there is an imminent threat to a resident's health; and provides consumer and provider education to improve quality of care.

How Drug Coverage Will Change

Beginning in January 2006, the Medicare Part D prescription drug benefit will dramatically transform the way prescription drugs are financed and delivered to nursing facility residents in California. Through its contracts with private drug plans, Medicare will become the most significant payer for prescription drugs provided in nursing facilities when it assumes responsibility for drug coverage for all Medicare beneficiaries who enroll. This includes all dual-eligible beneficiaries, whose drug coverage will automatically shift from Medi-Cal to Medicare on January 1, plus Medicare beneficiaries who currently pay out of pocket for their prescription drugs and who voluntarily enroll in a Medicare drug plan.[7] Most individuals who now use private health insurance, often through employer retiree benefits, to pay for their prescription drugs in this setting are expected to maintain their existing drug coverage.[8] Individuals whose care is covered under Part A will also be unaffected.

LTC pharmacies, and to a lesser extent nursing facilities, will be required to coordinate with every Medicare drug plan in which their facilities' residents enroll. Each Medicare drug plan will be permitted to establish its own formulary, cost-sharing structure, and other cost-management controls subject to CMS approval. CMS will require Medicare drug plans to develop networks of retail and LTC pharmacies (mail order optional) to ensure adequate access to drugs among nursing facility residents. This will require LTC pharmacies to contract with most drug plans in the regions they serve. Figure 2 on the following page illustrates the change from the current primary Medicaid environment to a primary Medicare drug plan environment.

Nursing facility residents will be subject to the same formulary and other cost-management controls as non-institutionalized beneficiaries under the Medicare drug benefit. To address the concern that nursing facility residents may be disproportionately affected by restrictive formularies, CMS permits them (and all dual-eligible beneficiaries) to switch drug plans on a monthly basis. CMS also requires each plan to establish an exceptions and appeals process which permits enrollees (or their authorized representatives) to seek coverage for off-formulary drugs. Certain classes of drugs, including benzodiazepines, barbiturates, weight control agents, and over-the-counter medications, have been entirely excluded from coverage under the new Medicare drug benefit. Lawmakers in California, however, have decided to cover these excluded drugs under Medi-Cal for dual-eligible beneficiaries.

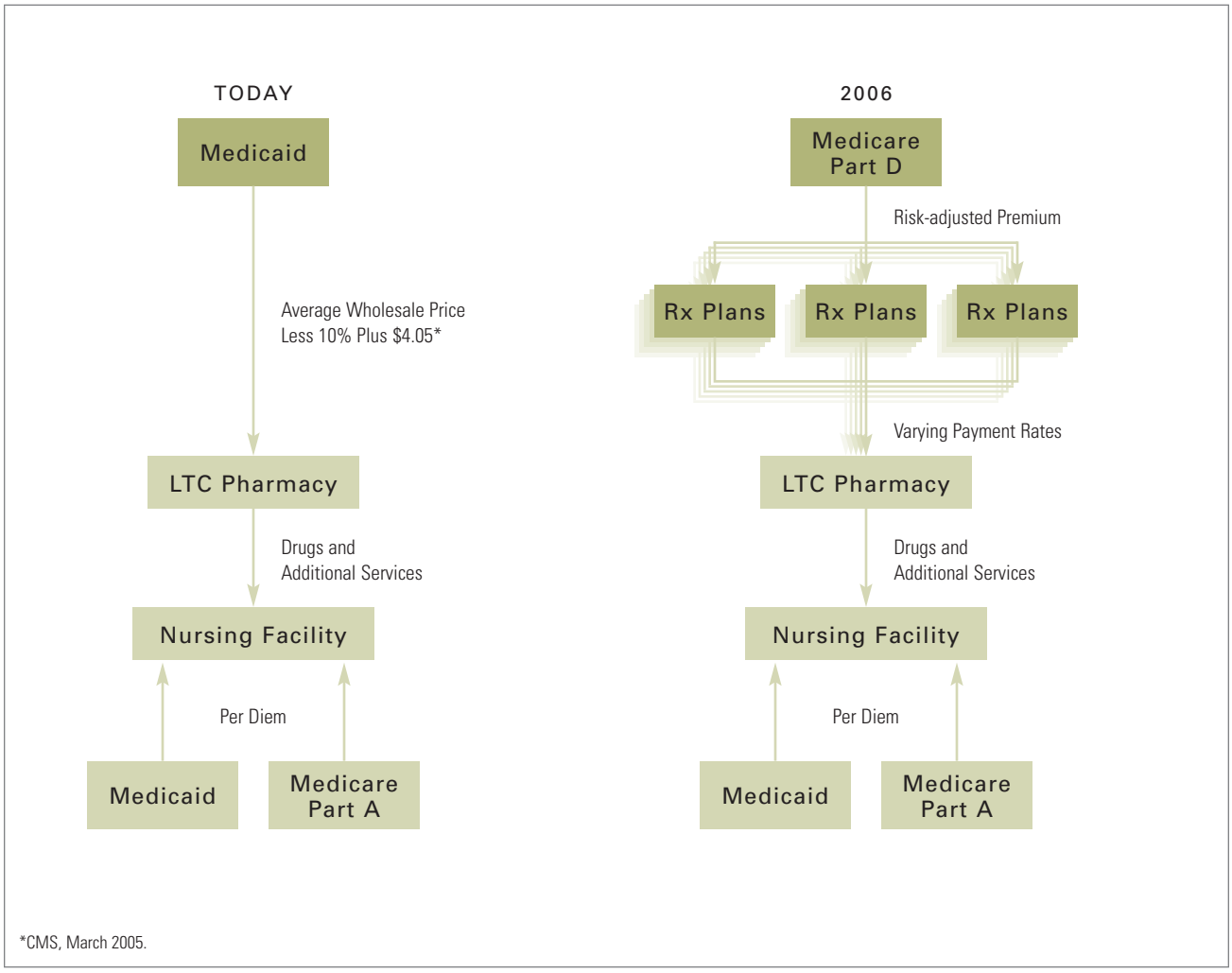
Impact of the Changes

Implementation of the Medicare drug benefit presents numerous challenges for nursing facilities and their residents. Some are short-term, either because they relate to the transition from the current system or will diminish in importance as participation in Medicare Part D grows over time. Other challenges will persist for the long term.

Many nursing facility residents will require help choosing a Medicare drug plan. The Medicare prescription drug benefit is both new and complex, requiring beneficiaries to compare plan benefits, formularies, and cost-sharing responsibilities, and to reconcile those options with current drug spending in order to choose the best plan.

For many Medicare beneficiaries, physicians and pharmacists will play a leading role in providing information about the new drug benefit. However,

Figure 2. Drug Delivery System for Dual-Eligible Nursing Facility Residents



*CMS, March 2005.

Medicare beneficiaries residing in nursing facilities are much less likely to make use of these providers — with whom they have little interaction — for this information. Also, because mail is typically sent to the beneficiary's home address or that of a family member, nursing facility residents are less likely to receive information sent by CMS or the drug plans. Moreover, the majority of nursing facility residents have a cognitive impairment, and very few are likely to evaluate their plan choices using the CMS Web site or other Internet resources. For some residents, the nursing facility has been designated as an authorized representative and will choose the drug plan for the resident.

For all these reasons, nursing facility staff likely will play a leading role in helping residents select a drug plan that provides adequate, affordable coverage. This will be a natural extension of the role nursing facility staff currently play in educating residents and their families about payer benefits and coverage rules, and about Medi-Cal eligibility and enrollment, but will require increased facility administrative capacity. Federal guidance detailing the extent to which nursing facilities may assist beneficiaries with plan selection has been ambiguous; it has been clearly indicated, however, that nursing facilities will not be permitted to steer beneficiaries into one or a few preferred drug plans.

Nursing facilities may not know which drug plans their residents have been assigned to. When a dual-eligible beneficiary is auto-assigned to a Medicare drug plan, CMS will notify the beneficiary (by mail, often to the beneficiary's home address) and the drug plan. However, CMS does not intend to notify nursing facilities of the drug plan assignments for their dual-eligible residents. Until nursing facility staff are notified (by the beneficiary, a family member, or the drug plan), they may not have sufficient information to manage a resident's prescription drug regimen in accordance with the rules of the new drug plan. The facility also may not know if its resident's drug plan has a network relationship with the facility's contracted LTC pharmacy. And a facility may not know if CMS has failed to enroll some of its dual-eligible residents.

Some beneficiaries may experience a coverage gap when they first enter a nursing facility. The 46 percent of beneficiaries who are first admitted to nursing facilities for post-acute care covered by Medicare Part A begin their stay with full Part A drug coverage.[9] During this period, they have an opportunity to enroll in Part D for continued drug coverage when their Part A coverage ends. However, for those who enter a nursing facility without Part A coverage for their stay, Medicare Part D coverage would not begin until the first of the month after the beneficiary applies for it. Prior to the Medicare drug benefit, Medi-Cal coverage of drug costs was retroactive for those residents who later qualified for Medi-Cal. Since such retroactivity will not apply under Medicare Part D, dual-eligible beneficiaries not enrolled in a Medicare drug plan who enter a nursing facility without Part A benefits may experience a coverage gap from the day of admission until at least the first of the month after they entered the facility.

It is unclear what impact this coverage gap will have, and it may vary among beneficiaries. For the many nursing facility residents who qualify for retroactive Medi-Cal coverage, these drug costs will be paid indirectly by Medi-Cal. This is because any out-of-pocket spending on health care is deducted from the beneficiary's income total prior to calculating the amount the beneficiary must contribute to the cost of their nursing facility care (known as "share of cost"). In cases where drug costs exceed the beneficiary's income, those costs may be shifted to the nursing facility as uncompensated care. The number of beneficiaries affected by this coverage gap will decrease as participation in Medicare Part D grows.

Many nursing facility residents may have an incentive to switch to plans with less-restrictive formularies and higher premiums. Most dual-eligible and low-income subsidy beneficiaries will enroll in, or be assigned to, drug plans which cost them nothing because the plans' premiums are below the regional benchmark. These plans are likely to have the most restrictive drug formularies, however, and so may not be the most appropriate option for nursing facility residents.

In response to these formulary restrictions, many nursing facility residents may enroll in or switch to higher-cost drug plans that will not actually end up costing them more. This phenomenon exists because of the concurrent operation of certain Medi-Cal regulations. Specifically, nursing facility residents must pay a share-of-cost to qualify for Medi-Cal. Part D plan premiums, like other out-of-pocket spending on health care, count towards their share-of-cost. For these residents, choosing a higher-cost drug plan will simply result in a redirection of some of their income from the nursing facility to the drug plan. The nursing facility, in turn, will be made whole by Medi-Cal, which pays the difference between its per diem rate and the amount the resident pays. In other words, Medi-Cal may end up subsidizing nursing facility residents to enroll in higher-cost, less-restrictive drug plans.

New systems and processes are needed to ensure proper coordination between nursing facilities and multiple drug plans. The new Medicare prescription drug benefit is designed to promote competition among drug plans and pharmacies in price and service. To work with multiple, competing drug plans, nursing facilities must:

- Determine which drug plan a new resident is enrolled in, whether the resident's drug plan works with the facility's LTC pharmacy, what drugs are covered under the formulary, and how a resident or authorized representative would navigate the plan's exceptions process. It is particularly important that this determination be made immediately upon admission for beneficiaries who enter nursing facilities without a stay covered by Medicare Part A.
- Establish systems and processes to navigate different rules for coverage, dispensing, and appeals among dozens of drug plans, so that the correct drugs are dispensed in a timely manner. For example, nursing facilities will have to alter admissions processes in order to gather information on Part D enrollment status and educate potential residents on how the facility will coordinate with its LTC pharmacy under the Part D plan rules; these changes may require the updating of admissions software, admissions manuals, drug therapy manuals et al., and the expanding of skills and tasks by admissions personnel. Also, for residents who are dual-eligible beneficiaries, nursing facilities must determine whether the resident is likely to be institutionalized for more than 30 days and notify the drug plans, so that the dual eligible does not have to pay any cost-sharing. This is necessary because an individual is defined by the new Medicare law as "institutionalized" for the purposes of determining copay amounts if he or she is expected to reside in an institution for more than 30 days.

These changes may drive up nursing facility administrative costs in two ways. First, new systems and processes require money to establish and maintain. Second, nursing facilities may have to pay for some of the services LTC pharmacies now provide free of charge. These changes could have a spillover effect both on Medi-Cal spending and the level of resources nursing facilities will have for staffing and other areas that affect quality of care. Recent research shows that half of nursing facilities in California are now operating at no profit or losing money.[10] The additional administrative burdens of managing Part D will likely worsen their financial outlook.

Many nursing facilities may try to maintain a "one facility, one pharmacy" arrangement by encouraging (or requiring) their preferred LTC pharmacies to participate in all available drug plan networks. Although this approach would allow residents to choose any drug plan, it does not address the underlying challenges nursing facilities and pharmacies would face in dealing with multiple formularies, plan benefit rules, and plan billing requirements. Another strategy for nursing facilities may be to encourage all residents to enroll in one drug plan (or some small subset of available drug plans), taking advantage of the residents' right to switch plans monthly. This approach would greatly reduce the administrative and clinical complexity of providing drugs to residents. Its success, of course, would hinge on residents' agreement to enroll in the facility's selected drug plan. A significant problem with this approach, however, is that not all residents' medication needs are likely to be best served by one plan. As a result, CMS has stated that steering beneficiaries to particular drug plans is inappropriate. CMS has not explicitly defined "steering," but it is likely that some actions taken by a nursing facility to encourage the selection of a single plan would be deemed improper.

Recommendations

Nursing Facility Operators and Staff

Nursing facilities will play an integral role in implementing the new prescription drug benefit, and face many challenges in doing so. Some of the high-priority actions they should take to prepare for the changes include:

- Develop systems to ensure that current and new residents are quickly assessed for drug coverage; for those without coverage, facilitate their enrollment into a Medicare drug plan, and into the low-income subsidy if appropriate. This could include designating a Medicare prescription drug benefit staff expert, with responsibility for coordinating with residents, their families, LTC pharmacies, CMS and the Social Security Administration to ensure that all residents have appropriate drug coverage on January 1, 2006 and after.
- Identify which residents require drugs that their Medicare prescription drug plan does not include in its formulary, and develop individual transition plans for each resident. Transition planners should not necessarily rely on CMS guidance that Medicare prescription drug plans provide non-formulary drug coverage for up to 180 days to nursing facility residents; plans are not required to comply with the agency's guidance, and are less likely to do so when, as in this instance, it would impose higher costs on the plan.
- Develop systems to ensure that nursing facility staff and prescribing physicians have accurate information on plan formularies and cost-sharing levels for each resident, and ensure that exceptions are promptly and properly requested when prescriptions are written for non-covered drugs. Nursing facilities should collaborate with pharmacists, physicians, and drug plans to facilitate exceptions and appeals processes.

Federal Officials

Federal officials have primary responsibility for ensuring that the transition to the new Medicare drug benefit is successful, and that quality of care and patient safety standards continue to be met. High-priority actions should include:

- Inform nursing facilities which drug plans their dual-eligible residents have been auto-enrolled into. Provide nursing facilities with rapid and updated plan assignments to assist them in transitioning beneficiaries to their new drug coverage.
- Provide training to nursing facility staff on how to counsel residents and their family members about their option to enroll in the Medicare prescription drug benefit, the availability of the low-income subsidy, and how to evaluate and select a drug plan.
- Develop systems to ensure that nursing facilities continue to have the latest accurate information on plan formularies, cost-sharing, and premiums. This could include a system to regularly update this information (such as by e-mail) that offers links to CMS and plan information, and provides notification when there is a change to the CMS rules regarding the Medicare prescription drug benefit or to coverage by a specific drug plan.
- Establish monitoring procedures and action plans to ensure that as the new Medicare drug benefit is implemented, drug error rates do not rise; quality of care and patient safety do not fall; residents are able to enroll in the drug plan of their choice; and coverage is provided for drugs dispensed on an emergency basis.

State Lawmakers and Program Officials

Even after the new Medicare drug benefit is implemented, DHS will maintain responsibility for ensuring the safe provision of drugs in California and will continue to oversee facility compliance with patient safety regulations and certification criteria. This quality

oversight will become more difficult, however, because the state will no longer have access to dual-eligible beneficiary drug utilization data. In addition, Medi-Cal will continue to pay for the non-drug costs of nursing facility care for dual-eligible beneficiaries, and major disruptions in prescription drug access could increase overall Medi-Cal spending as nursing facility residents experience adverse health outcomes. The following are high-priority actions state officials should take:

- Review and update state regulations and requirements to ensure that nursing facilities have the authority to assist beneficiaries in selecting a new Medicare drug plan when necessary, and to clarify whether any state anti-kickback rules apply if a nursing facility encourages its beneficiaries to enroll in or switch to a particular Medicare drug plan.
- Monitor progress made by federal officials and nursing facility operators to ensure that all necessary steps are taken for a successful transition, and prepare to take action if they are not.
- Measure the impact of the changes in drug coverage on the quality of care for nursing facility residents and Medi-Cal spending for this population. Given the impending lack of access to dual-eligible drug utilization data, new approaches will need to be developed.

Conclusion

The new Medicare prescription drug benefit will bring tremendous changes to the way drugs are financed and delivered in nursing facilities. Among the greatest changes are the transformation from a system with one dominant payer, Medi-Cal, to one with multiple payers and formularies, and potentially the end of the "one facility, one pharmacy" structure. These and other likely changes will increase the complexity of providing drugs to nursing facility residents and will require active new steps by facilities, pharmacies, and government officials to ensure quality of care and patient safety.

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For more background on the Medicare drug benefit and its implications for California — including other issue briefs in this series — visit the California HeathCare Foundation's Web site at www.chcf.org/topics/healthinsurance/drugbenefit.

Endnotes

1. Figure for the number of certified nursing facilities in California is 2003 data provided by The Kaiser Family Foundation, State Health Facts, Total Number of Residents in Certified Nursing Facilities, 2003, www.statehealthfacts.org. Figure for the number of nursing facility residents is 2005 data provided by CMS OSCAR Data Current Surveys, June 2005.
2. The universe of nursing facilities discussed in this Issue Brief includes those facilities certified by Medicare or Medi-Cal as meeting participation criteria. It does not include facilities that generally do not provide skilled nursing care (such as board and care homes, independent living facilities), or intermediate care facilities.
3. California residents are encouraged to use this pharmacy provider, although they may choose to use another pharmacy, as long as that pharmacy meets the standards of the nursing facility.
4. Dan Mendelson et al., *Prescription Drugs in Nursing Homes: Managing Costs and Quality in a Complex Environment,* National Health Policy Forum, 12 November 2002.

5. Manufacturer rebates collected by long-term care pharmacies, which are usually based on increased market share, are in addition to the rebates states collect under Medicaid.

6. The California Long Term Care Ombudsman Program, within the same agency as DHS (the California Health and Human Services Agency) also has the responsibility to investigate resident complaints.

7. For further discussion of how this shift will occur, see *The Medicare Drug Benefit: Implications for California,* April, 2005. California HealthCare Foundation, Oakland, CA, www.chcf.org/topics/healthinsurance/drugbenefit/index.cfm?itemID=110596.

8. Congressional Budget Office, *A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit,* July 2004; Kaiser Family Foundation and Hewitt Associates, *Current Trends and Future Outlooks for Retiree Health Benefits,* December 2004.

9. Centers for Disease Control, *The National Nursing Home Survey: 1999 Summary,* June 2002.

10. California HealthCare Foundation, *Snapshot: California's Fragile Nursing Home Industry, 2005,* www.chcf.org/topics/view.cfm?itemid=113183.