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Prescription Drugs in Nursing Homes: Managing Costs and Quality in a Complex Environment

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OVERVIEW — *This brief provides a description of prescription drug use in nursing homes and a summary of current policy issues in this area. The brief first profiles the nursing home pharmaceutical market, outlining the major trends in demographics and drug utilization, the supply chain by which drugs go from manufacturers to pharmacies to nursing home residents, and the alternative arrangements by which prescription drugs in nursing homes are financed. The brief then provides a synopsis of current policy issues, focusing in turn on cost containment and quality improvement initiatives.*

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Prescription Drug Use in Nursing Homes: Managing Costs and Quality in a Complex Environment

The rise in spending on prescription drugs has emerged as a central policy issue for the Medicare and Medicaid programs. At the federal level, debate about prescription drugs has focused primarily on the addition of an outpatient prescription drug benefit to the Medicare program. At the state level, concern has been driven by double-digit increases in Medicaid drug spending. Despite the prominence of the prescription drug cost issue, however, relatively little attention has been paid thus far to the unique and important topic of pharmaceuticals prescribed to nursing home residents.

Federal consideration of nursing home pharmacy issues in the past has mainly been limited to quality and safety concerns, specifically the prevention of inappropriate sedation. For a variety of reasons, however, the management of prescription drugs in nursing homes is now poised to emerge as a critical policy issue. First, state awareness of drug spending in nursing homes has grown as budget problems have forced increasingly aggressive state Medicaid cost containment. Second, as pharmaceutical innovation continues, new and expensive medications are rapidly being developed for the elderly population. Third, clinicians are concerned about the increasing utilization of pharmaceuticals by nursing home residents and the high incidence of drug-related adverse events.

DRUG THERAPY IN NURSING HOMES: MAJOR TRENDS

The United States faces a growing elderly population and an increasing level of frailty among its citizens living in long-term care facilities. The aging of the baby boom generation is predicted to propel a rise in the percentage of the population over age 75 from 5.8 percent in 1997 to 9.4 percent in 2025.[1] At the same time, advances in medical technology will allow sicker individuals to live longer, sometimes with inadequate housing, insufficient social supports, and/or significant nursing care requirements. While alternatives to nursing homes (such as home health and assisted living facilities) are likely to proliferate and become more important, a demand for nursing home care, if even only among the most frail, will likely grow concurrently with the growth of the elderly population.

Data from the National Nursing Home Survey indicate that, in 1997, there were an estimated 1.6 million nursing home residents living in

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approximately 17,000 nursing homes nationwide.[2] Of these residents, 90.3 percent were over age 65, and 46.5 percent were over age 85.[3] Data from the Agency for Healthcare Research and Quality (AHRQ) indicate that females comprise 71.6 percent of all nursing home residents and that 83 percent of residents receive help with three or more activities of daily living, or ADLs, including bathing, dressing, toileting, transferring from a bed or chair, feeding, and mobility.[4]

A 2000 study of nursing facilities revealed that individual nursing home residents receive an average of 6.7 routine prescription medications per day and 2.7 additional medications on an "as needed" basis.[5] The most commonly prescribed medications, according to an independent survey, are gastrointestinal agents (including laxatives, enemas, and acid secretion reducers), analgesics (including acetaminophen and aspirin), cardiovascular medications (including Digoxin, diuretics, and nitrates), vitamins and supplements (including multivitamins and potassium), and psychoactive medications (including sedatives and hypnotics, antipsychotics, and antidepressants).[6] This list accords with preliminary findings from the Office of the Assistant Secretary for Planning and Evaluation in the U.S. Department of Health and Human Services (DHHS), which is currently studying the use of pharmaceuticals among Medicare beneficiaries in nursing homes.[7] (Medicare recipients tend to have shorter lengths of stay than the average nursing home resident.)

The number of drugs prescribed to nursing home residents has been increasing. A recent survey of pharmacists showed that routine medication orders in nursing homes increased by 14 percent from 1997 to 2000.[8] The percentage of nursing home residents using nine or more prescription medications per day also rose from 18 percent in 1997 to 27 percent in 2000.[9] These trends have produced mixed reactions within the medical and policy communities: on the one hand, clinicians acknowledge the possible increase in quality resulting from increased use of appropriate medications; on the other, experts worry about the potential for inappropriate medication use, adverse drug reactions and interactions, and increasing drug costs.

The recent growth in nursing home drug utilization is due to a number of factors, including technologic innovation in pharmaceuticals. The last 15 years have seen the development of safer alternatives to traditional medications (for example, newer antipsychotic drugs with better side-effect profiles than traditional agents), as well as new categories of medications that fill important needs (for example, selective serotonin reuptake inhibitors for depression and statin drugs for reducing serum cholesterol). Pharmaceutical innovation and the rapid diffusion of more expensive therapeutics are likely to continue—a 2001 survey conducted by the Pharmaceutical Research and Manufacturers of America indicated that there are 261 drugs in development to treat diseases of aging (for example, Alzheimer's disease, osteoporosis, and arthritis), as well as 122 medicines for heart disease and stroke and 402 medicines for cancer.[10]

Routine medication orders in nursing homes increased by 14 percent from 1997 to 2000.

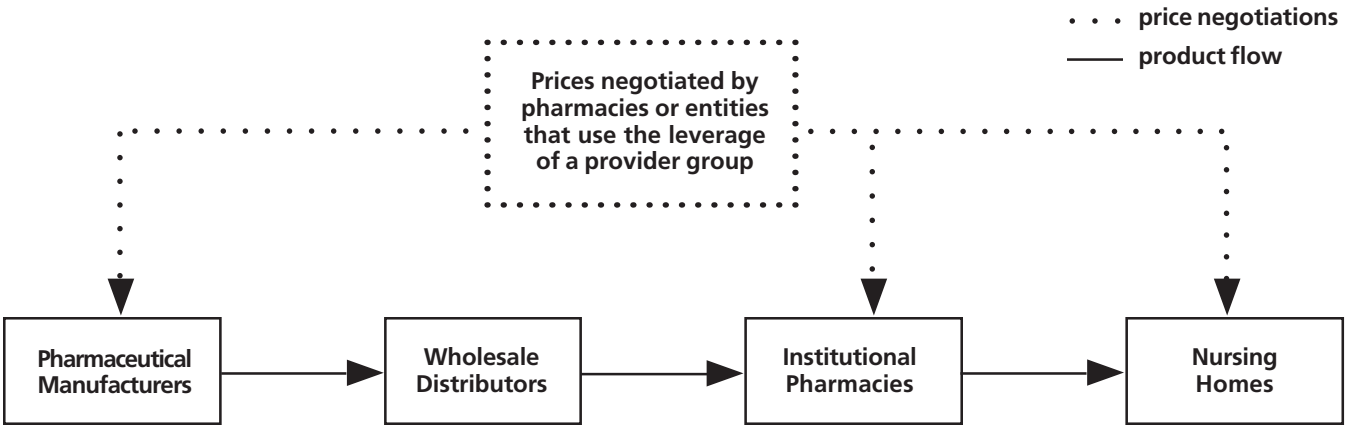
SUPPLY OF PHARMACEUTICALS TO NURSING FACILITIES

Nursing homes typically acquire drugs for administration to residents by means of a standard supply chain, illustrated in Figure 1. The pivotal role in this supply chain is played by pharmacies, which are involved not only in drug supply and distribution, but also in activities ranging from price negotiations to quality improvement efforts. Currently, over 80 percent of the nursing home beds in the United States are served by "institutional" pharmacies that cater specifically to nursing homes and other facilities.[11] However, some nursing homes are served by independent community pharmacies or retail pharmacy chains; the nursing home market share claimed by institutional pharmacies varies from state to state.

Regardless of the type of pharmacy, federal and state laws require pharmacies that serve nursing homes to maintain extended drug control and distribution systems that exceed the standards for pharmacies dispensing only to outpatients. As pharmacies that specialize in long-term care, institutional pharmacies tend to offer additional services to support the special needs of nursing homes, including 24-hour-a-day drug delivery, maintenance of medication profiles and drug inventory systems, repackaging of drugs from bulk supplies into unit doses for controlled administration, and maintenance of emergency kits.

Five national chains provide the bulk of institutional pharmacy services to nursing homes in the United States (Table 1). Two of the nation's five national institutional pharmacy chains (NeighborCare and Kindred Pharmacy Services) are owned by larger companies (Genesis Health Ventures

FIGURE 1
Typical Supply of Pharmaceuticals to Nursing Facilities



This schematic depicts general product flow; exceptions may exist.

and Kindred Healthcare, respectively) that also run nursing homes, and one (PharMerica) is a subsidiary of a wholesale distributor (Amerisource Bergen). The last few months have seen significant merger and acquisition activity within the industry. In July 2002, Genesis and NCS HealthCare announced that Genesis would acquire NCS and fold its operations into its NeighborCare division; in response, Omnicare launched a hostile tender offer for NCS shares. As this issue brief was being prepared, NCS had filed suit against Omnicare and was preparing shareholder proxies for the proposed NeighborCare merger.[12]

TABLE 1
Institutional Pharmacy Industry and 2001 Revenues

Company	2001 Revenue (in millions)	Beds
Omnicare	$2,159	662,000
PharMerica	$1,350	300,000
Genesis/NeighborCare	$1,100	255,000
NCS HealthCare	$626	209,000
Kindred Pharmacy Services	$230	56,400

Source: Company annual reports.

Federal law requires all nursing homes to contract with a consultant pharmacist, who is responsible for ensuring that resident drug use is safe and effective and that facilities are in compliance with federal and state regulatory requirements. Contractual arrangements vary widely—consultant pharmacists may be independent or may be employees of either the nursing home or a pharmacy. Most institutional pharmacies offer consultant pharmacy services as part of their standard negotiations with client nursing homes. New Jersey is the only state with a conflict-of-interest provision stipulating that consultant pharmacists may not be employed by long-term care pharmacies.[13]

In most states, both pharmacies and nursing homes are allowed to maintain formularies, that is, lists of drugs that are either recommended or accepted for payment. If the pharmacy or nursing home is large enough, it may extract rebates from manufacturers in exchange for listing their product(s) on the formulary. Industry representatives state that therapeutic value is the most important factor in the decision to include a drug on a formulary but that cost is also considered when comparing two drugs of equal therapeutic value.[14] Typically, neither pharmacies nor nursing facilities are required by law to pass their rebates on to the end payer.

FINANCING

Three different sources are available for financing nursing home care: Medicaid, Medicare, and private sources (including both personal funds and long-term care insurance). Medicare pays for nursing home care only for limited time periods after an acute hospitalization. For chronic long-term care, most individuals enter nursing homes as private-pay residents, using a combination of resources (such as Social Security or pension income and personal assets) to pay their expenses. Many residents eventually "spend down" their resources and meet the requirements for

Medicaid eligibility; consequently, the Medicaid program bears most of the financial responsibility for long-term care in the United States. Data from the AHRQ show that, in 1996, nursing homes received 44 percent of their total revenue from Medicaid, 19 percent from Medicare, and 34 percent from private sources (30 percent from out-of-pocket payments and 4 percent from long-term care insurance).[15]

In 1996, nursing homes received 44% of their total revenue from Medicaid, 19% from Medicare, and 34% from private sources.

The three payment sources in this market use markedly different financing structures to reimburse for drugs: Medicaid pays a discounted price for drugs on a per-drug basis, Medicare imposes financial risk on nursing homes by including drugs in the prospective payment rate, and residents paying out-of-pocket typically pay a nondiscounted price for drugs on a per-drug basis. These three reimbursement arrangements offer very different incentives to nursing home and pharmacy operators (discussed further in the "Cost Containment" section, below).

Medicaid

State Medicaid programs generally reimburse for nursing home care in a disaggregated fashion: payment for pharmaceuticals is done separately from payment for residents' care at the nursing facility. Pharmaceuticals are typically reimbursed on a per-drug basis, while nursing facility care is reimbursed according to a standard daily rate. (The exception to this rule is in New York, where some drug costs are lumped into the Medicaid daily rate for nursing facility care, thus placing the providers at risk for a portion of nursing home drug expenditure.) Reimbursement for drugs is paid directly from the Medicaid program to the pharmacy or is passed through to the pharmacy via the nursing home.

Medicaid programs typically reimburse institutional pharmacies according to the same methodology used for retail pharmacies, that is, reimbursement for brand-name drugs is the sum of an "ingredient" cost (usually set by the state at a certain discount from the average wholesale price, or AWP, a figure used by payers and manufacturers to benchmark the costs of drugs)[16] plus a standard dispensing fee. However, some states offer slightly higher reimbursement to institutional pharmacies to account for special differences between institutional pharmacies and retail pharmacies. There are two sources of such additional reimbursement to institutional pharmacies: (*a*) extra payments to cover institutional pharmacies' costs in procuring manufacturers' unit dose products,[17] and (*b*) specially designated "long-term care (LTC) add-on" reimbursement (currently found in 11 states) intended to compensate institutional pharmacies for extra services they provide that retail pharmacies do not.[18]

Because DHHS' Centers for Medicare and Medicaid Services (CMS) does not systematically analyze nursing home drug spending separately from overall Medicaid drug spending, there are no consistent national data on Medicaid expenditures attributable to drug spending in the long-term care setting.[19] Investigation on a state-by-state basis, however, demonstrates

that spending varies as a function of the Medicaid program demographics in any given state. In Georgia, for example, where only 2 percent of Medicaid recipients reside in nursing homes, the Medicaid program expends 14 percent of its total drug budget on long-term care pharmacy.[20] In contrast, in Indiana, where 7 percent of Medicaid recipients live in nursing homes,[21] 25 percent of total Medicaid pharmacy claims go toward prescription drugs in nursing homes.[22] These statistics lend support to the notion that nursing home residents consume a disproportionate share of Medicaid drug expenditures compared with their counterparts in the community setting.

Nursing home residents consume a disproportionate share of Medicaid drug expenditures.

Medicare

In direct contrast to Medicaid, the Medicare program pays for nursing home pharmaceuticals and nursing home facility care in one aggregated bundle. For elderly and disabled beneficiaries, Medicare covers all or some portion of the first 100 days of skilled nursing facility (SNF) care following a three-day hospital stay,[23] paying SNFs a per diem prospective rate set by CMS. Like the Medicare inpatient hospital payment, the SNF prospective rate covers almost all medically necessary drug use that occurs during a resident's stay.[24] This means that Medicare does not pay for any costs that exceed the previously determined rate and that SNFs are at risk for the costs of all resident drug use during a Medicare-covered stay.

In their negotiations with institutional pharmacies, nursing homes sometimes contract to pay a capitated amount for Medicare-covered drugs, thereby passing the risk of high drug use on to the pharmacy. However, pharmacies often secure fee-for-service exclusions to these capitated arrangements for some of the most expensive drugs. Institutional pharmacies are able to offer competitive drug prices to nursing homes because of manufacturer discounts they receive when they include certain drugs on their formulary; therefore, the pharmacies benefit when the prescribing physicians adhere to the pharmacies' formularies as closely as possible.

The American Society of Consultant Pharmacists has criticized the Medicare SNF prospective payment system for inadequately reimbursing nursing homes for resident drug use.[25] In its May 2001 proposed rule update to SNF payments, CMS acknowledged that it is difficult to account for pharmacy costs in case-mix systems because drug costs do not necessarily follow physical condition, resource use, or functional and clinical pathways.[26] CMS announced that it would address this problem and others by reexamining the SNF payment system. The proposed rule also includes a provision to update the base year for the SNF market basket index, which has the effect of giving drugs a higher weight within the index.[27]

Out-of-Pocket Payment

Residents paying out-of-pocket for nursing home care or assisted living are typically billed separately by the pharmacy for their prescription

drugs. To maintain quality and administration control, nursing homes and assisted living facilities strongly encourage or require residents to use the pharmacy with which the facility has a contract.

Nursing home advocates believe that residents pay a higher price for drugs dispensed by an institutional pharmacy than they would if they received the same drug from a retail pharmacy.[28] A recent media report described how one institutional pharmacy's charges for providing an assisted living resident's drugs were $6,702 a year higher than they would have been under a mail order plan.[29] In general, the institutional pharmacy and nursing facility industries justify their higher prices for drugs by citing the cost of additional specialized services provided to residents in an institutional setting.

POLICY ISSUES

Cost Containment

Concern over the rise in spending on prescription drugs has prompted a reexamination of opportunities for cost containment in all corners of the health care system. With respect to prescription drugs in nursing homes, state Medicaid programs have begun to emerge as laboratories for innovation and experimentation.

Ingredient Cost Reimbursement — Ingredient cost (the cost of the drug itself, considered separately from any dispensing fee paid to the pharmacist) is typically the largest component of the total reimbursement for any drug. Therefore, most state Medicaid cost containment efforts have included some element of ingredient cost reimbursement adjustment. In general, Medicaid programs have attempted to lower their ingredient cost reimbursements while attempting to guarantee pharmacies a reasonable profit.

Much of the research in this area has focused on trying to determine the pharmacies' actual drug acquisition costs, with the objective of using those figures to determine the level at which Medicaid reimbursement should be set. A recent DHHS Office of the Inspector General (OIG) study found that "nontraditional" pharmacies (including nursing home, hospital, and home infusion therapy pharmacies) acquired drugs at nearly a third below AWP for brand name drugs.[30] Since states typically reimburse pharmacies at much higher rates, the OIG report implies that a substantial portion of discounts received by pharmacies are not passed on to the state and are instead kept by the pharmacies. The OIG report has met with heavy criticism, however, especially from the pharmacy industry, which has raised concerns about how the OIG's figures were calculated. For example, a University of Texas study performed on behalf of the National Community Pharmacists Association and the National Association of Chain Drug Stores argues that the OIG extrapolated its national estimates from an unrepresentative sample of pharmacies and invoices.[31]

Research in the reimbursement area has focused on trying to determine the pharmacies' actual drug acquisition costs.

In response to this and other criticism, the OIG recently released additional analyses that broke out pharmacy acquisition costs by drug source category.[32]

At present, over a dozen states (including Arkansas, Colorado, Connecticut, Indiana, Kansas, Kentucky, Maryland, Massachusetts, Minnesota, Mississippi, North Carolina, Oregon, Virginia, Washington, and West Virginia) are considering or have recently considered proposals to lower their ingredient cost reimbursements for Medicaid pharmaceuticals. The proposed reimbursement rates, which vary from AWP minus 11 percent to AWP minus 30 percent, have met with varying levels of support.[33] All of the current proposals would apply equally in both the outpatient and nursing home settings; there appear to be no current proposals that would single out institutional pharmacies for greater or lesser reductions.

Dispensing Fees — Current legislative proposals vary with regard to their approaches to pharmacy dispensing fees. Some states (for example, Mississippi) are attempting to lower both ingredient reimbursements and dispensing fees, while other states (for example, Minnesota) would reduce ingredient reimbursement while increasing dispensing fees. A budget proposal from Kentucky would decrease dispensing fees for retail pharmacies but leave them unchanged for institutional pharmacies.[34]

Special Reimbursements for Institutional Pharmacies — The current policy environment is marked by a growing awareness of the special requirements (and costs) associated with dispensing pharmaceuticals in the nursing home setting. As mentioned above, some states recognize the unique circumstances of institutional pharmacies by offering them slightly higher reimbursements than they offer retail pharmacies. The first way this is done is by compensating institutional pharmacies for the additional cost associated with procuring manufacturers' unit dose products. Some states offer an even higher reimbursement when pharmacies buy manufacturers' products in bulk and then repackage the drugs themselves as unit doses. While all states allow pharmacies to reuse original manufacturer-packed unit dose products if certain conditions are met, recent legislation in several states has also allowed pharmacies to reuse *pharmacy*-repacked unit dose drugs under certain circumstances, thus lowering their costs.[35]

The second way in which states can offer higher reimbursement to institutional pharmacies is through designated "LTC add-on" reimbursement. Eleven states presently have arrangements to reimburse institutional pharmacies an additional amount ranging from $0.30 to $1.40 per prescription, above and beyond the ingredient cost and dispensing fee, as compensation for extra services performed in the institutional setting.[36]

A number of key questions underlie the current debate over institutional pharmacy reimbursement. How costly are the added services provided by institutional pharmacies? Are there offsetting savings that nursing homes can achieve? Should any net costs be added to Medicaid payment

Some states offer institutional pharmacies slightly higher reimbursements than they offer retail pharmacies.

rates? Two recent studies have attempted to shed light on these questions. A December 2000 study of institutional pharmacy dispensing costs released by the Pennsylvania General Assembly[37] found that long-term care pharmacies incur additional costs of $2.87 per prescription for the above services; the report recommended that Pennsylvania Medicaid consider an LTC add-on for institutional pharmacies above its standard reimbursement (AWP minus 10 percent plus a dispensing fee of $4.00 per prescription). A second study released by the Long-Term Care Pharmacy Alliance in April 2002 reported that institutional pharmacies face dispensing costs of $4.32 per prescription higher than traditional retail pharmacies.[38] It should be emphasized that both of these studies confined themselves to an analysis of dispensing costs and did not examine drug acquisition costs; therefore, the discounts on drugs and high margins for institutional pharmacies (as reported by the OIG) were not taken into consideration.

New York places nursing homes at financial risk for a portion of nursing home drug spending.

Alternative Risk Sharing Arrangements — As noted above, New York Medicaid has a unique arrangement for financing nursing home drug spending. By including the costs for many drugs into the prospective daily rate for nursing facility care, New York effectively places nursing homes at financial risk for a portion of nursing home drug spending, as takes place under Medicare. Several high-priced drugs are excluded from this arrangement and are reimbursed by the traditional per-drug methodology.

The economic incentives engendered by New York Medicaid and by Medicare are at odds with those produced by traditional Medicaid reimbursement. Under capitation, nursing homes may benefit when fewer drugs are prescribed, since fewer dollars are diverted to the pharmacy to pay for drugs. With the latter approach, nursing homes have no economic incentive to control drug utilization, and in fact pharmacies benefit when more drugs are prescribed. These different incentive systems raise important issues for nursing home care. On one hand, placing the nursing home at risk for drug spending might curtail overall pharmaceutical costs and may in fact encourage quality improvement programs aimed at reducing inappropriate medication use. On the other hand, risk sharing may encourage providers to limit access to medications and to deny care to sicker (and thus more expensive) beneficiaries.

Other Initiatives — Most states have been experimenting with a variety of approaches other than reimbursement cuts as avenues through which to control Medicaid drug spending. Programs such as preferred drug lists, limits on brand-name drugs, and therapeutic substitution are all currently used to varying degrees in many states. However, program policies differ by state with respect to their impact on nursing home populations. Legislation in Florida, for example, exempted nursing homes from a newly adopted preferred drug list but expanded the state's four-brand limit to Medicaid-covered nursing home residents. This policy requires that a Medicaid beneficiary must receive prior authorization from the state to receive a fifth or higher brand-name medication in any given

month. Michigan, on the other hand, included nursing homes in its current preferred drug list and prior authorization program.[39]

To date, five states have obtained approval from the Bush administration to implement Pharmacy Plus waivers, which allow prescription drug coverage for seniors who would not otherwise qualify for Medicaid. While the Pharmacy Plus program is targeted at low-income seniors who receive prescription drugs in an outpatient setting, it is conceivable that states could use Pharmacy Plus to provide drug-only coverage to nursing home residents that have not yet "spent down" to full Medicaid coverage. However, eligibility for Pharmacy Plus may be short-lived as residents continue to spend down into full Medicaid eligibility, and spending limits in some states could further limit the program's applicability in this context.

Quality Improvement

Nursing home quality of care emerged as a visible patient advocacy issue in the mid 1970s and early 1980s. Public concern over poor nursing home quality culminated in a landmark Institute of Medicine report in 1986 that highlighted widespread quality problems and recommended stronger federal regulations.[40] In response, Congress passed the Nursing Home Reform Act as part of the Omnibus Budget Reconciliation Act (OBRA) of 1987.[41] By strengthening quality standards, upgrading the survey process, and stipulating quality requirements that must be met for nursing homes to participate in the Medicare and Medicaid programs, OBRA 1987 set the stage for subsequent quality improvement efforts, some of which are well established and some of which continue to evolve. The most significant quality assurance initiatives related to drug therapy include limits on chemical restraints, limits on other unnecessary or harmful drug use, efforts to discourage polypharmacy (the practice of prescribing too many medicines to a patient), mandated drug regimen reviews by consultant pharmacists, and initiatives to disseminate geriatric best practice information to physicians.

Limits on Chemical Restraints — A major quality improvement goal of the patient advocacy movement has been to limit use of chemical restraints in nursing facilities. Because of concerns that nursing homes were using drugs to sedate residents inappropriately, OBRA 1987 mandated that nursing home residents be free from "physical or chemical restraints imposed for the purposes of discipline or convenience and not required to treat a resident's medical symptoms."[42] A nursing home may impose restraints only to ensure resident safety and only under a physician's written order. These orders must specify the duration and circumstances under which the restraints may be used.

DHHS regulations further limit chemical restraints by requiring nursing homes to ensure that residents "who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the

Patient advocates have sought to limit the use of chemical restraints in nursing facilities.

clinical record." For residents who use antipsychotic drugs, nursing homes must make an effort to discontinue these drugs by making gradual dose reductions and by conducting behavioral interventions.[43]

There is evidence that these laws and regulations have been effective in preventing inappropriate use of chemical sedation. In November 2001, the OIG found that 85 percent of nursing home residents' psychotropic drug use was medically appropriate and 8 percent was inappropriate (the remainder was unclear).[44] Despite these positive findings, advocates remain concerned that, faced with increasing difficulties in hiring and retaining staff, nursing homes may use chemical restraints inappropriately as a substitute for maintaining adequate staffing levels.[45] The OIG report does not specifically address the relationship of psychotropic drug use to staffing levels, but at least one facility in the study with low psychotropic drug use had high staffing levels, while at least one facility with high drug use had low staffing levels.[46]

Limits on Unnecessary and Harmful Drug Use — Limits on chemical restraints led naturally into broader regulation of unnecessary and harmful drug use. DHHS now mandates that each nursing home resident's drug regimen be free from unnecessary drugs, with an unnecessary drug defined as "any drug used in excessive dose, for excessive duration, without adequate monitoring or without adequate indications for its use, or in the presence of adverse consequences."[47] In order to ensure appropriate drug dispensing and monitoring, OBRA 1987 requires "pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident."[48]

Over the last ten years, efforts to limit unnecessary and harmful drug use have incorporated the results of emerging clinical research on drug metabolism, side effects, and interactions in geriatric patients. For example, since 1991 a group of clinicians led by Mark Beers, M.D., editor of the *Merck Manual,* has produced a list of drugs to be avoided in elderly patients along with a list of recommended alternatives. DHHS incorporated many of the "Beers' list" recommendations into the drug therapy guidelines issued in its 1999 Survey Procedures and Interpretive Guidelines. The Beers' list recommendations are also included in CMS surveys on unnecessary drug use and in the monthly drug regimen reviews described below. Recent research suggests significant room for improvement in this area—some 50 percent of nursing home residents in a recent AHRQ-funded study were found to have at least one potentially inappropriate medication prescription, defined according to Beers' criteria.[49]

Efforts to Discourage Polypharmacy — Polypharmacy is frequently cited as a serious quality issue facing nursing home residents. Clinical studies have shown that the number of drugs prescribed is correlated with adverse drug events (preventable or nonpreventable events related to the use of medications).[50] A person taking seven medications is about 14 times more likely to have an adverse drug event than a person taking one.[51]

Polypharmacy is frequently cited as a serious quality issue facing nursing home residents.

CMS monitors polypharmacy through the collection of nursing home resident data via its Long-Term Care Minimum Data Set (MDS).[52] Using MDS data, the University of Wisconsin's Center for Health Systems Research and Analysis has developed quality indicators for state surveyors and CMS. In the most recent set of CMS quality indicators, residents who are on more than nine different drugs are flagged for further investigation. Some groups, such as the American Society of Consultant Pharmacists, have characterized the nine-medication flag as arbitrary, stating that it could "compromise residents' ability to receive needed and appropriate medications."[53]

Drug Regimen Reviews by Consultant Pharmacists — To provide a vehicle for monitoring drug safety and facilitating compliance with regulatory requirements, OBRA 1987 included a provision requiring monthly (or more frequent) drug regimen reviews by consultant pharmacists.[54] DHHS regulations have since elaborated on the consultant pharmacist requirement, stipulating that nursing homes "employ or obtain the services of a licensed pharmacist who: (1) provides consultation on all aspects of the provision of pharmacy services in the facility; (2) establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and (3) determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled." The regulations also require the review of each resident's drug regimen at least once a month by a licensed pharmacist; the pharmacist "must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon."[55]

The primary focus of the consultant pharmacist's drug regimen review is to ensure that residents are receiving medications appropriate to their medical diagnoses, their age, and their functional status. Since a number of physicians may be prescribing for any one nursing home resident, consultant pharmacists ensure that the drugs do not have any interactions with each other. Consultant pharmacists make recommendations about resident drug use to the nursing facilities and to residents' physicians.[56] Physicians, however, bear ultimate responsibility for the resident and must decide whether to take the consultant pharmacist's advice.

As mentioned above, New Jersey prohibits nursing homes from using consultant pharmacists affiliated with the nursing home's institutional pharmacy. The requirement for independent consultant pharmacists addresses the potential conflict of interest that exists when consultant pharmacists make recommendations regarding residents' drug regimens.

Disseminating Best Practice Information to Physicians — The last few years have produced a growing body of research regarding the special needs and characteristics of geriatric patients with respect to drug use. An emerging consensus in the clinical literature suggests that, as a result of the natural aging process, elderly patients undergo physiologic changes

New Jersey prohibits nursing homes from using consultant pharmacists affiliated with the nursing home's institutional pharmacy.

that affect drug metabolism, side effects, and interactions. The implication for nursing home residents is that physicians need to be familiar with the differences between elderly patients and their younger counterparts and to adjust their prescribing patterns accordingly.

However, prescribing physicians are not always equipped with the most up-to-date information regarding drug effects in geriatric patients, for several reasons.[57] First, physicians in the nursing home setting may come from several different training backgrounds (for example, internal medicine, psychiatry, dermatology) and may lack specialty training in geriatric medicine.[58] Second, physicians may be either too busy or too inundated by a steady barrage of new information to distill and incorporate new recommendations affecting elderly patients. Third, good research data on elderly patients is still hard to find for even the most common clinical situations—a 2001 report in the *Journal of the American Medical Association* found that while people over 75 accounted for 37 percent of myocardial infarction (heart attack) hospitalizations in 1995, only 13 percent of the total population of all clinical trials for acute coronary syndromes fell within this age group.[59] Finally, physicians may just not know where to look for information; a physician recently interviewed by the *Wall Street Journal* reported that "information about dosing and how certain drugs affect the elderly can be impossible to come by."[60]

Some states are trying to address this problem by conducting outreach initiatives to communicate best practice information to physicians of nursing home residents. In Arkansas, for example, a decision support system tied into the Medicaid claims system identifies physicians whose prescribing patterns deviate from standard guidelines and flags them as candidates for educational programs.[61] The program has achieved limited success, however, due primarily to its voluntary nature and lack of physician interest.[62]

Other Efforts — A number of new quality improvement initiatives have been gaining momentum in tandem with growing public concern over medical error prevention and with growing awareness of the capabilities of health care information technology. Pharmacy automation, for example, can both increase operating efficiencies and improve quality of care by reducing dispensing errors and ensuring that physician orders are accurate.[63] Additionally, robotic packaging in patient-specific unit-dose envelopes can help reduce labor demands while ensuring that residents are receiving the appropriate medications.

CONCLUSION

As policymakers begin to consider a variety of issues surrounding drug therapy, the management of drug costs in the long-term care setting deserves special attention. It is critical to consider the unique elements of the nursing home environment, the alternative arrangements for financing nursing home drug expenditures, the nuanced debate over long-

term care pharmaceutical reimbursement, and evolving initiatives related to quality of care.

As often happens, state policy in this area is changing more rapidly than federal policy, and differences among states provide an opportunity for the identification of best practices. Federal policymakers may find it useful to closely monitor state activities and assess which innovations in payment, quality, and operations may be appropriate for national application to the Medicaid and Medicare programs.

Unfortunately, there is a dearth of data on which to base policy evaluations in this area. Despite the fact that the federal government pays more than half of Medicaid costs, CMS has not systematically analyzed data on which drugs are used by nursing home residents and how much is paid for them. Moreover, not all states have data available that are public or accessible. In the absence of a federal reporting requirement, evaluations of nursing home drug spending on a state-by-state basis will be a critical tool for illuminating the details of this important policy area. More states will likely become interested in such evaluations as they continue in their efforts to control Medicaid pharmaceutical spending.

Finally, nursing home residents stand to benefit from further research on quality, especially with regard to the effects of prescription drugs on geriatric patients. As pharmaceutical therapies continue to emerge rapidly, public programs could serve an important function in collecting, evaluating, and disseminating information to providers. Establishing continuous quality improvement processes in nursing homes would also help to ensure that residents reap the benefits of practice guidelines and other quality improvement initiatives.

ENDNOTES

1 U.S. Census Bureau, "Aging in the Americas into the XXI Century," wallchart, U.S. Department of Commerce; available November 6, 2002, at http://www.census.gov/ipc/www/agingam.html.

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