



The LEWIN GROUP

CMS Review of Current Standards of Practice for Long-Term Care Pharmacy Services

Long-Term Care Pharmacy Primer

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I. INTRODUCTION

The Medicare Modernization Act of 2003 recognizes that beneficiaries who reside in long-term care (LTC) facilities¹ have needs for specialized pharmacy services. Today, approximately 3.5 million Medicare beneficiaries, or just under 10 percent of the Medicare population, reside in a LTC facility. Most are admitted to a nursing facility for management of multiple chronic diseases requiring 24-hour nursing care. These individuals are generally older and frailer than the average beneficiary and on average take 8 to 10 medications per day. The combination of multiple disease states and chronic conditions requires specialized knowledge of the needs of frail elderly by clinicians and pharmacists who need to regularly monitor these beneficiaries for drug interactions and other adverse reactions to medications.

Specialized pharmacy services, including specialized compounding, alternative forms of drug administration, access to a pharmacist 24 hours per day seven days per week, and emergency deliveries of medication, help assure that residents receive timely access to appropriate medication therapies. These services are generally beyond the scope of services provided by retail pharmacies to beneficiaries who reside in the community. In order to meet these special needs, many nursing facilities contract with a long-term care pharmacy (LTCP) to provide prescription drugs and consultant pharmacist services.

Standards of practice in long-term care pharmacy have evolved over several decades in response to a complex set of Federal and state regulations governing the provision of prescription drugs in the LTC setting. While in most cases the regulations do not explicitly prescribe the nature of services to be provided, they drive nursing facility priorities and decision-making, as regulatory violations can result in significant penalties for a facility. As a result, over time the market has settled on a set of customary services that most nursing facilities expect from their pharmacy provider. There is some variation in the range of services that nursing facilities receive, primarily between urban and rural markets, but it is possible to generalize with some confidence about the minimum set of services a nursing facility would need to be compliant with Federal and state regulations.

In today's environment, LTCPs provide many services to nursing facilities at little or no charge. When LTCPs do charge for services, the pricing for services is difficult to determine since services are often bundled together. As a result there is a great deal of uncertainty in the market regarding the cost to LTCPs of providing services or the potential charge structure that would exist in the market if LTCPs were reimbursed directly for the services they provide.

Pharmacies can afford to offer extensive service to nursing facilities at no charge and still achieve acceptable margins because they can acquire and dispense drugs at costs that are substantially lower than their reimbursement rates for Medicaid and Medicare Part A, which cover the majority of nursing facility residents. In addition, to the extent that LTCPs can direct market share to specific drugs, they can also collect rebates from drug manufacturers.

Today, many health plans and pharmacy benefits managers (PBMs) that are potential PDP sponsors have limited experience serving nursing facility residents, as they make up only a

¹ In this paper, we define LTCPs as skilled nursing facilities (SNF) and nursing facilities (NF).

small portion of the commercially insured population. PBMs and private health plans frequently pay LTCs at lower rates for drug acquisition and dispensing than Medicaid, and so LTCs usually do not accept private insurance coverage as payment in full and bill residents for additional charges. Currently, there appear to be few incentives for either LTCs or health plans and PBMs to establish contractual relationships with each other.

However, with the implementation of Medicare Part D, drug coverage for dual eligibles will no longer be provided by Medicaid and will instead be provided through a Prescription Drug Plan (PDP) or a Medicare Advantage plan that offers drug coverage (MA-PD). When this transition occurs, PDPs and MA-PDs will be the source of coverage for the great majority of nursing facility residents. This transition is likely to reshape the industry dynamics, as LTCs may not be able to maintain as large a difference between drug acquisition costs and reimbursement, and may also not be eligible for rebates if the PDP or MA-PD sets the formulary. This raises the question of whether LTCs will be able to continue providing customary services at little or no charge to nursing facilities or payers.

Under Medicare Part D, both PDPs and MA-PDs must assure that all of their enrolled members, including residents of LTC facilities, have access to appropriate and medically necessary drugs. With this in mind, the purpose of this primer is to review:

- the array of services provided by LTCs;
- the regulatory context in which these services are provided; and
- the ways in which LTCs are compensated.

Section II provides a summary of the various Federal and state requirements that influence pharmacy services in the LTC setting. These requirements include Federal conditions of participation in Medicaid and Medicare, state nursing facility licensing regulations and pharmacy regulations, and Medicaid program specifications.

Section III describes the range of specialized services currently provided by LTCs, and how these LTC pharmacy services relate to regulatory requirements. For example, specialized blister packs or other unit dose packaging are used to help avoid medication errors and maintain the integrity of the medication, thereby enhancing the nursing facility's ability to meet its regulatory obligation to provide safe and effective distribution of drugs.

Section IV reviews how LTC pharmacies are compensated for the services they provide. Today, the majority of Medicare beneficiaries residing in nursing facilities receive prescription drug coverage through Medicaid, and we provide a detailed discussion of Medicaid's approach to payment. We also outline approaches to reimbursement by other payers for this population, including Medicare Part A, commercial health plans and PBMs, the Federal Employee Health Benefit Program (FEHBP), and private pay residents.

Section V contains estimated costs of LTC services, and Section VI contains a brief discussion.

We conclude in Section VI with a brief discussion of the issues that arise in assuring smooth implementation of Medicare Part D in the LTC setting.

II. SUMMARY OF FEDERAL AND STATE REGULATIONS

The regulations governing the practice of pharmacy in nursing facilities are designed to protect the health and safety of nursing facility residents. Nursing facility residents have special care needs that in many cases require more intensive medication management and alternative forms of medication administration. Regulations governing pharmacy practice in nursing facilities have evolved over time to ensure that the special needs of nursing facility residents are met. The “conditions of participation” required of nursing facilities accepting Medicare and Medicaid funding mandate that nursing facilities properly order, record, store, administer and monitor medications. As shown in *Figure 1*, these detailed requirements have translated into standards of practice that are integral to the provision of appropriate medication therapy for nursing facility residents.

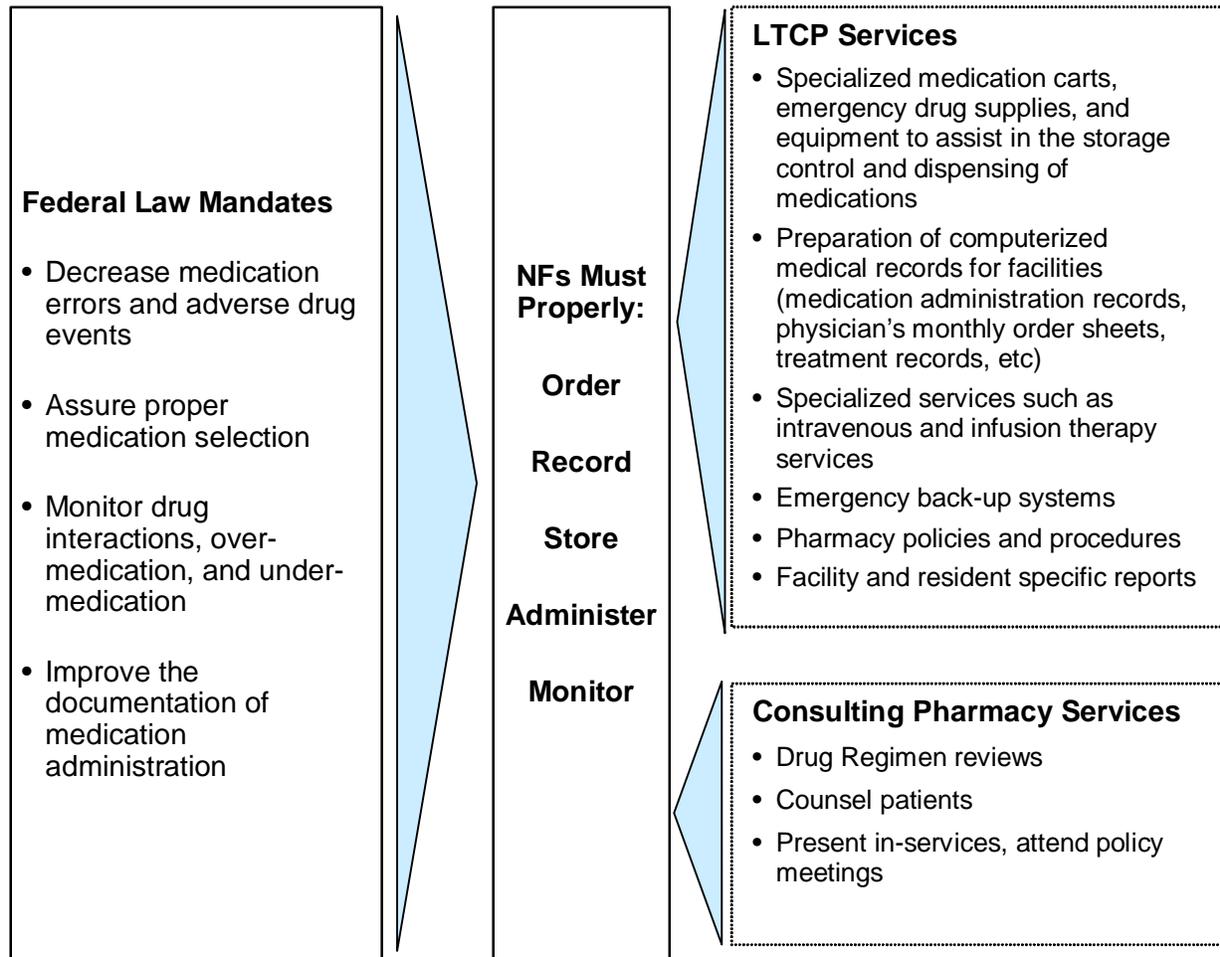
The standards of practice are designed to fulfill Federal mandates to:

- Decrease medication errors and adverse drug events;
- Assure proper medication selection;
- Monitor drug interactions, over-medication, and under-medication; and
- Improve the documentation of medication administration.

At the state level, regulations relate to the licensing of nursing facilities and those professionals working within the nursing facility (e.g., nursing facility administrators, registered nurses).

Federal and state laws and regulations also govern the practice of pharmacy. The Federal government regulates drug products distributed by state-licensed pharmacies. State governments generally establish regulations concerning the requisite credentialing of those who practice pharmacy (e.g., pharmacists, pharmacy technicians) and the licensing of pharmacy practice sites (e.g., hospital pharmacies, long-term care pharmacies, or nuclear pharmacies) where they perform their duties.

Figure 1: Influence of Federal Regulation on LTC Pharmacy



A. Federal Regulation of Nursing Facilities

The Omnibus Budget Reconciliation Act of 1987 (OBRA-87) generated new standards, or conditions of participation, for nursing facilities accepting Medicare and Medicaid funding in the area of quality of care, rights of residents, resident assessment, and quality of life. OBRA-87 and implementing regulations (42 Code of Federal Regulations) also addressed several issues related to pharmacy practice, including drug regimen review and the avoidance of medication errors. The following outlines the key provisions in OBRA-87 related to the practice of pharmacy and the provision of drug therapy in the nursing facility setting:

- **Self-administration of medications.** Residents may self-administer medications if an interdisciplinary team (e.g., attending physician, nurse, resident, and resident's family) has determined that the practice is safe.
- **Unnecessary drugs.** Resident's drug therapy must be free from unnecessary medications, those given in excessive doses, in excessive duration, or without adequate monitoring.

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- **Medication error rate.** Nursing facilities must ensure that the medication error rate does not exceed five percent.
 - **Pharmacy services.** Nursing facilities must provide “routine and emergency drugs and biologicals to its residents.”² The provision of pharmaceutical services includes assurances of accuracy in acquiring, receiving, dispensing, and administering of medications and biologicals for each resident.

In addition, nursing facilities must employ or obtain the services of a licensed pharmacist who: 1) provides *service consultation* on all aspects of the provision of pharmacy services in the facility; 2) establishes a record-keeping system that tracks the receipt and disposition of all controlled substances; and (3) determines that medication records are in order.

At least once per month, a licensed pharmacist must perform a *drug regimen review (DRR)* for each resident. The pharmacist must report any irregularities to the attending physician or director of nursing. Furthermore, these reports must be acted upon.

Nursing facilities must also ensure the proper *labeling and storage of medications and biologicals*. Medications must be labeled according to accepted standards of practice, and include instructions and expiration date when applicable. Medications must also be stored in a locked compartment and only authorized personnel have access to these compartments. In addition, the nursing facility must have a separate locked compartment for controlled substances.

Several years later, the Omnibus Budget Reconciliation Act of 1990 (OBRA-90) was passed. This legislation was intended to lower prescription drug-related costs by improving the quality of medication therapy. OBRA-90 expanded the pharmacist’s role in both the retail and institutional settings by mandating that pharmacists perform prospective drug use review, offer patient counseling, and document patient medication regimen. Although provisions in OBRA-90 were adopted as conditions of participation for the Medicaid program, states subsequently passed pharmacy practice acts that extended these pharmacy services to all consumers. Some important provisions of OBRA-90 are summarized below:

- **Rebates.** Drug manufacturers are required to provide state Medicaid programs with their “best” price.
- **Prospective drug utilization review (DUR).** Pharmacists are required to review recipients’ drug profile before filling their prescription(s). The evaluation of the drug therapy includes: therapeutic duplication; drug-disease contraindications; drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and evidence of clinical abuse/misuse.
- **Patient counseling.** The legislation also requires states to establish standards governing patient counseling. Pharmacists must offer to discuss the recipient’s unique drug therapy regimen after filling prescription(s). In addition, pharmacists should discuss other

² 42 CRF § 43.860

information that is relevant to the recipient's situation. In many states, patient counseling is waived in the institutional pharmacy setting.

- **Maintenance of patient records.** Pharmacists should make reasonable efforts to maintain patient information (e.g., known allergies or adverse drug reactions) and the pharmacists' notes regarding the individual's drug therapy.

B. State Regulation of Nursing Facilities

All states license and regulate nursing facilities by establishing business practices and setting standards for quality and the types of services provided. Each state's Department of Health generally establishes the licensing requirements for nursing facilities. The degree of regulation among the states varies widely. If nursing facilities choose to participate in Medicaid, the State Survey and Certification Agency must certify that the facility has met the Federal conditions of participation. In addition, state licensing requirements may include:

- Administrative requirements (e.g., staff qualifications, clinical records);
- Environmental conditions (e.g., location and physical plan of facility);
- Care of residents (e.g., residents treated with dignity and respect);
- Admissions policy (e.g., defines conditions of admission or expedited admission); and
- Rights of residents (e.g., residents have right to privacy and confidentiality).

Furthermore, personnel working in nursing facilities (e.g., registered nurses) must meet professional licensing standards. For example, nursing facility administrators are licensed and disciplined by the Department of Health (e.g., Alabama) or the Department of Professional and Financial Regulation (e.g., Maine).

C. Federal and State Regulation of the Practice of Pharmacy

Both Federal and state laws and regulations govern the practice of pharmacy. At the Federal level, drug product approvals, labeling, and drug manufacturing standards are under the purview of the Food and Drug Administration (FDA) while the Drug Enforcement Administration (DEA) assures that drugs that are intended for medical use are not diverted to non-medical uses. Pharmacists must comply with rules promulgated by these agencies.

At the state level, regulations governing the practice of pharmacy can be found under the Board of Pharmacy. The state Board of Pharmacy governs the licensing of pharmacists and facilities, and enumerates the rules regarding pharmaceutical care. Generally, the scope of regulation by state Boards of Pharmacy includes:

- Formation, organization, and operation of Pharmacy Board,
- Initial licensing of pharmacists, transfer or renewal of license and registration,
- Licensing of facilities involved in storage, distribution and sale of medications,
- Standards for pharmacy practice sites (e.g., hospital pharmacy, nuclear pharmacy), and

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- Rules regarding pharmaceutical care, which may include facility, personnel, issuance of medication order, labeling, records, storage, patient counseling.

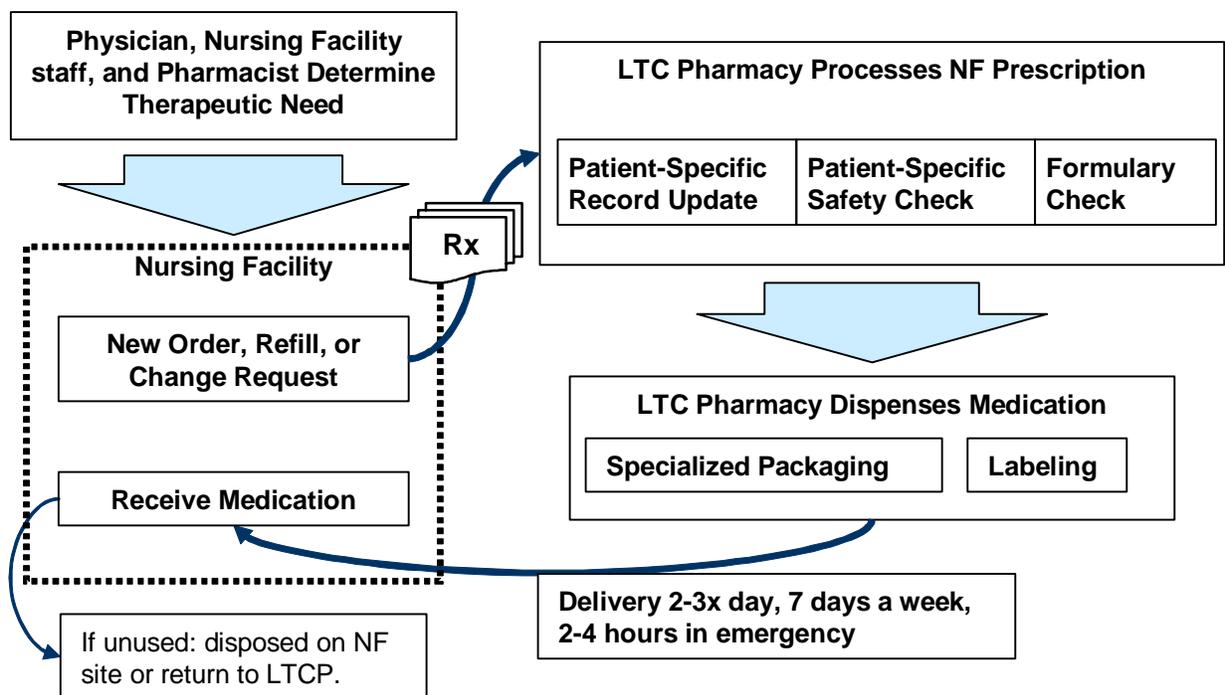
In at least 29 states, LTCPs are regulated under the broader category of institutional pharmacies, which also includes pharmacies in hospitals, penal institutions, or hospices. Some states recognize LTCPs as a distinct type of institutional pharmacy and specify separate requirements for them. Twelve states have regulations that are specific to LTCPs. The remaining states are silent on this issue. However, in most states where separate regulations are detailed in the Board of Pharmacy regulations, LTCPs differ very little from retail pharmacy. Certain issues, such as emergency kits, unit dose packaging recommendations, first-dose inventories, and the role of consultant pharmacists comprise the majority of these specific regulations. The range of detail in the regulations varies as well, from just a brief acknowledgement that LTCPs exist and must comply with already specified regulations, to a detailed accounting of specific functions within an LTCP.

III. STANDARDS OF PRACTICE FOR LONG-TERM CARE PHARMACIES

Services provided by LTCPs have evolved over time in response to the regulations described in Section II. Below, we discuss how LTCPs provide services to nursing facilities at each stage of the drug therapy service delivery process, from the time a physician writes the prescription for a nursing facility resident, through administration of the drug by nursing facility personnel and ultimately, disposal of unused doses (See *Figure 2*):

- Prescription Processing
- Dispensing and Delivery
- Medication Administration
- Ongoing Medication Management
- Return/Re-use and Disposal

Figure 2: Process Map of LTC Pharmacy



Finally, we discuss how regulatory requirements and current market practices work together to create an environment in which nursing facilities prefer to contract with a single LTCP.

The most important services typically provided at each stage of the drug therapy service delivery process are shown in *Figure 3*.

Figure 3: LTC Pharmacy Services

Prescription Processing	Dispensing and Delivery	Medication Administration and Management	Return/Re-Use and Disposal
<ul style="list-style-type: none"> ▪ Create medication record ▪ Clarify, if necessary, medication order ▪ Respond to emergency medication orders ▪ Perform drug utilization review ▪ Apply formulary/ PDL 	<ul style="list-style-type: none"> ▪ Package medications in unit doses ▪ Ensure proper labeling ▪ Provide timely delivery ▪ Maintain emergency kits, interim kits and floor stock 	<ul style="list-style-type: none"> ▪ Perform quality assurance checks ▪ Supply medication carts ▪ Perform Consultant Pharmacist services (e.g., drug regimen review) 	<ul style="list-style-type: none"> ▪ Accept return of unused medications ▪ Assist in disposal of controlled and non-controlled substances

A. Prescription Processing

Commonly, LTCPs work with hospital discharge planners and physicians to establish appropriate medication regimens for incoming residents and obtain prescription orders. Pharmacists in the LTCP make recommendations to eliminate duplicate medication orders and inappropriate medications, and to identify medications that should be discontinued after discharge from hospital. LTCPs also work with state ombudsmen, social workers, family members, and personal physicians to determine appropriate medication regimens.

Prescription orders are transmitted to the LTCP via facsimile.³ After the LTCP receives medication orders, they are reviewed and processed.

Standard Prescriptions. Pharmacists and technicians working on-site at the LTCP update an existing patient record or create a new one. In some cases, the pharmacy must clarify this information with nursing facility personnel or the physician to generate a complete medication record. The computerized recording of prescriptions serves multiple purposes, including tracking actual and potential drug interactions before the actual dispensing of the drug. The pharmacist will also review the chart for any other potential problems that could exist with the prescription. Most state Medicaid programs require on-line DUR for all recipients.

Pharmacists also perform a formulary check prior to filling the order. In states where Medicaid programs have Preferred Drug Lists (see Appendix 2), pharmacists verify whether the prescribed drug is covered by the Medicaid program. If a prescription is dispensed for a non-covered drug, the LTCP is at risk for the cost of the drug and the dispensing fee.

In the case of large pharmacy chains that have their own formularies, the pharmacist may also check the prescription against the LTCP's formulary; if a prescription is written for a non-preferred drug, the pharmacist may contact the physician to suggest a change to the prescription or, in very specific circumstances, the pharmacist may be able to make the change

³ DEA regulations permit faxes of prescriptions for Schedule II controlled substances to serve as the original prescription. A limited number of states however, still prohibit this practice.

without consulting the physician⁴. This formulary check at the pharmacy represents an opportunity to prospectively (before the prescription is dispensed) enhance formulary compliance thereby potentially leading to higher rebates for the pharmacy. Formularies created by LTCPs are developed specifically for the nursing facility population, taking into account the dynamics associated with the process of aging. These formularies are developed collaboratively among a committee of physicians, consultant pharmacists, and other health care professionals who have expertise in geriatrics and geriatric pharmacotherapy.

A critical role of pharmacists is to ensure rational, appropriate and safe medication use through the review of medication therapy and patient history for potential adverse drug reactions. State regulations do not speak to the specifics of how pharmacists and pharmacy staff implement this process, but all states note in their regulations that these activities comprise a core feature of a pharmacist's responsibilities. Regulations generally specify that policies and procedures for monitoring and reporting adverse drug reactions should be developed and that patient information be collected in such a way as to facilitate the drug review process.

Many states explicitly allow pharmacists to perform therapeutically equivalent substitutions (unless a physician explicitly specifies the branded product). In the Medicaid and Board of Pharmacy regulations where substitution is mentioned (e.g., Hawaii), there is often language that encourages generic substitution for cost-saving purposes, and requires the pharmacy to inform patients if a generic version is available.

Refills and Changed Prescriptions. Refills and changed prescriptions are processed in a similar fashion. By the time medications are refilled, a consultant pharmacist has reviewed the resident's initial drug regimen, and the LTCP has a more complete record for the patient. This information further helps the LTCP evaluate whether new prescriptions present potential for medication-related problems or whether modifications to existing medication therapy are necessary or appropriate.

Pharmacy computer systems also monitor the need for a routine schedule of refills that are automatically processed unless the order has been changed or discontinued.

Prescriptions for Controlled Substances. The Federal DEA and state regulatory agencies, including state Boards of Pharmacy, have requirements for dispensing controlled substances. A pharmacist must ensure that the prescription itself complies with the Federal and state regulations that govern dispensing of controlled substances.

Controlled substances used for pain management (Schedule II, III) generally have more stringent requirements than medications in Schedules IV, V due to their high potential for abuse and dependence. In some cases, patients with chronic pain from cancer, HIV/AIDS, extreme cases of arthritis, diabetic neuropathy, and other indications, require regular prescriptions for Schedule II, III controlled substances.

⁴ In states that allow "collaborative practice agreements" it is possible for a pharmacist to change a prescription from one drug to another as long as the agreement specifies that the pharmacist can do so. Where allowed by state regulation, collaborative practice agreements set forth a list of drugs which can be interchanged and substituted by the pharmacist without contacting the doctor. The details of the agreement are between the pharmacist and physician.

To help nursing facilities comply with Federal standards for controlled substance distribution, LTCs prepare separate medication records for controlled substances. This system helps ensure that nursing facilities properly account for administration of controlled substances.

Emergency Prescription Orders. LTCs must be equipped to dispense emergency prescription medications to a resident 24 hours a day. Emergency prescription orders include controlled substance pain medications and specially prepared intravenous antibiotics. LTCs have a pharmacist and pharmacy technician staff on call 24 hours a day to handle such urgent requests.

State regulations generally do not specify a timeframe in which delivery must take place, calling for “timely” delivery of medications. The industry practice for emergency delivery time is approximately two to four hours. LTCs in rural areas and other areas where timely emergency deliveries to nursing facility are not feasible may contract with independent and chain community pharmacies as back-up to handle the dispensing and delivery of emergency medications.

B. Dispensing and Delivery

Medication dispensing refers to the preparation and delivery of a medication or device to a patient (or a patient’s proxy) under a lawful order of a practitioner, in an appropriately labeled container suitable for administration. Dispensing, and in particular the labeling and packaging of medications, is consistent across states, though there are certain areas where state regulations outline dispensing practices in varying levels of detail.

Pharmacy Trained Staff. Pharmacy technicians are trained to perform routine functions in the dispensing of drugs under the supervision of a licensed pharmacist. States generally outline the tasks that pharmacy technicians are not allowed to perform, such as:

- Evaluate the patient’s profile relative to the medication being dispensed,
- Consult the patient concerning the utilization of medications, and
- Interpreting data for the effective drug dosage regimens

Some states specify the number of technicians that can be supervised by a pharmacist. A 1:2 ratio of pharmacist to pharmacy technicians is the most common (e.g., Colorado, Kansas, Mississippi, Nebraska, New Jersey, New York, North Dakota, Oklahoma, South Dakota). This means that one pharmacist may supervise up to two pharmacy technicians. Other states, such as Tennessee, allow more technicians to be supervised per pharmacist if a technician is certified. Wisconsin specifies a 1:5 ratio, with one of the technicians being an intern.

The range in pharmacist to technician ratios across states has different cost and efficiency implications. For example, having a low pharmacist to technician ratio may be more costly, but in a high-volume, high complexity setting, having more licensed pharmacists on hand may be more efficient--there are greater demands for interpretation and dispensing skills that technicians alone cannot undertake.

Specialized Medication Packaging. After the particular medications selected are determined to be appropriate, the LTC uses pharmacy technicians (under the supervision of a licensed

pharmacist) to fill medications using specially packaged administration systems designed to assist the nursing facility in reducing medication administration errors and tracking medication administration. Examples of specialized packaging include blister packages, unit dose systems, and boxes. Although neither Federal nursing facility conditions of participation nor state regulations specify particular forms of packaging, facilities must have a system in place to organize dispensing and reduce medication errors. The standards of practice, however, have evolved to emphasize the use of unit dose systems, particularly in institutional settings.

Labeling. Labeling requirements are standard across states, but are typically reserved for other than unit dose packaging (e.g., vial), as unit dose packaged medications are rendered patient-specific through the use of medication carts and specialized packaging. As a result, medications in unit dose packaging generally have less detailed labels that include the name and address of the facility, date dispensed, name of prescriber, name of patient, directions for use, name and strength of drug and expiration date.

Emergency Kits, Interim/Supplemental Kits, and Floor Stock Medications. Most nursing facilities maintain a stock of medications at the facility for emergency dispensing. DEA permits the storage of controlled substances for this purpose. Most state Boards of Pharmacy permit storage of medications in emergency kits.

Nursing facilities and LTCPs work together to determine what medications are necessary for the emergency kit according to each state's regulatory requirements. The LTCP is responsible for ensuring that the emergency kit is properly stocked. Most kits contain a supply of controlled substance pain medications, oral antibiotics, seizure medications, including benzodiazepines, and other medications necessary to immediately manage emergency situations.

Soon after a drug is used from the emergency kit, the provider pharmacist must be notified, a written prescription must be obtained from a physician, and the dose must be replaced. Seventy-two hours is the most common timeframe within which emergency drug doses must be replenished and their prescriptions documented by a licensed practitioner. The shortest turn-around time is 24-hours or next business day (e.g., Florida, Maine), whereas some states specify only "within a reasonable timeframe" (e.g., Montana, North Dakota, Oregon, Rhode Island, Tennessee, Vermont). See Appendix 1.

Due to restrictions on emergency drugs and the follow-up, documentation, and replacement required with emergency drug kits, many states indicate that they must be provided by only one pharmacy (e.g., Indiana, Iowa, Montana, North Dakota, Rhode Island, South Carolina).

Occasionally a nursing facility needs to be able to provide an immediate dose of medication to a resident either upon arrival or between deliveries. The LTCP provides an interim or supplemental kit containing a small supply of commonly used drugs for immediate use. Similar to the emergency kit, the LTCP and nursing facility determine the contents of these kits, within the guidelines established by the state.

Some states such as Virginia have strict regulations limiting the contents of supplemental dose kits: no more than one Schedule III, IV, V drug in each therapeutic class and no more than five doses of each. Alabama requires that if more than one cabinet is needed in a facility, a request

must be approved by the state's Board of Health. Many states do not impose specific regulations on interim or supplemental kits.

Commonly used over-the-counter medications, such as Tylenol and antacids, are often maintained in the facility as "floor" stock or "house" stock. When nursing facilities purchase floor stock, the pharmacy bills the nursing facility for the product and the facility may or may not be reimbursed for a portion of the cost by the state's Medicaid program through the nursing facility rate, depending on the state's specific policy (See Appendix 4 for state-by-state OTC coverage for selected categories of medications).

Deliveries to Nursing Facilities. After medications are dispensed and packaged at the LTCP, medications are then delivered to the nursing facility. The number of regular deliveries per day varies based on the facility and geographic location, but facilities typically receive two to three regular deliveries per day of new prescriptions and refills. Upon delivery, nursing facility personnel check in the medications and the driver returns a manifest to the LTCP. LTCPs must also have the capacity to deliver emergency medications when ordered. If the LTCP contracts with a back-up community pharmacy, then this pharmacy will also be required to deliver the medications to the nursing facility.

Nursing facilities in all states specify that pharmaceutical services must be responsive to the needs of a resident. "Timely" delivery of drugs is necessary so that a resident's prescribed treatment plan is not disrupted. Oregon is the only state to specifically quantify delivery frequency in its Board of Pharmacy regulations: a provider pharmacy must deliver at least five days per week or deliver medication carts every other day, with service available seven days per week. In most cases, frequency of drug delivery varies by the provider pharmacy and geographic location. Daily deliveries are more prevalent in urban locations, with as many as four scheduled deliveries per day. Rural northern locations (e.g., Wyoming, South Dakota) can usually rely on deliveries five to six times per week, weather permitting.

C. Administration of Medications by Nursing Facility Personnel

Nursing facility personnel administer medications pursuant to the prescription order. The personnel designated to administer medications must be trained by the nursing facility, often with assistance from the LTCP to administer medications.

Quality Assurance. Multiple steps are conducted to ensure that medications received and administered to nursing facility residents are the intended ones. Nursing facility regulations specify that the facility "must develop and implement appropriate policies and procedures for accurate acquiring, receiving, and administering of all medications." Before medications are packed for delivery, a LTCP employee checks that individual contents of a package match the prescription label on the package. Idaho's nursing facility regulations require the pharmacist at facility to coordinate services when more than one supplier of medications is used by the facility. Furthermore, regulations stipulate that emergency drug kits and medicine cabinets must be checked at various intervals (24-hours to 90 days) for outdated or missing drugs.

Medication Carts. Medication carts are most often provided by the LTCP. The carts contain locked, non-removable drawers for each resident's medications. Medication carts are often

equipped with bar coding technology or a manual medication administration record (MAR) that tracks the administration of each medication. Strict regulations surround controlled substances, so that these medications are often kept in a separate drawer with a separate lock and key. Medication carts must be supervised at all times by the nurse administering medications. When medication carts are not in use, they must be stored in a designated locked area with all drawers locked.

D. Ongoing Medication Management

Consultant Pharmacists. The role of consultant pharmacists in nursing facilities has developed beyond the OBRA-87 requirements of performing the Federally mandated DRR, a retrospective review of a patient's medications. DRR is required for each resident of a nursing facility on a monthly basis. Today, most consultant pharmacists are in a nursing facility more often than every 30 days.

Consultant pharmacists review patient charts and visit with residents to monitor their response to therapy in an effort to avoid medication-related problems. Special clinical software programs that contain information regarding drug interactions, disease states, pharmacokinetics, and other critical information aid consultant pharmacists' interventions. In addition, consultant pharmacists provide formulary recommendations as well as educating facility staff on cost-effective therapies to assist in managing the nursing facility's medication costs.

Federal law requires the facility to "act upon" any recommendation made by a consultant pharmacist, including recommendations based on formulary considerations. This provision has been interpreted to mean a simple acknowledgement of the recommendation, placing no responsibility on the nursing facility personnel to accept the recommendation. Nevertheless, the ability of the consultant pharmacist to promote formulary compliance contributes to LTCs' ability to negotiate manufacturer rebates.

The consultant pharmacist logs each visit and a report is maintained both at the pharmacy and in the medical record at the facility. Consultant pharmacists are also involved in the facility's operations and clinical care of residents in other ways, including:

- Development of policies and procedures for medication administration and disposal;
- Performing in-service training activities for facility staff related to medication administration and other aspects of medication therapy;
- Rounding with physicians to examine patients and make recommendations for changes to medication regimens;
- Educating family members, residents, and ombudsmen regarding medication therapy and policies and procedures within the facility; and
- Assisting the facility with compliance with laws and regulations, such as OSHA standards for hazardous chemicals.

The following states represent exceptions to the typical duties of consultant pharmacists listed above:

- Colorado: Consultant pharmacist responsibilities include legal compounding, evaluation of the implementation of policies of the Pharmacy Advisory Committee; and quarterly reports to the Pharmacy Advisory Committee on the status of pharmacy services.
- Idaho: Consultant pharmacist must coordinate services when more than one supplier of medications is utilized by nursing facility.
- Mississippi: Consultant pharmacist must attend Board-approved seminar.
- Oklahoma: Consultant pharmacist must assist with medication destruction and discuss policies and procedures related to destruction of medications with facility staff.

The prevailing regulatory practice in states is to allow a consultant pharmacist employed by the primary pharmacy provider to provide these services. However, nursing facilities generally have separate contracts that outline the activities for pharmacy dispensing services and consultant pharmacy services. New Jersey is the only state that requires the separation of these services in that the consulting pharmacist cannot be in the employ of the dispensing pharmacy.

E. Return/Re-use and Disposal of Unused Medications

As discussed above, there are often occasions when medications are unused. The issue of unused medication has been controversial, and in some states, consensus for a mechanism to dispose of unused medications has been particularly difficult to achieve.

Return and Re-use. Some state Medicaid programs encourage the return and reuse of unused medications except controlled substances. These programs require LTCs to accept returned medications from nursing facilities, credit unused doses back to Medicaid and then return the items to stock. Most policies provide little payment for this service so this tends not to be cost effective for pharmacies.

State regulations vary substantially regarding circumstances in which medications are accepted for return and acceptable scenarios for re-use. In general, states will accept uncontaminated prescriptions (e.g. uncompromised packaging) for reuse if returned from a facility or a controlled environment, such as an automated dispensing system. With a few exceptions (e.g., Washington, Connecticut, Alabama), states have regulations prohibiting the reuse of medications that have left the dispensing facility. At least five states explicitly prohibit the reuse of medications (e.g., Arizona, Kentucky, Mississippi, New Mexico, and Texas). An issue related to return and reuse is whether or not the payer (e.g., institution, patient, government agency) is credited for the returned medication.

The practice of crediting, or reimbursing, a pharmacy for returned prescriptions is addressed in State Medicaid regulations, although these regulations are not always explicit. At least 10 states allow crediting, noted in regulations or permitted as a standard of practice, while at least 12 states prohibit crediting. Still other states, such as the District of Columbia and New York, have no clear standard or regulation on crediting, or allow crediting but do not have any mechanism instituted for the crediting process to occur (e.g., Ohio). In Connecticut, for

example, the regulations explicitly acknowledge that unused medications purchased for one resident in a facility may be used for another resident at no additional cost to the second resident, but the regulation does not permit the medication to be credited to the first resident.

Disposal of Non-Controlled Substances. State regulations contain varying levels of detail on how non-controlled drugs should be destroyed. The specifics of destruction and disposal are not spelled out, but regulations often do note what type of personnel can destroy the drug and how many and what types of witnesses need to be present. An exception is Delaware, which notes that medications should be flushed into the sewage system. In general, there is reference to “disposal in accordance with state and Federal laws.”

Disposal of Controlled Substances. Federal DEA regulations do not permit controlled substances to be removed from the nursing facility for disposal without special approval according to procedures established by regional DEA offices. LTCPs and facilities must submit extensive record keeping for the disposal of controlled substances. Controlled substances can never be returned to the pharmacy for re-use. (See Appendix 1.)

An overarching theme is that controlled substances are more tightly regulated, and so must often be destroyed by a licensed pharmacist or nurse practitioner with another licensed medical staff person as witness. In particular, there are detailed regulations surrounding the storage and packaging of controlled substances. A surprising number of states (17) are silent on the specific process of destruction, however.

LTCPs assist nursing facilities with proper handling, monitoring and disposal of such medications. In certain instances, the LTCP can provide staff to serve as witnesses in the destruction process, or destroy the controlled substances directly. As state regulations do not specify where the personnel must be employed (e.g. nursing facility or LTCP), there are a variety of arrangements between the LTCP and nursing facility that can exist to engage in proper destruction and disposal of controlled substances.

F. Use of a Single Preferred Pharmacy

The regulatory requirements described in Section II, together with current market practices described above, make it advantageous for most nursing facilities to contract with a single LTCP and encourage their residents to obtain all of their prescription drugs through that pharmacy. Nursing facilities report that using a single pharmacy has several advantages, including:

- Improved efficiency of placing orders and receiving deliveries;
- Single point of contact for emergency kits, first-dose kits, and after-hours service; and
- More comprehensive, streamlined maintenance of patient medication history.

Of course, the use of a single pharmacy reduces the ability of a beneficiary to choose his or her preferred vendor, and limits the ability to shop for the best available price. This is not generally a concern for beneficiaries covered by Medicaid, but can be an issue for private pay patients. Generally, nursing facilities discuss this with residents when they are first admitted, and will

support a resident's use of their pharmacy of choice if the pharmacy selected by the resident provides the same labeling and packaging services provided by the facility's primary pharmacy provider. However, discussions with nursing facility administrators and clinical directors indicate that residents almost never exercise this choice, with the exception of residents eligible to receive their medication from the Veteran's Administration (VA) at no cost (in which case they use the VA mail order service for most routine medications).

There are some exceptions to this predominant pattern. We found that in rural areas and in a small number of states -- Arkansas, Kansas, Mississippi, Minnesota, Oklahoma, and Texas -- nursing facilities report working with multiple pharmacies. However, it appears that even in these areas, nursing facilities generally contract with one pharmacy for all of their Medicaid and Medicare Part A patients.

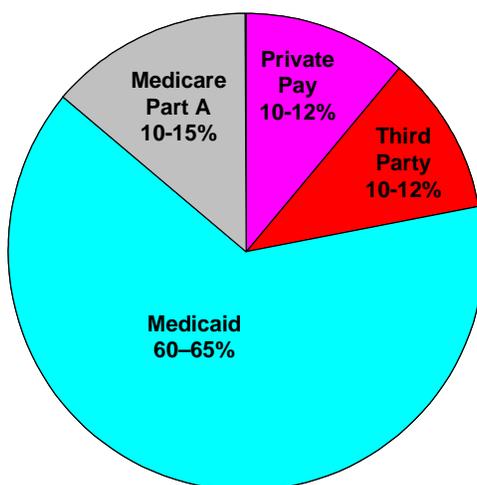
At least 17 states have enacted legislation to assure consumers freedom of choice among all sources of pharmaceutical services, such as the local community pharmacy or mail order facility that best suits their needs (See Appendix 2). Interestingly, however, nursing facilities in states with freedom of choice legislation are not more likely to report that their residents use multiple pharmacies.

IV. LONG-TERM CARE PHARMACY REIMBURSEMENT

In this section, we discuss the ways in which LTCPs are reimbursed for drug ingredient costs, dispensing of medications, and other pharmacy services provided to nursing facilities. We describe differences across payers in their reimbursement methodologies for long-term care pharmacy, provide a state-by-state listing of pharmacy reimbursement rates for Medicaid programs, and explore the different ways long-term care pharmacy services are paid for in today's environment.

In 2002, almost 67 percent of nursing facility residents were Medicaid recipients, 11 percent were Medicare beneficiaries and just over 23 percent of residents were private pay or had some other form of coverage.⁵ This distribution of coverage for nursing facility residents is reflected in estimated sources of revenue to LTCPs. Industry-wide, Medicaid is the biggest payer, accounting for 60 percent to 65 percent of LTCPs' revenue as shown in *Figure 4*. Individual may LTCPs have different revenue mixes, particularly those that serve nursing facilities with higher proportions of private pay or Medicare Part A residents. Reimbursement to LTCPs, services covered and the degree to which LTCPs have the flexibility to negotiate payment varies across payers, as described in the following section.

Figure 4: Estimated Sources of Revenue to LTCPs



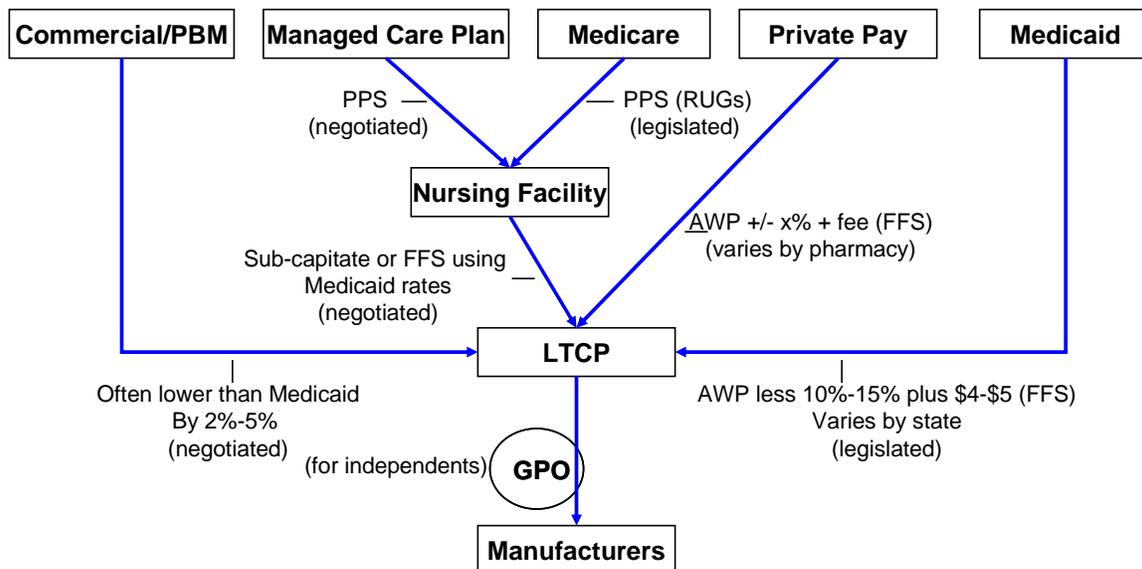
Source: Lewin discussions with LTCPs.

LTCPs are usually reimbursed on a fee-for-service basis for the drugs they dispense to residents in nursing facilities. LTCP reimbursement rates generally cover only ingredient and dispensing costs only, with no additional payment for other services LTCPs provide to nursing facilities. As illustrated in *Figure 5*, Medicaid reimburses LTCPs at legislatively determined rates on a fee-for-service basis. Commercial insurers and PBMs as well as private pay residents also

⁵ Source: Harrington, C. et al., "Nursing Facilities, Staffing, Residents, and Facility Deficiencies, 1996 Through 2002." Department of Social and Behavioral Sciences, University of California. August, 2003.

reimburse LTCPs on a fee-for-service basis. Reimbursement for Medicare Part A residents and residents covered by capitated managed care contracts is often based on fee-for-service Medicaid rates but may be paid on a per diem basis. Self-pay residents typically pay the highest rates in the market and commercial insurers/PBMs tend to pay the lowest rates, in part because LTCPs are able to pass on additional charges for non-covered services directly to residents. A detailed description of reimbursement methodologies and rates for each payer is provided in the following section.

Figure 5: LTCP Reimbursement Methodologies



A. Medicaid

All 50 states offer Medicaid beneficiaries a prescription drug benefit that covers drugs in both ambulatory and institutional settings. Medicaid pharmacy reimbursement rates have an ingredient cost component as well as a dispensing fee component, both of which are based on cost surveys of retail and long-term care pharmacies.⁶ The majority of states use the same reimbursement rate for both retail and long-term care pharmacies, but there are a few states that offer additional reimbursement for LTC pharmacies or services typical to LTC pharmacies such as unit dose packaging, compounding or home infusion therapy. Two states, Rhode Island and South Carolina, pay LTC pharmacies lower dispensing fees than retail pharmacies. Appendix 3 shows state by state Medicaid reimbursement for ingredient costs and dispensing fees and highlights states where reimbursement rates for retail and LTC pharmacies are different.

Medicaid reimbursement rates are important to LTCPs not only because Medicaid accounts for the largest portion of LTCP revenue, but also because Medicaid rates are often used to set a pricing “floor” in the industry, effectively setting the lowest price in the market and thereby guaranteeing minimum reimbursement rates to LTCPs. This practice arises for two reasons.

⁶ In addition to standard reimbursement rates for ingredient costs, states also utilize Federal Upper Limits (FUL), and some states use state-specific Maximum Allowable Cost (MAC), as reimbursement standards for certain generics.

First, LTCPs are concerned that offering nursing facilities rates lower than Medicaid's for non-Medicaid residents could be viewed as an "inducement" to attract Medicaid business and would be in violation of Fraud and Abuse statutes. Second, some Medicaid programs include a "most favored nation" status clause in their contracts that require LTCPs to grant Medicaid the best price in the market; effectively, if a LTCP contracts with a nursing facility for a reimbursement rate below that of Medicaid, it must extend that same price to the Medicaid program.

Ingredient Reimbursement. Rates paid by state Medicaid agencies for ingredient costs vary by state, although there does not appear to be a difference in acquisition costs by pharmacies based on location. Nationally, the average reimbursement for acquisition cost of brand drugs is AWP less 12 percent. States on the high end reimburse at AWP less 5 percent and states on the low end reimburse at AWP less 16 percent. Medicaid is considered by many LTCPs to be the best payer for pharmacies in the reimbursement for ingredient costs.⁷ In a series of reports issued by the Office of the Inspector General (OIG) of the Department of Health and Human Services in 2001 and 2002, the OIG found that Medicaid pharmacy reimbursement rates often substantially exceed pharmacies' actual acquisition cost of prescription drug products.⁸

It is important to recognize that while Medicaid is paying LTCPs on average AWP less 12 percent, the effective price to the Medicaid program is actually lower because of manufacturer rebates due to Medicaid programs as a result of Medicaid "best price" provisions. Under the Federal Medicaid "best price" rule, manufacturers provide Medicaid programs a rebate amount equal to 15.1 percent of average manufacturer price (AMP) or the difference between AMP and the best price offered to any customer, whichever is higher⁹.

Dispensing Fees. According to a national accounting firm that has assisted 19 state Medicaid programs in determining pharmacy dispensing costs and setting reimbursement rates, state Medicaid programs view the drug benefit as a strictly *outpatient* benefit and consider only the labor and overhead required to fill an individual's prescription and the cost of delivery to be "allowable" costs for setting the state dispensing rate. States show variation in dispensing fees with a range of \$1.75 to \$5.77, with Alaska paying up to \$11.46 based on specific definitions and formulas¹⁰. Variable costs such as salaries, rent or mortgage and taxes may drive state variation in dispensing fees.¹¹ However, it is difficult to determine if state variations in such costs account for the differences between states. In addition to the standard dispensing fee, a few states pay

⁷ In conversations with state Medicaid agencies, long-term care pharmacies and nursing facilities, it was reported Medicaid is considered the best payer in the pharmacy business.

⁸ "Medicaid Pharmacy - Actual Acquisition Cost of Brand Name Prescription Drug Products" (A-06-00-00023) dated August 10, 2001 and "Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products" (A-06-01-00053) dated March 14, 2002 and "Medicaid Pharmacy - Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products (A-06-02-00041) dated September 16, 2002.

⁹ The best price due to Medicaid is the lowest price available to "any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States" excluding certain entities such as VA, DOD and PHS and IHS.

¹⁰ In a discussion with a major nursing facility chain, it was reported that California has recently revised its reimbursement methodology to \$8.25 for dispensing and AWP-17 percent for ingredients. Lewin has not confirmed this information with state officials.

¹¹ Staffing costs play an important role in the cost of dispensing services. Pharmacy staffing costs may vary significantly by state. For example California has one of the highest pharmacist salary cost in the nation, estimated at \$93,610 as of Nov 2003 compared to a national average of \$81,180 (Bureau of Labor Statistics).

an additional amount for unit dose packaging or specialized therapies (Idaho, Maine, Maryland, Minnesota and South Dakota).

Nursing Facility vs. Pharmacy Rates. LTC pharmacies provide a wide range of services to nursing facilities, including traditional dispensing services along with additional services to ensure safe and effective medication administration within the facility. Medicaid programs define the costs of these services as allowable under either pharmacy reimbursement or nursing facility reimbursement. Pharmacists' time filling an individual's prescription is considered allowable cost under *pharmacy* reimbursement and is considered when determining dispensing rates. Medication administration services are considered allowable costs under *nursing facility* reimbursement rather than *pharmacy* reimbursement and are considered when determining nursing facility rates. For example, medication carts are often supplied by LTCPs to nursing facilities to enhance the nursing facility's ability to comply with state and Federal regulations and simplify the workload of nursing facility staff. States almost always consider this service to be medication administration and the cost to be associated with the nursing facility. See *Figure 6* for the list of services that are technically covered under the pharmacy rate versus the nursing facility rate.

In practice, although states would allow nursing facilities to bill many of the LTCP services as nursing facility costs, most facilities receive these services from LTCPs at no charge and therefore do not have any associated costs to include in their cost reports.

Currently in the LTC pharmacy industry it is customary for LTCPs to compete for nursing facility business by offering high levels of service at little or no charge to nursing facilities. LTCPs are able to offer many medication administration services at no additional charge because the Medicaid pharmacy reimbursement rates are high enough to cover the cost of these services. In essence, states are cross-subsidizing the cost of medication administration services through ingredient and dispensing rates rather than paying them directly through nursing facility rates.

Figure 6: Medicaid Reimbursement -- Pharmacy vs. Nursing Facility Rates

Ingredient Cost	AWP – X%	Pharmacy Rate
Dispensing	Specialized packaging (labor and overhead)*	
	Medication delivery	
Medication Administration	LTCP Services Specialized medication carts, emergency drug supplies, and equipment to assist in the storage control and dispensing of medications	Nursing Facility Rate
	Preparation of computerized medical records for facilities (medication administration records, physician’s monthly order sheets, treatment records, etc)	
	Specialized services such as intravenous and infusion therapy services*	
	Emergency back-up systems	
	Pharmacy policies and procedures	
	Facility and resident specific reports	
	Consultant Pharmacy Services	
	Drug Regimen reviews	
	Counsel patients	
	Present in-services, attend policy meetings	

*Some Medicaid dispensing rates include additional fees for unit dose, compounding or infusion therapy.

Coverage of Over-the-Counter (OTC) Prescriptions. Medicaid rules permit states to reimburse for over-the-counter (OTC) prescriptions. States must offer over-the-counter coverage for children covered through the Early Periodic Screening Diagnosis and Treatment (EPSDT) program, but are allowed to require a physician’s prescription as proof of medical necessity. For adults, states have broad latitude in whether or how to cover OTCs. According to a 2003 survey conducted by the Kaiser Commission for Medicaid and the Uninsured, 39 of 43 states surveyed covered some OTCs in their prescription drug program.

States including OTC coverage in their Medicaid prescription drug program typically do so through the pharmacy benefit for both community and institutional beneficiaries. As shown in Appendix 4, the specific types of OTCs covered through the pharmacy benefit vary by state. When a nursing facility resident needs non-covered OTCs or when a state does not cover OTCs in the outpatient prescription drug program, it may allow the facility to include the cost of the non-covered OTCs in their nursing facility cost reports.

Specific policies regarding inclusion of OTCs in the nursing facility rate also vary by state. For example, in Texas, if a physician writes a prescription for an allowable OTC for any Medicaid beneficiary, including those residing in nursing facilities, the dispensing and acquisition costs are reimbursed through the pharmacy program. Incidental OTCs are allowable costs for the nursing facility cost report, but this is a nominal amount. However, Nebraska covers OTCs in

the pharmacy benefit but not in the nursing facility rate while North Carolina allows OTCs in the nursing facility rate but does not cover OTCs in their pharmacy benefit. And in Wisconsin, OTC analgesics and medically necessary non-covered OTCs are included in the facility rate, while covered OTCs are billed directly to Medicaid by the pharmacy.

In practice, nursing facilities have two incentives for having OTCs covered through the drug benefit whenever possible. Quality of care is better protected when a physician prescribes the OTC drug, taking into consideration possible drug interactions or dosage requirements specific to the patient, particularly for the frail elderly population. Financially, direct billing to the Medicaid pharmacy program for the drug removes any possibility of the nursing facility having to absorb some portion of the cost of the acquisition or dispensing of the drug.

B. Medicare Part A

Medicare pays for a portion of skilled nursing facility care for up to 100 days per benefit period under the Part A benefit. Medicare uses a prospective payment system to reimburse nursing facilities a Federally determined all-inclusive rate based on Resource Utilization Groups (RUGS). The nursing facility contracts with an LTCP to provide medications and services for Medicare Part A residents using one of two basic reimbursement structures. The most common contractual arrangement is a fee-for-service reimbursement rate that is the same as the Medicaid rate in that state. In some cases LTCPs will contract for a “usual and customary” rate though this is relatively unusual. The alternative reimbursement structure found in the market is a negotiated per diem rate that allows nursing facilities to shift some portion of the risk for Medicare Part A residents to LTCPs. Typically there are exclusions for certain expensive drugs, risk bands and “true ups”¹² that limit the risk the LTCP actually bears and brings the per diem rates closely in line with Medicaid rates. On the whole, LTCPs prefer fee-for-service reimbursement based on Medicaid rates and the industry appears to be moving away from per diems.

C. Commercial Insurers/PBMs

Health plans typically have only minimal involvement in the area of LTC pharmacy. For those third party payers that do provide some LTC pharmacy coverage, reimbursement to LTCPs is similar to retail reimbursement rates, generally in the neighborhood of AWP less 14 percent-20 percent for brand drugs. PBMs or health plans may contract directly with LTCPs, though LTCPs often refuse to accept their payment terms. If there is a dominant health plan in the market, LTCPs may agree to contract but will try to negotiate more favorable terms. In some cases LTCPs may accept the lower reimbursement rate and will then bill the patient or nursing facility additional fees to cover the cost of dispensing, delivery, maintenance of computerized medical records, etc.

Alternatively, some health plans contract directly with nursing facilities on an all-inclusive capitated basis much like Medicare does for Part A beneficiaries. As with Part A residents,

¹² LTCPs perform a “true up” at the end of a period to compare the per diem rate to an estimated Medicaid payment for the medications dispensed and will adjust the per diem accordingly in the following month.

nursing facilities typically contract with LTCPs for fee-for-service reimbursement based on Medicaid rates. Medicare Advantage plans may elect to adopt either of these payment approaches for long-term care pharmacy.

The Federal Employees Plan (FEP) offered by Blue Cross-Blue Shield stands out as an exception to the rule that health plans do not get involved in LTC pharmacy. FEP does have a network of LTCPs, with approximately 760 participating LTCPs. Reimbursement rates to LTCPs are higher than to retail pharmacies and may be as high as Medicaid reimbursement rates though are usually below Medicaid rates. The reimbursement rate is expected to cover the cost of the medication, dispensing and additional services such as delivery and medication administration records. LTCPs can but generally do not charge residents for additional services such as consultant pharmacy services. FEP does not provide coverage to members if their LTCP is not in-network.

D. Private Pay

Charges for private pay patients vary widely across LTCPs. Residents can be charged rates ranging from Medicaid rates to AWP plus 5percent. Private pay patients may be billed separately for services such as emergency delivery (approximately \$150 per emergency delivery) and a bundled fee for additional services provided by the LTCP (this can vary from \$2.50 - \$25 per month depending on the level of service the patient requires).

V. ESTIMATED COST OF LTCP SERVICES

Payment from Medicaid, third party payers and nursing facilities includes a reimbursement amount for ingredient cost and a dispensing fee but no explicit payment for other services. Lewin conversations with industry observers and LTCPs indicate that LTCPs usually charge nursing facilities a small fee for consultant pharmacy services and occasionally charge for maintaining medical records, but provide a number of other services at no additional charge to LTCPs. *Figure 7* below lists the services most often provided by LTCPs, together with information about how much nursing facilities are typically charged for the services (if at all) and an estimate of the cost to LTCPs of providing these services. *Figure 7* also indicates where state regulation or local custom dictates that the LTCP can or must charge at least a nominal fee for services.

Figure 7: Cost of Providing LTC Pharmacy Services

Service	Fee Charged* (Monthly, 100 bed facility)	Cost to Provide* (Monthly, 100 bed facility)
Specialized packaging	None	\$1,000 - \$2,000 ¹
Medication delivery	None	\$1,000 - \$3,500
Medication and treatment carts	None	\$150 - \$300
Emergency back up system	None	\$50 ²
Medical records	Often none or \$200 - \$500	\$400 - \$500 ³
Fax machines	None	\$50-\$80
Drug Regimen reviews	\$400-\$1,000	\$500 - \$1,500
Facility and resident specific reports		
Counsel patients		
Present in-services, attend policy meetings		
Med pass observation		
On-call, 24 hour pharmacist		
Disposal of controlled substances		
Total		

Source: Charges for services and estimated costs based on Lewin Group conversations with national chain and independent long-term care pharmacies.

¹ Iowa regulations require pharmacies to charge for medication and treatment carts.

² Cost of inventory is \$1,000, cost of capital estimated at 5%.

³ California, Pennsylvania and Texas require pharmacies to charge for medical records.

The estimates in *Figure 7* indicate that the cost to LTCPs of providing dispensing and medication administration services ranges from approximately \$3 to \$8 per prescription, while current payment for these services ranges from \$0.60 to \$1.50 per prescription, if we assume that

residents use 10 prescriptions per month. Put another way, these costs probably represent from 5-10 percent of the pharmacy's cost to acquire the drug, net of rebates.

To illustrate the relationship of these costs to total reimbursement, *Figure 8* below shows the difference between the acquisition price for a hypothetical single source brand name drug and Medicaid reimbursement rate. In this illustration, the LTCP is able to acquire the drug for \$83 and to obtain a manufacturer rebate of \$5, for a net cost of \$78. Assuming that the LTCP was reimbursed at average Medicaid rates, it would be paid \$99 for the drug, yielding a \$21 margin to cover operating costs, including the \$3 to \$8 estimated cost of services described above. The lions' share of LTCPs' margins appears to come from the difference between the cost of acquiring and dispensing the drug and the amount that LTCPs are reimbursed. For some LTCPs, drug manufacturer rebates also contribute to their margins.

Figure 8: Relationship of Acquisition Cost to Reimbursement

AWP	\$ 107
Acquisition Cost (AWP - 22%)	\$ 83
Rebate (5% AWP)	5
Net Cost	\$ 78
Medicaid Reimbursement	\$ 99
Spread per script	\$ 21
Cost of Services	\$ 6
Payment for Services	\$ 1
Net Cost of Services	\$ 5

VI. DISCUSSION

Integrating the new Medicare Part D drug benefit into the long-term care setting is likely to create a number of challenges for LTCs, nursing facilities, and PDPs. Today's reimbursement environment, which makes it financially viable for LTCs not to charge nursing facilities for many services, creates a set of "hidden" costs that are effectively cross-subsidized by generous reimbursement for ingredient cost and dispensing fees. In practice, Medicaid reimbursement rates on ingredient and dispensing combined with manufacturer rebates (for national chain LTCs) more than cover the cost of the high level of service provided by LTCs.

Under Part D, reimbursement for many nursing facility beneficiaries will shift from state Medicaid programs, which currently have generous reimbursement rates, to private PDPs and MA-PDs which may reimburse at lower rates similar to third party payers today. In addition, nursing facilities may find that their residents are enrolled in a number of different PDPs or MA-PDs, each of which may have different formularies, policies and procedures.

While it is unclear how these changes in reimbursement will affect industry dynamics, a number of questions emerge:

- Will reimbursement rates from PDPs be sufficient to maintain the current business practice of providing medication management-related services at no additional cost to nursing facilities? If not, how will the market respond?
- How will the need to coordinate with multiple PDPs and MA-PDs affect operating procedures for nursing facilities, consultant pharmacists, and LTCs?
- How can differences in coverage, such as reimbursement for OTCs and excluded drugs, be managed so as to ensure a smooth transition from Medicaid coverage to Medicare Part D for dual eligible beneficiaries?

Appendix 1. Features of LTCP Practice

State	Specific Emergency Kit Regulation	Specific Medication Destruction Regulation	Allows Rx Return	Allows Rx Re-Use
Alabama	X	X	X	X
Alaska	X	X	X*	--
Arizona	X	--	X*	--
Arkansas	X	--	--	--
California	X	X	X	X
Colorado	X	--	X	X
Connecticut	X	--	X	X
Delaware	X	X	X	X
District of Columbia	--	--	--	--
Florida	X	X	X	X
Georgia	X	X	X*	X*
Hawaii	X	X	X*	X*
Idaho	X	X	X	X
Illinois	X	X	X	X
Indiana	X	X	X	X
Iowa	X	X	X	X
Kansas	X	X	X	X
Kentucky	X	--	X	X
Louisiana	X	X	X	X
Maine	X	X	X	X
Maryland	X	--	X	X
Massachusetts	X	X	X	
Michigan	X	X	X	X
Minnesota	X	X	--	--
Mississippi	X	X	--	--
Missouri	X	--	X*	X*
Montana	X	--	X*	X*
Nebraska	X	X	X	X
Nevada	X	--	X	X*
New Hampshire	X	--	X	X
New Jersey	X	X	X	X
New Mexico	--	--	X	
New York	X	--	X	X
North Carolina	X	--	X	X
North Dakota	X	X	X	X
Ohio	--	--	X	X
Oklahoma	X	X		
Oregon	X	X	X*	X*
Pennsylvania	X	--	X	X

State	Specific Emergency Kit Regulation	Specific Medication Destruction Regulation	Allows Rx Return	Allows Rx Re-Use
Rhode Island	X	X	X	X
South Carolina	X	X	X	X
South Dakota	X	X	X	X
Tennessee	X	X	--	--
Texas	X	--		X
Utah	X	X	X	X
Vermont	X	--	X	X
Virginia	X	X	X	X
Washington	X	X	X	X
West Virginia	X	X	X	X
Wisconsin	X	X	X	X
Wyoming	X	X	X	X

Notes:

* Returns or re-use only for institutional facilities.

-- Indicates that no information found in state regulations.

Appendix 2: Infrastructural/System of Care

State	Freedom of Choice	Separate LTC or Institutional Pharmacy Regulations	Preferred Drug Lists	Pharmacist: Tech Ratio	Collaborative Practice Agreement
Alabama	X	Inst.	X	1:2	
Alaska		Inst.	X	--	X
Arizona		LTCP	X*	--	X
Arkansas		LTCP		1:2	X
California		Inst.	X	1:2	X
Colorado			X	1:2	
Connecticut			Pending	1:2	X
Delaware	X	LTCP		--	
District of Columbia			X	--	
Florida	X	Inst.	X	1:3	X
Georgia		LTCP	X	1:2	X
Hawaii		Inst.	Pending	--	X
Idaho	X	Inst.	X	1:2	X
Illinois		LTCP	X	--	X
Indiana	X	Inst.	X	1:4	X
Iowa	X	LTCP	X	--	X
Kansas		Inst.	X	1:2	X
Kentucky		Inst.	X	--	X
Louisiana		Inst.	X	1:2	X
Maine			X	1:3	X
Maryland		Inst.	X	--	X
Massachusetts		Inst.	X	1:2	
Michigan		Inst.	X	--	X
Minnesota			Pending	1:2	X
Mississippi		Inst.	Pending	1:2	X
Missouri		LTCP	X	--	
Montana	X	Inst.	X	1:1	X
Nebraska				1:3**	X
Nevada		Inst.	Pending	1:1	X
New Hampshire		Inst.	Pending	--	
New Jersey	X	Inst.		1:2	X
New Mexico		LTCP	Pending	1:2	X
New York			Pending	1:2	
North Carolina		Inst.	Pending	1:2	X
North Dakota	X	LTCP		1:2	X
Ohio		Inst.	X	--	X
Oklahoma			X	1:2	
Oregon	X	Inst.	X	1:3	X
Pennsylvania	X	Inst.	Pending	--	X
Rhode Island		LTCP		--	X
South Carolina		Inst.	Pending	1:3	X
South Dakota	X	Inst.	Pending	1:2	X
Tennessee	X	Inst.	X	1:3**	X

State	Freedom of Choice	Separate LTC or Institutional Pharmacy Regulations	Preferred Drug Lists	Pharmacist: Tech Ratio	Collaborative Practice Agreement
Texas	X		X	--	X
Utah		Inst.	Pending	1:3**	X
Vermont		Inst.	X	--	X
Virginia	X	LTCP	X	1:3**	X
Washington		LTCP	X	1:3	X
West Virginia	X	Inst.	X	1:4	
Wisconsin			X	1:5**	X
Wyoming	X	Inst.	Pending	1:3	X

Source: Lewin analysis of state Board of Pharmacy and other regulation. Information on Medicaid PDLs from Kaiser Commission on Medicaid and the Uninsured (*Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey, 2003*).

* For managed care plans

** Special requirements

Appendix 3: Medicaid Pharmacy Reimbursement Rates

State	Ingredient Cost		Dispensing Fee	
	Retail	LTC/Institutional	Retail	LTC/Institutional
Alabama	WAC+9.2% then AWP-10%		\$5.40	
Alaska	AWP-5%		\$3.45-\$11.46 (based on pharmacy/Medicaid volume)	
Arizona	Set by MCO		Set by MCO	
Arkansas*	AWP-20% (generic); AWP-14% (brand)		\$5.51 (brand); \$7.51 (generic)	
California	AWP-10%		\$4.05	
Colorado* ¹	AWP-35% (generic); AWP-13.5% (brand)		\$4.00	
Connecticut*	AWP-40% (generic); AWP-12% (brand)		\$3.15	
Delaware	AWP-14%	AWP-16%	\$3.65	
DC	AWP-10%		\$4.50	
Florida*	Lower of AWP-13.25% or WAC+7%		\$4.23	
Georgia	AWP-10%		\$4.63 brand & for profit, \$4.33 brand & non profit, \$5.13 generic & for profit, \$4.63 generic & non profit	
Hawaii	AWP-10.5%		\$4.67	
Idaho	AWP-12%		\$4.94 and \$5.54 unit dose	
Illinois	AWP-25% generic; AWP-12% brand		\$4.60 generic; \$3.40 brand	
Indiana	AWP-20% generic; AWP-13.5% brand		\$4.90	
Iowa	AWP-12%		\$4.26	
Kansas*	AWP-27% generic; AWP-13% single source		\$3.40	
Kentucky	AWP-12%		\$4.51	
Louisiana	AWP-13.5%, AWP-15% for chains		\$5.77	

State	Ingredient Cost		Dispensing Fee	
	Retail	LTC/Institutional	Retail	LTC/Institutional
Maine	AWP-15%; direct supply drug list - UCR or AWP-17% plus \$3.35 professional fee or FUL or MAC plus \$3.35 professional fee (Mail order lowest of UCR, AWP-20% plus \$1.00 professional fee for exceptions see State plan, FUL or MAC plus \$1.00 professional fee		\$3.35, \$4.35 & \$5.35 (compounding); \$12.50 (insulin syringe)	
Maryland*	Lower of AWP-12% or WAC +8%, direct price +8% or distributor price when available		\$3.69 generic; \$2.69 brand	\$4.69 generic; \$3.69 brand; \$7.25 home IV therapy
Massachusetts	WAC +6%		\$3.50 single source; \$5 multi source	
Michigan* ²	AWP-13.5% independent; AWP-15.1% chain		\$2.50	\$2.75
Minnesota*	AWP-11%		\$3.65; additional \$.30 for unit dose	
Mississippi	AWP-12%		\$3.91; reasonable for OTC	
Missouri	Lower of AWP-10.43% or WAC + 10%		\$4.09	
Montana	AWP-15%		\$4.70	
Nebraska* ³	AWP-11%		\$3.27-\$5.00 (average \$4.66)	
Nevada	AWP-15%		\$4.76	
New Hampshire*	AWP-16%		\$1.75	
New Jersey*	AWP-12.5%		\$3.73-\$4.07	\$.59 per census day
New Mexico	AWP-14%		\$3.65	
New York	AWP-12%	Paid via nursing facility rate	\$4.50 generic; \$3.50 brand	Paid via nursing home rate
North Carolina	AWP-10%		\$5.60 generic; \$4.00 brand	
North Dakota	AWP-10%		\$5.60 generic; \$4.60 brand	
Ohio	Lower of WAC+9% or AWP-12.8%		\$3.70	
Oklahoma	AWP-12%		\$4.15	
Oregon*	AWP-15%	AWP-11%	\$3.50	\$3.91
Pennsylvania	AWP-10%		\$4.00	

State	Ingredient Cost		Dispensing Fee	
	Retail	LTC/Institutional	Retail	LTC/Institutional
Rhode Island*	WAC+5%		\$3.40	\$2.85
South Carolina	AWP-10%		\$4.05	\$3.15
South Dakota	AWP-10.5%		\$4.75, \$5.55 for unit dose	
Tennessee	AWP-13%			\$2.50 (long-term care dual eligible); \$5.00 NH only if 28 days +
Texas	Lower of AWP-12% or WAC+12%		\$5.14	
Utah	AWP-15%		\$3.90 urban, \$4.40 rural	
Vermont	AWP-11.9%		\$4.25	
Virginia*	AWP-10.25%, AWP-25% for hemophilia drugs		\$3.75	
Washington	AWP-14% (single and multi source w/2-4 manufacturers), AWP-50% (multi source from 5+ manufacturers), AWP-19% brand-mail order, AWP-15% generic mail order		\$4.20-\$5.20 based on 3-tiered pharmacy volume; \$3.25 mail order	
West Virginia	AWP-12%		\$3.90 plus \$1.00 compounding	
Wisconsin*	AWP-13%		\$4.88, \$4.38 for legend drugs	
Wyoming	AWP-11%		\$5.00	

Note: Figures in **bold** indicate different reimbursement for retail vs. LTC/institutional pharmacies. Data was compared in the CMS Medicaid Prescription Reimbursement by State--Qtr Ending September 2004 and the Kaiser Commission on Medicaid and the Uninsured, Medicaid Benefits as of January 2003. State Medicaid programs were contacted when clarification or additional information was needed. Discussions with state Medicaid officials are noted (*).

1. Colorado pays a dispensing fee of \$1.89 to hospitals.
2. New dispensing fees effective November 1, 2004, separates retail and long-term care. Prior to 11/1/04, the dispensing fee was \$3.77 for both.
3. Dispensing range based on services the pharmacy provides (hours of service, delivery service, charge accounts, medication management programs) and its location (urban, rural).

Appendix 4: Medicaid Coverage of Over-the-the Counter Medications

State	Allergy, Asthma, and Sinus	Analgesics	Cough and Cold	Smoking Deterrents
Alabama	Covered	Covered	Covered	Not Covered
Alaska	Not Covered	Not Covered	Not Covered	Not Covered
Arizona*	-	-	-	-
Arkansas	Limited Coverage	Limited Coverage	Limited Coverage	Not Covered
California	Limited Coverage	Limited Coverage	Limited Coverage	Covered w/Restrictions
Colorado	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions
Connecticut	Covered	Not Covered	Covered	Not Covered
Delaware	Covered	Covered	Covered	Covered
District of Columbia	Not Covered	Covered w/Restrictions	Not Covered	Not Covered
Florida	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions	Not Covered
Georgia	Not Covered	Covered w/Restrictions	Covered w/Restrictions	Not Covered
Hawaii	Covered	Covered	Limited Coverage	Covered w/Restrictions
Idaho	Not Covered	Not Covered	Not Covered	Not Covered
Illinois	PA Required	Covered	Not Covered	Covered
Indiana	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions
Iowa	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions	Not Covered
Kansas	Not Covered	Covered	Limited Coverage	Covered w/Restrictions
Kentucky	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions	Not Covered
Louisiana	Not Covered	Not Covered	Not Covered	Not Covered
Maine	Covered	Covered	Not Covered	Covered w/Restrictions
Maryland	Not Covered	Not Covered	Not Covered	Not Covered
Massachusetts	Limited Coverage	Limited Coverage	Limited Coverage	Not Covered
Michigan	Limited Coverage	Limited Coverage	Not Covered	Limited Coverage
Minnesota	Limited Coverage	Limited Coverage	Limited Coverage	Covered
Mississippi	Limited Coverage	Limited Coverage	Limited Coverage	Limited Coverage
Missouri	Limited Coverage	Limited Coverage	Limited Coverage	Not Covered
Montana	Covered w/Restrictions	Covered w/Restrictions	Not Covered	Covered w/Restrictions
Nebraska	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions	Not Covered
Nevada	Covered	Covered	Covered	Covered
New Hampshire	Covered	Covered	Covered	Covered
New Jersey	Covered	Covered	Limited Coverage	Limited Coverage
New Mexico	Covered	Covered	Covered	Covered
New York	Limited Coverage	Limited Coverage	Limited Coverage	Limited Coverage
North Carolina	Covered	Limited Coverage	Limited Coverage	Not Covered
North Dakota	Covered w/Restrictions	Covered	Not Covered	Covered w/Restrictions
Ohio	Selective Coverage	Selective Coverage	Selective Coverage	Selective Coverage
Oklahoma	Limited Coverage	Not Covered	Not Covered	Covered w/Restrictions
Oregon	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions
Pennsylvania	Covered w/Restrictions	Covered	Covered w/Restrictions	Covered
Rhode Island	Covered	Covered w/Restrictions	Covered w/Restrictions	Not Covered
South Carolina	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions	Not Covered
South Dakota	Not Covered	Not Covered	Not Covered	Not Covered
Tennessee*	Covered	Covered	Not Covered	Not Covered
Texas	Covered	Covered	Covered	Covered
Utah	Limited Coverage	Limited Coverage	Limited Coverage	Not Covered
Vermont	PA Required	PA Required	PA Required	PA Required
Virginia	Covered	Covered	Covered	Covered
Washington	Limited Coverage	Limited Coverage	Limited Coverage	Not Covered
West Virginia	Limited Coverage	Limited Coverage	Limited Coverage	PA Required
Wisconsin	Covered w/Restrictions	Covered	Covered w/Restrictions	Not Covered
Wyoming	Covered	Covered	Covered	Not Covered

*Within Federal and State guidelines, individual managed care and pharmacy benefit management organizations make formulary/drug decisions.

PA= Prior Authorization

Source: Pharmaceutical Benefits Under State Medical Assistance Programs 2003, National Pharmaceutical Council.

Medicaid Coverage of Over-the-the Counter Medications (continued)

State	Digestive Products		Feminine Products	Topical Products
	(non- H2 antagonists)	H2 Antagonists		
Alabama	Covered	Covered	Not Covered	Covered w/Restrictions
Alaska	Not Covered	Not Covered	Limited Coverage	Limited Coverage
Arizona*	-	-	-	-
Arkansas	Limited Coverage	Covered	Limited Coverage	Limited Coverage
California	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions
Colorado	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions
Connecticut	Covered w/Restrictions	Covered w/Restrictions	Not Covered	Covered
Delaware	Covered	Covered	Not Covered	Covered
District of Columbia	Covered w/Restrictions	Not Covered	Not Covered	Not Covered
Florida	Not Covered	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions
Georgia	Not Covered	Not Covered	Not Covered	Not Covered
Hawaii	Covered	Limited Coverage	N/A	Limited Coverage
Idaho	Not Covered	Not Covered	Not Covered	Not Covered
Illinois	PA Required	Not Covered	Not Covered	PA Required
Indiana	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions
Iowa	Not Covered	Not Covered	Not Covered	Covered w/Restrictions
Kansas	Not Covered	Covered	Not Covered	Covered w/Restrictions
Kentucky	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions
Louisiana	Not Covered	Not Covered	Not Covered	Not Covered
Maine	Covered	Covered w/Restrictions	Covered	Covered
Maryland	Not Covered	Not Covered	Limited Coverage	Not Covered
Massachusetts	Limited Coverage	Limited Coverage	Limited Coverage	Limited Coverage
Michigan	Limited Coverage	Limited Coverage	Limited Coverage	Limited Coverage
Minnesota	Limited Coverage	Limited Coverage	Limited Coverage	Limited Coverage
Mississippi	Limited Coverage	Not Covered	Limited Coverage	Limited Coverage
Missouri	Limited Coverage	Not Covered	Not Covered	Limited Coverage
Montana	Covered w/Restrictions	Covered w/Restrictions	Not Covered	Not Covered
Nebraska	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions
Nevada	Covered	Covered	Not Covered	Covered w/Restrictions
New Hampshire	Covered	Covered	Covered	Covered
New Jersey	Not Covered	Not Covered	Not Covered	Covered
New Mexico	Covered	Covered	Not Covered	Covered w/Restrictions
New York	Limited Coverage	Not Covered	Limited Coverage	Limited Coverage
North Carolina	Not Covered	Not Covered	Not Covered	Not Covered
North Dakota	Covered	Covered	Not Covered	Not Covered
Ohio	Selective Coverage	Selective Coverage	Selective Coverage	Selective Coverage
Oklahoma	Limited Coverage	Not Covered	Not Covered	Not Covered
Oregon	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions
Pennsylvania	Not covered	Covered w/Restrictions	Covered	Covered
Rhode Island	Covered	Not Covered	Not Covered	Covered w/Restrictions
South Carolina	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions	Covered w/Restrictions
South Dakota	Not Covered	Not Covered	Not Covered	Not Covered
Tennessee*	Covered	Covered	Not Covered	Covered
Texas	Covered	Covered	Not Covered	Covered
Utah	Not Covered	Not Covered	Limited Coverage	Limited Coverage
Vermont	PA Required	PA Required	PA Required	PA Required
Virginia	Covered	Covered	Covered	Covered
Washington	Limited Coverage	Limited Coverage	Limited Coverage	Limited Coverage
West Virginia	Limited Coverage	Not Covered	Limited Coverage	Limited Coverage
Wisconsin	Covered w/Restrictions	Not Covered	Covered w/Restrictions	Covered w/Restrictions
Wyoming	Not Covered	Covered	Covered	Covered

*Within Federal and State guidelines, individual managed care and pharmacy benefit management organizations make formulary/drug decisions.

PA= Prior Authorization

Source: Pharmaceutical Benefits Under State Medical Assistance Programs 2003, National Pharmaceutical Council.