



Perspectives on Oversight of Compounding in Long Term Care

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Long Term Care Facility Information

- Nursing Homes, Adult Foster Care, Assisted Living Facilities, ICF/ID, Group Homes
 - Pharmacies serving these facilities are a hybrid of both community and hospital pharmacy services
 - Must be able to package in compliance packaging
 - Must be able to compound sterile IV's for patients
- Most facilities are licensed by the state and many are Medicare and Medicaid certified by CMS¹
- Must meet stringent Medicare and Medicaid (CMS) conditions of participation and must establish organized medication distribution
- Must meet state requirements – state survey once per 1-2 years in SD
- All SNF, ICF/ID and ALF licensed facilities must have a Consultant Pharmacist to review medications of residents regularly (monthly or quarterly depending on license) and must review medication storage
- Residents may self administer or facility staff may administer medications based upon orders by prescriber

Payment for Pharmacy in LTC

- Medicare ~ 14% of all nursing home residents; resident is in facility for a rehabilitation stay, must have a qualifying 3 day stay in a hospital; low co-pay ~100 day stay if progress in therapies continues; medication costs paid by Medicare per diem agreement with facility (facility pays pharmacy), determined by facility prior expenses; average length of stay 26.4 days
- Private Pay ~ 24% of all nursing home patients, tends to go to ALF with home nursing care; however, medications paid by Medicare Part D after this was enacted in 2006
- Medicaid ~ 62% of all nursing home patients, generally resident stay is long term; facility care and medications are paid by Medicaid (or managed care alternative selected by states)

Why Do LTC Pharmacies Compound?

- If a prescriber wants a patient to be on IV therapy, it needs to be provided
 - All compounded sterile and non-sterile products must have a patient specific chart order for a long term care pharmacy to fill it
- Studies show that keeping a resident in their home (room) is much more beneficial to resident health, especially those with cognitive issues and it saves \$\$ over hospitalization
- Transport to hospital is expensive
- LTC is trying to assist with avoiding re-hospitalizations
- Hospital length of stays are shorter and patients may be discharged requiring continuation of IV fluid and/or antibiotics or TPN/lipids
- A liter of fluid tends to perk everyone up!
- This is not a large revenue component of LTC pharmacy services, but they must offer it to take care of residents

What do LTC Pharmacies Compound?

- IV Fluids
 - IV Antibiotics
 - Total Parenteral Nutrition (TPN)
 - Chemotherapy
 - Enteral Feeding
 - IV Anti-inflammatory Drugs and Steroids
 - IV Gammaglobulin and Blood Products
 - Pain Management
- } Most common
in LTC

SD Compounding Oversight in LTC

- The SD Board of Pharmacy inspects all pharmacies yearly
- The SD Board of Pharmacy treats LTC pharmacies the same as other compounding pharmacies - no licensure distinction
- Held to standards of USP<795>, USP <797>, and USP <800> (July 2018)
- Includes appropriate P&P's, IV room construction, equipment, ACPH, venting, calibrating, validations, BUD calculation, etc.
- Costs to comply with new standards are substantial when volume of compounds is considered

LTC Facility Packaging

- Most LTC facilities require compliance packaging to assist LTC facility nursing staff and/or med aides to efficiently provide the right dose, right drug, for right patient, at right time, without omissions, dropped doses, etc. – often blister cards 14 or 30 day supply
- Storage must meet requirements for security, temperature, etc
- Obviously many items may not be packaged outside manufacturer container i.e., nitroglycerin s.l. tablets
- For maximized safety and track-ability, bar coding has become industry standard for product validation at pharmacy, nursing home, medication administration record (MAR) and many have bedside bar code scanning for medication administration (BCMA)

LTC Pharmacy Packaging

- LTC pharmacies have been packaging products in unit of use (blisters or other compliance type) packaging for over 40 years
 - Not to be confused with FDA registered re-packagers
- Guidance has varied over the years, however, USP revised its BUD guidance in 2000, to allow a 12 month BUD when using material considered better than PVC. The USP never defined “better than PVC” and therefore there has been confusion and inconsistency
- Most of 15,000 Medicare/Medicaid certified facilities use Class B packaging with a BUD of 12 months or $\frac{1}{4}$ of the expiration date of the product, whichever is sooner
- Class A packaging supplies are not readily available
- Packaged products are recorded with and display the manufacturer’s lot or a special packaging lot number so that recalls can trace back to the original product



LTC Automated Dispensing Devices

- Two types of AMDD's in Long Term Care Facilities
 1. Use of AMDD, i.e., Omnicell, Pyxis, etc. for Emergency Kit medications only – majority of AMDD in LTC
 2. Use of AMDD to package each residents medications for each med pass time with all oral dosage forms that can be put in same sleeve, sealed together for that med pass i.e., AlixaRx, Talyst, RxNow
 - Products not used are not returnable to the pharmacy

Senior Care Facts

- Baby Boomer population are those born in 1946 – 1960
- The oldest began turning 70 in 2016 – direct impact on the system; their consumption of medications and services will skyrocket!
- Today, there are over 46.2 million adults aged 65 and older in the US; by 2060, that number is expected to double to 98 million
- Approximately 10,000 baby boomers celebrate a 65th birthday each day and will every day for the next 19 years
- Seniors currently represent 14.5% of the US population, about 1 in 7 Americans
- Nearly 70% of Americans are on at least one prescription drug and more than 50% take two

Relative Cost of Care of all Types of LTC

 Cost of Care		Genworth 	
		Sioux Falls, SD	
Monthly Cost		2016	
Home Health Care			
Homemaker Services			\$4,195
Homemaker Health Aide			\$4,195
<i>Based on annual rate divided by 12 months.</i>			
Adult Day Health Care			
Adult Day Health Care			\$2,080
<i>Based on annual rate divided by 12 months.</i>			
Assisted Living Facility			
Private, One Bedroom			\$2,880
<i>As reported, private, one bedroom.</i>			
Nursing Home Care			
Semi-Private Room			\$6,144
Private Room			\$6,509
<i>Based on annual rate divided by 12 months.</i>			

Nursing homes are key providers of long-term care in the US, supplying medical, skilled nursing, and rehabilitative services on an inpatient basis to individuals who need help with self-care, such as bathing and dressing. As of 2015, there were 1.4 million people, primarily seniors, served in nearly 16,000 nursing homes.

Medicaid is the primary payer for nursing home care, providing needed long-term care services not offered by Medicare that would otherwise be unaffordable for seniors with low incomes and relieving the care burden from families.

Medicaid currently provides federal matching funds with no pre-set limit that help states cover nursing home care. Medicaid restructuring and cuts in federal funds as proposed in the American Health Care Act could limit states' ability to provide these services.

Long Term Care Need Continues to Grow Due to an Aging Population

15% of the total US population was 65+ in 2015, and the total number of seniors is expected to **double** by 2060.



1 in 3 people turning 65 will require nursing home care at some point during his or her life



In 2015, **1.4 Million** people were in nursing homes:



\$82,000

Typical annual cost of nursing home care in 2016, which is nearly 3x the annual income of most seniors

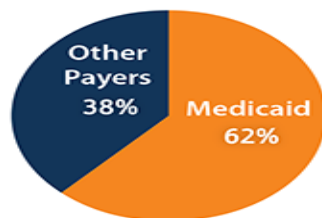


Medicaid is the Primary Payer for Nursing Home Care, Providing Needed Services not Offered by Other Coverage

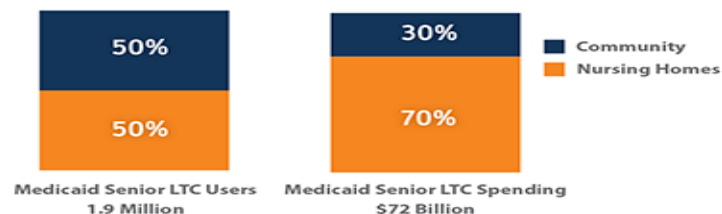
Medicaid is the **primary payer** for long-term care, including **\$55 billion** in 2015 for nursing homes. Medicare only covers limited post-acute care, and few people can afford private coverage.



Medicaid covers **6 in 10** nursing home residents.



50% of seniors using Medicaid long-term care services in 2013 were in nursing homes, accounting for **70%** of seniors' Medicaid spending on long-term care.

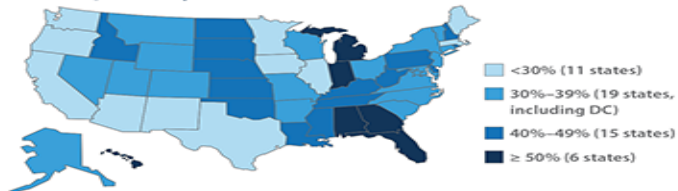


Changes to Medicaid Financing Could Limit Access to Nursing Home Care for Seniors

44 states that extend financial eligibility up to 300% SSI* for people who need long-term care beyond the federal minimum of SSI could be at risk if states scale back this optional coverage.

*SSI = 73% of the Federal Poverty Level (FPL) in 2017

Capping Medicaid financing could **lock in differences in the share of long-term care spending** devoted to nursing homes, which varies significantly across states as of FY 2015.



Medicaid is a **key payer** for nursing home care.

- Reductions in federal Medicaid financing as proposed by the American Health Care Act could **limit states' ability to respond to these needs**
- Lower reimbursement rates can lead to **reductions in staffing**, which can result in **lower nursing home care quality and poor care outcomes**.

Sources for this document are available at: <http://kff.org/infographic/medicaids-role-in-nursing-home-care>.

The Henry J. Kaiser Family Foundation Headquarters: 2400 Sand Hill Road, Menlo Park, CA 94025 | Phone 650-854-9400
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Filling the need for trusted information on national health issues, the Kaiser Family Foundation is a nonprofit organization based in Menlo Park, California.

Consultant Pharmacist – Unique to LTC

A “consultant” or “senior care” pharmacist is a medication therapy management expert who provides advice on the use of medications by older adults. Consultant Pharmacist is responsible for:

- Monthly review of every residents medications in SNF facilities
 - Contraindications
 - Adverse drug reactions
 - Change of condition
 - Clinically appropriate medication change requests
 - Lab results and labs necessary to be run
 - Reduction of antipsychotics
- Ensure appropriateness of medication storage conditions i.e., locking cabinets, refrigerator temperatures, topicals away from orals, narcotic security
- Ensures MAR matches order by sample checking
- Ensures outdates are not in facility by sample checking

References

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MTS Packaging Comments to FDA <https://www.fda.gov/ohrms/dockets/dockets/05d0174/05D-0174-EC12-Attach-1.pdf>

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LTCA Cost of Care <http://www.genworthltcquote.com/default.aspx?SearchNetwork=Bing>



Questions?

