Distinguished Members of the Healthcare Advisory Committee
U.S. Centers for Medicare and Medicaid Services
Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244
Delivered by email to: HAC@cms.hhs.gov

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Dear HAC Committee Members,

On behalf of the **Senior Care Pharmacy Coalition (SCPC)**, the national trade association representing long-term care (LTC) pharmacies, I wanted to provide additional background from our initial comment input on LTC pharmacy value and expand on LTC pharmacies and their historical role and challenges in the health sector. As the aging population immensely grows, this effective industry with expertise in medication management and deprescribing will be needed more than ever. However, sustaining these pharmacies and ensuring that they are reimbursed in a fair manner to manage all of the clinical services they offer is essential. Below is a history of development of these services, alongside the challenges the sector has faced, particularly recently with drug pricing changes and the impacts on these pharmacies (with highlight indicating specific areas of focus).

We urge the HAC to closely examine long-term care pharmacies and consider hosting an in person meeting with our sector and government to better understand the implications of their current reimbursement model and discuss ways to improve access to the sector as it grows rapidly. We believe a thoughtful approach to long-term care pharmacy will provide significant savings across Medicare and Medicaid programs and result in expansion of the incredible outcomes we previewed with data in our first comment letter to the HAC.

Long-Term Care Pharmacy: Evolution of the Federal Regulatory Framework
A Legislative, Regulatory, and Policy Timeline (1987–Present)

Executive Summary
Unlike community retail pharmacy, LTC pharmacy has evolved through a series of federal statutes, Medicare regulations, CMS guidance, DEA requirements, and Medicare Part D operational policies that collectively define both the services LTC pharmacies provide and the manner in which they are reimbursed.

Many of today's policy debates-including reimbursement, PBM reform, Medicare Part D redesign, and the Medicare Drug Price Negotiation Program cannot be understood without appreciating this regulatory history.

I. Before the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987)

Prior to 1987
Before OBRA 1987:

- Pharmacy services varied considerably among nursing facilities.
- Consultant pharmacist services were inconsistent.
- Medication reviews were not uniformly required.
- Federal standards governing medication management in nursing facilities were limited.

II. OBRA 1987 (Nursing Home Reform Act)

Why Congress Acted
Congress sought to improve quality of care following widespread concerns regarding:

- inappropriate medication use
- overuse of psychotropic medications
- medication errors
- poor consultant pharmacist oversight
- inadequate resident protections

What OBRA Created
This remains the single most important federal law governing LTC pharmacy.
Created:

- Monthly Drug Regimen Reviews (MRRs)
- Consultant pharmacist requirements
- Unnecessary drug standards
- Medication error standards
- Pharmacy service requirements
- Emergency medication availability
- Controlled substance accountability
- Medication recordkeeping

These requirements were implemented primarily through **42 C.F.R. § 483.45 (Pharmacy Services).**

III. 42 C.F.R. § 483.45

This regulation governs pharmacy services in Medicare- and Medicaid-certified nursing facilities.
Key requirements include:
Pharmaceutical Services
Facilities must provide procedures ensuring:

- acquiring medications
- receiving medications

- dispensing medications
- administering medications

Consultant Pharmacist

Facilities must obtain a licensed pharmacist who:

- oversees pharmacy services
- maintains controlled substance accountability
- reconciles drug records

Monthly Drug Regimen Reviews

Every resident must receive:

- monthly pharmacist review
- chart review
- identification of medication irregularities
- communication to physicians and nursing leadership

Unnecessary Drugs

Residents' regimens must be free from:

- excessive doses
- duplicate therapy
- excessive duration
- inadequate monitoring
- inappropriate indications
- avoidable adverse consequences

Emergency Medications

Facilities must provide:

- routine drugs
- emergency drugs

This requirement became the basis for today's pharmacy-managed emergency medication kit model.

IV. Medicare Modernization Act (2003)

The creation of Medicare Part D fundamentally changed LTC pharmacy.
Major changes:

- What was previously mostly Medicaid drug coverage moved into new Medicare Part D.
- PBMs became central to LTC pharmacy reimbursement.
- LTC pharmacies entered Part D pharmacy networks.
- Contracting shifted toward private plans.

This shift created many of today's reimbursement challenges.

V. CMS Implementation of Medicare Part D (2005–2006)

CMS recognized that LTC pharmacy differs fundamentally from retail pharmacy.
CMS established:

- LTC pharmacy network standards
- convenient access requirements
- transition fill policies
- emergency supply requirements

- specialized dispensing expectations

These policies remain largely in the Medicare Prescription Drug Benefit Manual.

VI. Affordable Care Act (2010)

Short-Cycle Dispensing
Congress required CMS to reduce medication waste in nursing facilities.
CMS initially proposed:
7-day dispensing
Stakeholders demonstrated this would create excessive operational burden.
CMS adopted:
14-day dispensing
effective January 1, 2013.
Why 14 Days?
CMS concluded that 14 days balanced (and limited to certain drug types - high cost brands):

- reducing waste
- minimizing labor burden
- limiting delivery costs
- preserving patient safety

CMS also acknowledged:

- more dispensing events
- higher pharmacy costs
- need for appropriate dispensing fees

VII. 42 C.F.R. § 423.154

This regulation governs:
Short-cycle dispensing
Requires:

- ≤14-day increments
- no proration of dispensing fees
- incentives for efficient dispensing
- reporting of unused drugs
- return-for-credit provisions where permitted

This regulation significantly increased operational costs for LTC pharmacies.

VIII. CMS Part D Manual

The Medicare Prescription Drug Benefit Manual established operational protections including:
LTC Transition Fills

- 91–98 day transition supplies
- multiple incremental fills

Emergency Supplies
Requirements for emergency access to medications.
LTC Networks
Standards governing network participation.

Convenient Access
Special rules recognizing LTC pharmacy operations.

IX. DEA Rules

DEA regulations recognize LTC pharmacies through special rules for Schedule II controlled substances.
Examples include:

- partial filling
- faxed prescriptions
- LTC-specific controlled substance provisions

These accommodate the unique medication management needs of LTC residents.

X. CMS Nursing Home Reform Updates (2016)

CMS modernized the Conditions of Participation.
Updates included:

- expanded psychotropic medication oversight
- documentation requirements
- stronger consultant pharmacist responsibilities
- enhanced medication safety standards

These changes further increased the clinical responsibilities of LTC pharmacies.

XI. Inflation Reduction Act (2022)

The IRA represents the largest reimbursement change since Part D.
Key impacts:

- Medicare Drug Price Negotiation
- Manufacturer Discount Program
- Part D redesign
- $2,000 beneficiary cap
- reduced product margins
- increased reliance on dispensing fees
- Medicare Transaction Facilitator
- manufacturer refunds

These changes directly affect LTC pharmacy economics. SCPC has been actively involved in the monthly pharmacy industry calls with CMS around implementation and has also been active at weighing in on proposed rules and guidance from the administration. In addition, the long-term care pharmacy issue has advocated to Congress and the administration to mitigate the economic hit from Inflation Reduction Act to its services.

XII. Medicare Drug Negotiation Program (2025–Present)

Current issues include:

- Maximum Fair Price
- Standardized Default Refund Amount (SDRA)

- manufacturer refund timing
- reconciliation
- MTF implementation
- Part B expansion
- reimbursement adequacy

These are the primary focus of SCPC's current advocacy.

Policies where SCPC has spent significant time to ensure LTC pharmacy access is not disrupted and we believe HAC can create relief:

1. FDA Repackaging Guidance (2014–2020)
Background
LTC pharmacies routinely repackage manufacturer stock bottles into:

- unit-dose packaging,
- blister cards,
- strip packaging,
- bingo cards,
- and other patient-specific packaging required by nursing facilities.

This is a foundational component of the LTC pharmacy model.

After enactment of the Drug Quality and Security Act (DQSA), FDA issued draft guidance regarding repackaging by pharmacies. The initial proposals raised significant concern that routine LTC pharmacy repackaging could become subject to conditions that were impractical for the LTC setting.

LTC pharmacy concerns
Stakeholders were concerned the guidance could:

- shorten beyond-use dating for repackaged medications,
- increase operational burden,
- require more frequent repackaging,
- increase medication waste,
- disrupt established unit-dose systems,
- increase costs for nursing facilities,
- ultimately reduce patient access.

Because LTC pharmacies repackage millions of doses annually, even modest restrictions could have had substantial operational and financial consequences.

Outcome
Following stakeholder engagement, including advocacy by organizations like SCPC, FDA's final guidance was more workable for pharmacy operations, and FDA later issued additional guidance addressing expiration dating for unit-dose repackaged oral solid dosage forms.

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2. Pharmacy Lock-In Policies (Medicare Part D)
Background

CMS established the **Part D Drug Management Program ("lock-in")** to address opioid misuse by allowing plans to limit certain at-risk beneficiaries to selected prescribers and/or pharmacies. The program was designed primarily for the retail setting.

LTC pharmacy concern

The concern was that if LTC residents were swept into lock-in programs:

- residents could be forced to use pharmacies other than the LTC pharmacy serving their facility,
- the longstanding **one pharmacy–one facility** model could be disrupted,
- medication administration could become fragmented,
- emergency medication access could suffer,
- consultant pharmacist services could be affected,
- nursing facility workflows could become significantly more complicated.

This would have undermined decades of federal policy recognizing the integrated LTC pharmacy model.

Outcome

CMS ultimately recognized these concerns and **excluded "exempt individuals," including residents of long-term care facilities, from the Part D Drug Management Program (lock-in).** That exemption preserved the LTC pharmacy model while allowing the program to operate in the community setting.

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3. CMS Requirements for Participation ("Mega Rule") (2016)

Background

In 2016, CMS issued the most comprehensive update to the Medicare and Medicaid Requirements for Participation for nursing facilities since OBRA '87. The rule modernized nursing facility standards and significantly expanded expectations around quality of care, medication management, infection prevention, and behavioral health.

LTC pharmacy concerns

Although directed primarily at nursing facilities, the rule substantially increased the responsibilities of LTC pharmacies and consultant pharmacists, including:

- enhanced medication regimen review expectations,
- increased oversight of psychotropic medications,
- greater documentation and communication responsibilities,
- expanded participation in quality assurance and performance improvement (QAPI),
- increased infection prevention and antibiotic stewardship activities,
- additional support for facility compliance during surveys.

These expanded responsibilities required significant additional pharmacist time and operational resources without corresponding increases in reimbursement.

Outcome

The rule strengthened medication safety and resident protections, **but it also expanded the clinical and regulatory responsibilities of LTC pharmacies without establishing a payment mechanism for many of the additional services expected.** This in part led the industry to push for a federal definition to acknowledge the specific services and costs - the Long-Term Care

Pharmacies Definition Act, a bipartisan federal definition bill, was reintroduced multiple times in Congress but never became law.

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4. MAJOR ISSUE - Inflation Reduction Act (2022–Present)

Background

The Inflation Reduction Act fundamentally restructured Medicare Part D through the creation of the Medicare Drug Price Negotiation Program, redesign of the Part D benefit, the Manufacturer Discount Program, and the Medicare Transaction Facilitator (MTF). These changes shifted financial responsibility throughout the Part D supply chain while significantly altering reimbursement for selected drugs.

LTC pharmacy concerns

SCPC has consistently raised concerns that implementation of the IRA did not adequately account for the LTC pharmacy payment model. Key concerns include:

- reduced brand drug margins that historically helped support federally required LTC pharmacy services (reminder that LTC pharmacies are heavily Part D reimbursed, have no front of store, and their operations generally survive on brand dispensing which accounts for less than 10% of all dispensing due to PBM contract constructs),
- delayed manufacturer refunds creating cash-flow pressures,
- manufacturer reimbursement methodologies (including the Standardized Default Refund Amount) that may not reflect actual acquisition costs,
- increased administrative burden associated with MTF registration, reconciliation, and refund tracking,
- greater reliance on dispensing fees despite those fees often failing to reflect the true cost of providing LTC pharmacy services,
- increased financial pressure on Part D plans, leading to more aggressive PBM contracting and reimbursement practices.

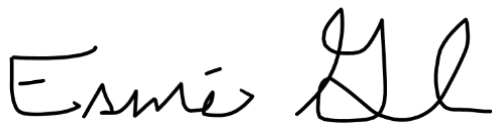
Outcome

Implementation remains ongoing. Early data from SCPC's analysis with ATI Advisory indicate that reimbursement for negotiated drugs has declined substantially (-8% operating margin) and that manufacturer refunds have not fully restored pharmacy operations. CMS assisted greatly in mitigating impact with three distinct memos outreaching to payers to help support LTC pharmacies. However, even the additional support was not substantial enough to provide break-even results.

The evolution of long-term care pharmacies has created a sector that yields incredible adherence and safety outcomes for the most comprehensive patients, but is also dependent on an unsustainable payment model that cannot adjust for drug pricing changes or significant alterations to the Part D structure. SCPC recognizes that its members are going to be called upon to serve growing aging and complex populations and we believe our pharmacies have the expertise to address the need. Our hope is to work collaboratively with government partners to explore sustainability so that this sector can focus more on the innovation of service delivery and less on the day to day survival. **We encourage the HAC to create an opportunity for the sector to convene with experts across HHS and CMS (both in pharmacy and long-term care divisions) to culminate solutions that ensure that beneficiaries continue to receive this specialized pharmacy service well into the future.**

Thank you for your consideration of these comments and request for a convening of this important sector.

Sincerely,



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