Date: Monday, October 20, 2014
Time: 4:00 pm – 5:30 pm
Location: Austin Convention Center, Room 18AB, Level 4

Title: Long Term Care Legislative and Regulatory Update
ACPE #: 207-000-14-226-L03-P : 0.15 CEUs
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Activity Type: Application-based
Speaker: Susan Rhodus, RPh, Vice President, Contract Administration, GeriMed
James Vasquenza, Vice President, Preferred Provider Network, Innovatix
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Ronna Hauser, Vice President, Pharmacy Affairs, NCPA
Carolyn Ha, Senior Director, Professional Affairs, NCPA

Pharmacist and Pharmacy Technician Learning Objectives:
Upon completion of this activity, participants will be able to:
1. Summarize key legislation and regulation important to the independent pharmacy Long Term Care (LTC) operators.
2. Discuss the legislative and regulatory perspectives of the major LTC GPOs.
3. Describe developing legislation for 2015 and beyond that may affect the LTC market for the independent practitioner.

Disclosures:
Susan Rhodus declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

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Craig Douglas declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

Ronna Hauser declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

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Long-Term Care Legislative, Regulatory Update and Industry Forecast

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Agenda

• Overview of NCPA’s LTC Division
• Legislative/Regulatory Update
• Industry Forecast Discussion

NCPA LTC Division

• Formed in 2010, Division is dedicated to issues impacting providers of LTC services in a variety of settings, including: assisted living, group homes, residential care, nursing homes, skilled nursing, and more!
• Assures independent LTC pharmacy’s voice is heard loud and clear in Washington D.C. in both legislative and regulatory arenas.
• Advocating on your behalf: short-cycle dispensing, pro-rated dispense fees, controlled substance issues, generic pricing fluctuations, audits, MTM, and more.

LTC Advocacy Strategy

• Legislative priorities are guided by LTC Advisory Board, member feedback
• NCPA also part of broader LTC stakeholder coalition that includes
  – American Health Care Association (AHCA)
  – LeadingAge
  – Society for Post-Acute and Long-Term Care Medicine (AMDA)
  – American Society of Consultant Pharmacists (ASCP)
NCPA LTC Advocacy

NCPA’s LTC Division members have been represented here:

- Federal Agencies: HHS/FDA, CMS, DEA

NCPA LTC Legislative Initiatives

- Prohibition of pro-rated dispense fees
- MAC transparency and Fair Audits
- Medicare Part D – Any Willing Pharmacy
- Controlled Substances
- Pharmacist as Provider

NCPA LTC Legislative Initiatives

- Pro-rated Dispense Fees
  - S. 1493: Medicare Efficient Drug Dispensing Act of 2013: to encourage the use of dispensing techniques that foster efficiency and reduce wasteful dispensing of outpatient prescription drugs in long-term care facilities (LTCFs). The common-sense legislation prohibits Medicare Part D plan sponsors from using payment structures, including pro-rated daily dispensing fees that discourage the adoption of techniques to minimize the dispensing of unused drugs.
  - CMS may also choose to finalize proposed provision in Part D at some point in the future
NCPA LTC Legislative Initiatives

- MAC Transparency and Fair Audits
  - H.R. 4437: Generic Drug Pricing Transparency Act: provides transparency and fairness to community pharmacies regarding their reimbursements for generic drugs. PBMs would be required to disclose the source and reimbursement rate in the contract and to update that rate at least once every seven days to reflect fluctuations in the market.
  - S. 867: PBM Audit and Generic Drug Pricing Transparency: addresses the lack of generic pricing transparency on the part of PBM's in the Medicare Part D programs and promotes fairness by curbing abusive PBM audit practices. The bill would ban extrapolation, prohibit recoupments based on minor typographical errors that have no financial harm to patient or plan and assure recoveries made in cases of fraud, waste and abuse be returned to taxpayers and beneficiaries, not retained by PBMs.

- Medicare Part D Any Willing Pharmacy
  - H.R. 4577 - The Ensuring Seniors Access to Local Pharmacies Act. Introduced by Reps. Morgan Griffith (R-VA) and Peter Welch (D-VT). So far, more than 70 members of the House of Representatives are publically supporting H.R. 4577, which would allow any willing pharmacy located in a medically underserved area to participate in all Medicare Part D networks.
  - A strong display of bipartisan support is needed force a vote in the House, most likely during lame duck session after the midterm elections Nov. 4. Organizations endorsing the legislation to date include the National Rural Health Association, Medicare Rights Center, Consumers Union, Health HIV, National Grange and National Senior Citizens Law Center.

- Controlled Substances:
  - H.R. 4709: Ensuring Patient Access and Effective Drug Enforcement Act of 2014 seeks to prevent prescription drug abuse and diversion and ensure patient access to necessary medications by creating a more collaborative partnership between drug manufacturers, wholesalers, retail pharmacies and federal enforcement and oversight agencies. Most importantly it would, if enacted, allow pharmacies the opportunity to submit a corrective action plan prior to having their DEA license revoked or suspended.
  - S. 2862: Regulatory Transparency, Patient Access, and Effective Drug Enforcement Act of 2014
NCPA LTC Legislative Initiatives

• Pharmacist Provider Status
  – H.R. 4190 - To amend title XVIII of the Social Security Act to provide for coverage under the Medicare program of pharmacist services.
  – Legislation that would enable patient access to and payment to pharmacists for providing Medicare Part B services in medically underserved communities is gaining support in the House of Representatives. H.R. 4190 was introduced by Reps. Brett Guthrie (R-KY), G.K. Butterfield (D-NC), and Todd C. Young (R-IN) in April 2014. The list of bipartisan backers is now over 100.
  – NCPA is a member of the Patient Access to Pharmacists’ Care Coalition (PAPCC), the driving force behind H.R. 4190.

LTC Regulatory Issues

• TRICARE
• Coverage of Hospice Drugs
• Controlled Substances
• Medicare Part D

LTC Regulatory Issues

• TRICARE for Life Mail Order Pilot Program
  – NCPA met with TRICARE leadership and discussed concerns about the mail order pilot program for TRICARE for Life beneficiaries for certain brand medications and requested that consideration be given to a more streamlined approach to granting such waivers, and TRICARE assured us they are working on such a process.
  – While there is a waiver process available for nursing home residents to be exempted, it is only on an individual patient basis and could be cumbersome, as it requires the resident or their caregiver to call Express Scripts to try and resolve.
  – NCPA also joined a LTC stakeholder letter addressed to the DoD asking for a broader exemption for both skilled and assisted living patients.
CMS Revises Hospice Guidance for Part D Sponsors—Limits Prior Authorization Policy

Since the release of the previous guidance on Part D Payment for Drugs for Beneficiaries Enrolled in Medicare Hospice in the spring, hospice stakeholders, including NCPA, have relayed operational challenges to CMS. After convening with stakeholders to discuss the implementation of the final 2014 guidance on Part D payment for beneficiaries enrolled in the Medicare hospice benefit, CMS has revised its policy requiring prior authorizations (PA) on all drugs. The agency stated that it recognizes these challenges and has decided to encourage plans to place PA requirements on just four categories of drugs:

1. Analgesics
2. Anti-nauseants (antiemetics)
3. Laxatives
4. Antianxiety drugs (anxiolytics)

Sponsors should use the existing standard PA process which begins when a Part D sponsor receives a pharmacy claim for a beneficiary who has elected hospice and rejects the claim with the following NCPDP-approved reject coding:

- A3: This Product May Be Covered Under Hospice – Medicare
- 75: Prior Authorization Required
- 569: Provide Notice: Medicare Prescription

If a claim has been rejected by a sponsor, the pharmacy or beneficiary may contact the hospice provider for a statement that the drug is unrelated to the terminal illness and related conditions.

Sponsors should implement processes to handle payment resolution directly with hospice providers and beneficiaries without requiring the pharmacy reverse and rebill the original claim in the retail setting. The hospice provider should contact the Part D sponsor to provide an oral or written statement or provide a written statement to the pharmacy or the beneficiary to transmit to the Part D sponsor. Sponsors should communicate with their network pharmacies to encourage the pharmacies to assist plan members by faxing the documentation to the sponsor and note that the sponsor will accept this information so the beneficiary level hospice PA edit can be overridden at POS.

CMS expects all sponsors will have implemented this process by October 1, 2014.
LTC Regulatory Issues

• CMS Revises Hospice Guidance for Part D Sponsors—Limits Prior Authorization Policy
  – Note: NCPA has been tracking industry efforts to work on solutions to address the communication pathway during the prior authorization process between hospice facility and Part D sponsor. A generic form has been developed by NCPDP, designed for use by the hospice provider and/or prescriber to communicate with a Part D plan.
  – Additionally, CMS recognizes that coverage determinations will be pending for some previously rejected claims for drugs other than those in the four categories. Since these claims should no longer to be subject to hospice PA reject edits, the drugs should be considered covered under the Part D benefit without the sponsor obtaining documentation regarding the relatedness of the drug.

LTC Regulatory Issues

• Controlled Substance Issues:
  – Hydrocodone Rescheduling from CIII to CII: effective October 6th
  – NCPA advocated against rescheduling of HCPs as part of LTC stakeholder group and will continue to work for nurse as agent fix
  – Recommended an exemption from stricter dispensing requirements for residents in LTCFs or modification in current interpretation of agency relationships
  – Drug Disposal of Controlled Substances
  – Final rule released: effective October 9th
  – NCPA, along with several LTC groups met with staff from the White House Office of Information and Regulatory Affairs (OIRA), Office of National Drug Control Policy (ONDCP), and the Drug Enforcement Administration (DEA)
  – Senators have also weighed in with concerns about handling in LTCF
  – LTC win: change from proposed rule – facilities can continue disposal protocols

LTC Regulatory Issues

• Drug Disposal of Controlled Substances
  – Secure and Responsible Drug Act of 2010
  – Proposed rule – late 2012; Comment Period closed – early 2013
  – Final rule issued by DEA – September 2014
• Expands registrants deemed “authorized collectors”
  – Manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with on-site pharmacy and retail pharmacies
• Voluntary program; modification in DEA registration
  – Maintain collection receptacle inside registered location or at LTCF
  – Operate mail-back program
  – Relaxed two-employee requirement for inner liner handling at LTCF
• Currently available disposal options to ultimate users (e.g. flushing) remain in effect.
LTC Regulatory Issues

• Medicare Part D: electronic prescriptions
  – CMS has had ruling in place since 2005 mandating the use of the NCPDP SCRIPT Standard for all electronic prescriptions payable under Part D. The rule did, however, include multiple exemptions to this requirement:
    1. Computer-Generated Faxes
    2. Long-Term Care
    3. Same Legal Entity
  – CMS removed the exemption for computer-generated faxes effective January 1, 2012.

LTC Regulatory Issues

• Medicare Part D: electronic prescriptions
  CMS description of e-prescribing: “means the transmission using electronic media, of prescription or prescription related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser.”

LTC Regulatory Issues

• Medicare Part D: electronic prescriptions
  – Until November 1, 2014, entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser are exempt from the requirement to use the NCPDP SCRIPT Standard adopted by this section in transmitting such prescriptions or prescription-related information. As of November 1, 2014, such entities will be required to use the adopted NCPDP SCRIPT standard(s).”
  – NOTE: the rule does NOT mandate the use of e-prescribing. It does, however, require the use of the NCPDP SCRIPT Standard for those opting to e-prescribe.
LTC Regulatory Issues

**Medicare Part D: electronic prescriptions**
- Are physician medication orders considered prescriptions or prescription-related information and therefore subject to e-Prescribing regulations?

*Yes, a physician’s medication order serves as the patient’s prescription and is subject to the federal regulations regarding e-Prescribing.*

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LTC Regulatory Issues

**Medicare Part D**
- Effective November 1, 2014, the following will not be allowed for electronic order transmission from a nursing facility to the dispensing pharmacy for covered Part D drugs for Part D eligible individuals:
  1. HL7
  2. Computer-Generated Faxes
- Manual faxing of orders from paper (i.e. either handwritten, or printed to paper from the facility’s EMR system) will continue to be allowed.

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LTC Regulatory Issues

**Medicare Part D**
- Part D sponsors must establish and maintain an electronic prescription drug program that complies with the applicable standards in paragraph (b) of this section when transmitting, directly or through an intermediary, prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals.”
- Pharmacy considerations: audit recoupments
- Establish communications with facility partners
LTC Regulatory Issues

• Medicare Part D: 2015 Final Rule
  — CMS announced the agency will not finalize at this time:
    • Changes to the protected class definition
    • Clarification to the non-interference provisions
    • Preferred pharmacy network standards
  — Number of plans a Part D sponsor may offer
  — On May 19th CMS issued the final rule which includes requiring the disclosure of individual Maximum Allowable Cost (MAC) prices prior to being used for reimbursement purposes and mandatory MAC updates and a revision of the definition of “negotiated price”.
  — CMS has said the 41 provisions which were not addressed in the final Part D 2015 rule (not the ones they withdrew), could be considered delayed provisions and may be finalized at a later date with no additional comment period. These included pro-rated dispense fee for short cycle dispense, MTM.

LTC Regulatory Issues

• Medicare Part D: additional issues of interest
  — Prescriber enrollment in Medicare Part D – effective June 2015
  — Use of anti-psychotics in LTC:
    • CMS remains concerned with unnecessary use of antipsychotic drugs in nursing homes; continues to pursue strategies to increase awareness of antipsychotic use through stakeholders.
    • Display measure starting in 2014
  — Expansion of Part D data, release of public use files
    • LTC elements
    • MTM

LTC Townhall Industry Discussion

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Disclosures

Craig Douglas is the Senior Vice President Long Term Care with Managed Health Care Associates, Inc. The conflict of interest was resolved by peer review of the slide content.

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LTC Townhall Industry Discussion

• What are top tier issues affecting the long-term care industry and bottom line of owners and operators?
  – Pro-rated dispense fees
  – Part D Preferred Networks
  – MAC, Audits

• What are some potential opportunities for LTC pharmacies to engage in?
  – Clinical services
  – Integrated care models
Origin of Population Health Management (PHM)

• The US Department of Health and Human Services (DHHS) proposed the initial set of guidelines for establishment of Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program (Section 3022 of the Patient Protection and Affordable Care Act).

• These guidelines stipulate the necessary steps that voluntary groups of physicians, hospitals, and other health care providers must complete in order to partake in ACOs.

Population Health Management - A network of physicians and other health care providers who work together and accept responsibility to improve quality and reduce the costs of health care services for a defined population.

Accountable Care Organization - A network of physicians and other health care providers who work together and accept responsibility to improve quality and reduce the costs of health care services for a defined Medicare population.

Medical Home - A model or philosophy of primary care that is patient-centered, comprehensive, team-based, coordinated, accessible, and focused on quality and safety.

Medicare ACOs

| Minimum Number of Beneficiaries | 5,000 | 15,000
| Upside/Downside Risk | Track 1: Upside risk only | Uplide and downside throughout participation
| Payment Model | Fee-for-service (FFS) + Shared Savings |
| Shared Savings/Losses Potential | Track 1: 0-99% max shared savings potential; no shared losses | Increased percentage of shared savings and losses based on quality score
| Beneficiary Assignment | Quarterly preliminary prospective assignment; annual final retrospective reconciliation | Choice of prospective or retrospective alignment

Medicare Shared Savings Program

Panor ACO Model

5,000 for rural ACOs
LTC Townhall Industry Discussion

States with Medicare ACOs

LTC Townhall Industry Discussion

PHM/ACO Growth Nationwide

- 360 Medicare ACOs in 43 states operational.
- An additional 123 MSSP ACOs approved on 1/1/14.
- Over 500 PHM/ACOs operating nationwide.
- CMS Bundled Payment initiative has 450+ participants and growing.

LTC Townhall Industry Discussion

Influence of PHM on healthcare

- Increasing focus on value and quality.
  - Ongoing transition to value-based payment models.
  - Increased regulatory complexity will lead to greater transparency.
  - Growth in evidence based medicine (i.e. choosing wisely).
- Collaboration and consolidation are on the rise.
  - Blending of delivery systems, health insurance plans, and technology firms.
  - Consolidation of hospitals, health systems, physicians, and the continuum of care.
- Significant investments in technology to continue.
  - Information technology will drive data integration and care redesign.
LTC Townhall Industry Discussion

Transitioning from traditional healthcare to PHM

Traditional Healthcare → Population Health Management

- Pay for volume
- Fragmented care
- Fee for service
- Treats sickness
- Adversarial payors
- Disjointed technology
- Duplication and waste

- Pay for value
- Accountable care
- Global payment
- Fosters wellness
- Payor partners
- Integrated technology platforms
- Right care, right setting, right time

LTC Townhall Industry Discussion

Preparation is critical

- The future of healthcare delivery is PHM and ACO models.
- Failure to prepare for PHM and ACO business will result in the loss of patients for many providers.
- Healthcare providers must establish relationships with PHM and ACO entities now.
- There will be criteria (benchmarks, IT infrastructure, and clinical pathways and disease state management programs) providers will need to adhere to in order to be reimbursed by a PHM or ACO.
- Reimbursement will move away from traditional fee for service methodology.

LTC Townhall Industry Discussion

How to prepare

- **Preparatory** – education, assessment, gap analysis, and operational plan.
- **Transformational** – health informatics, clinical integration, care management, and network development.
- **Implementation** – defined population and payor partner relationships.
- **Expansion** – employee health plan, commercial arrangement, Medicare, Medicaid, employer contracting, and the uninsured.