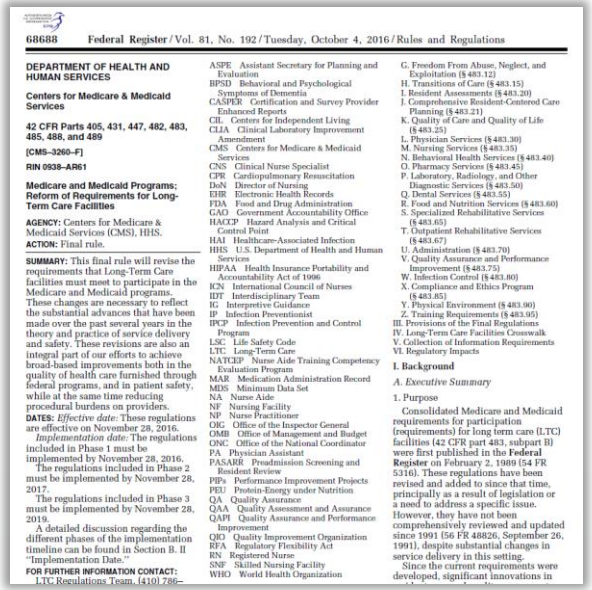

68688 Federal Register / Vol. 81, No. 192 / Tuesday, October 4, 2016 / Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 431, 447, 482, 483, 485, 488, and 489

[CMS–3260–F]

RIN 0938–AR61

Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will revise the requirements that Long-Term Care facilities must meet to participate in the Medicare and Medicaid programs. These changes are necessary to reflect the substantial advances that have been made over the past several years in the theory and practice of service delivery and safety. These revisions are also an integral part of our efforts to achieve broad-based improvements both in the quality of health care furnished through federal programs, and in patient safety, while at the same time reducing procedural burdens on providers.

DATES: *Effective date:* These regulations are effective on November 28, 2016.

Implementation date: The regulations included in Phase 1 must be implemented by November 28, 2016.

The regulations included in Phase 2 must be implemented by November 28, 2017.

The regulations included in Phase 3 must be implemented by November 28, 2019.

A detailed discussion regarding the different phases of the implementation timeline can be found in Section B. II "Implementation Date."

FOR FURTHER INFORMATION CONTACT:

LTC Regulations Team, (410) 786–

ASPE Assistant Secretary for Planning and Evaluation
BPSD Behavioral and Psychological Symptoms of Dementia
CASPER Certification and Survey Provider Enhanced Reports
CIL Centers for Independent Living
CLIA Clinical Laboratory Improvement Amendment
CMS Centers for Medicare & Medicaid Services
CNS Clinical Nurse Specialist
CPR Cardiopulmonary Resuscitation
DoN Director of Nursing
EHR Electronic Health Records
FDA Food and Drug Administration
GAO Government Accountability Office
HACCP Hazard Analysis and Critical Control Point
HAI Healthcare-Associated Infection
HHS U.S. Department of Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996
ICN International Council of Nurses
IDT Interdisciplinary Team
IG Interpretive Guidance
IP Infection Preventionist
IPCP Infection Prevention and Control Program
LSC Life Safety Code
LTC Long-Term Care
NATCEP Nurse Aide Training Competency Evaluation Program
MAR Medication Administration Record
MDS Minimum Data Set
NA Nurse Aide
NF Nursing Facility
NP Nurse Practitioner
OIG Office of the Inspector General
OMB Office of Management and Budget
ONC Office of the National Coordinator
PA Physician Assistant
PASARR Preadmission Screening and Resident Review
PIPs Performance Improvement Projects
PEU Protein-Energy under Nutrition
QA Quality Assurance
QAA Quality Assessment and Assurance
QAPI Quality Assurance and Performance Improvement
QIO Quality Improvement Organization
RFA Regulatory Flexibility Act
RN Registered Nurse
SNF Skilled Nursing Facility
WHO World Health Organization

G. Freedom From Abuse, Neglect, and Exploitation (§ 483.12)
H. Transitions of Care (§ 483.15)
I. Resident Assessments (§ 483.20)
J. Comprehensive Resident-Centered Care Planning (§ 483.21)
K. Quality of Care and Quality of Life (§ 483.25)
L. Physician Services (§ 483.30)
M. Nursing Services (§ 483.35)
N. Behavioral Health Services (§ 483.40)
O. Pharmacy Services (§ 483.45)
P. Laboratory, Radiology, and Other Diagnostic Services (§ 483.50)
Q. Dental Services (§ 483.55)
R. Food and Nutrition Services (§ 483.60)
S. Specialized Rehabilitative Services (§ 483.65)
T. Outpatient Rehabilitative Services (§ 483.67)
U. Administration (§ 483.70)
V. Quality Assurance and Performance Improvement (§ 483.75)
W. Infection Control (§ 483.80)
X. Compliance and Ethics Program (§ 483.85)
Y. Physical Environment (§ 483.90)
Z. Training Requirements (§ 483.95)
III. Provisions of the Final Regulations
IV. Long-Term Care Facilities Crosswalk
V. Collection of Information Requirements
VI. Regulatory Impacts

I. Background

A. Executive Summary

1. Purpose

Consolidated Medicare and Medicaid requirements for participation (requirements) for long term care (LTC) facilities (42 CFR part 483, subpart B) were first published in the **Federal Register** on February 2, 1989 (54 FR 5316). These regulations have been revised and added to since that time, principally as a result of legislation or a need to address a specific issue. However, they have not been comprehensively reviewed and updated since 1991 (56 FR 48826, September 26, 1991), despite substantial changes in service delivery in this setting.

Since the current requirements were developed, significant innovations in

The RoPs are here!

Do you know what's changing?

Mary Madison, RN, RAC-CT, CDP

Clinical Consultant, LTC/Senior Care

Briggs Healthcare®

March 7, 2017

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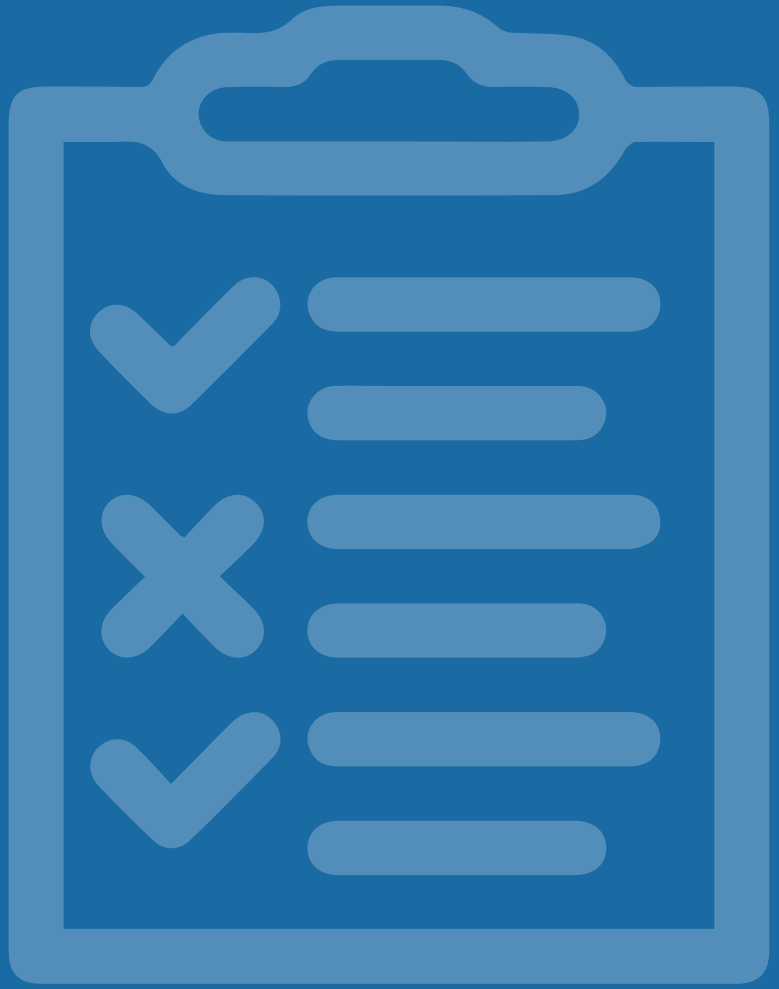
What we'll cover today

- ✓ CMS goals behind the updated regulations
- ✓ Implementation and timelines
  - ❑ Phase 1 Focus Areas
  - ❑ Phase 2 Focus Areas
  - ❑ Phase 3 Focus Areas
- ✓ Tips on working with these RoPs

BACKGROUND



A bit of background

- 1st major regulatory update since 1991
  - Remember OBRA '87?
- RoPs = Requirements of Participation
  - Health & safety standards to be met in order to participate in Medicare or Medicaid programs
  - 42 CFR 483 Subpart B
  - Additional guidance – Appendix PP of State Operations Manual (SOM)
- Proposed rule published July 16, 2015
  - More than 9,800 public comments received
  - Revisions to proposed rule made because of the number of comments
- Final rule published October 4, 2016
  - 713 pages (in case you're counting)

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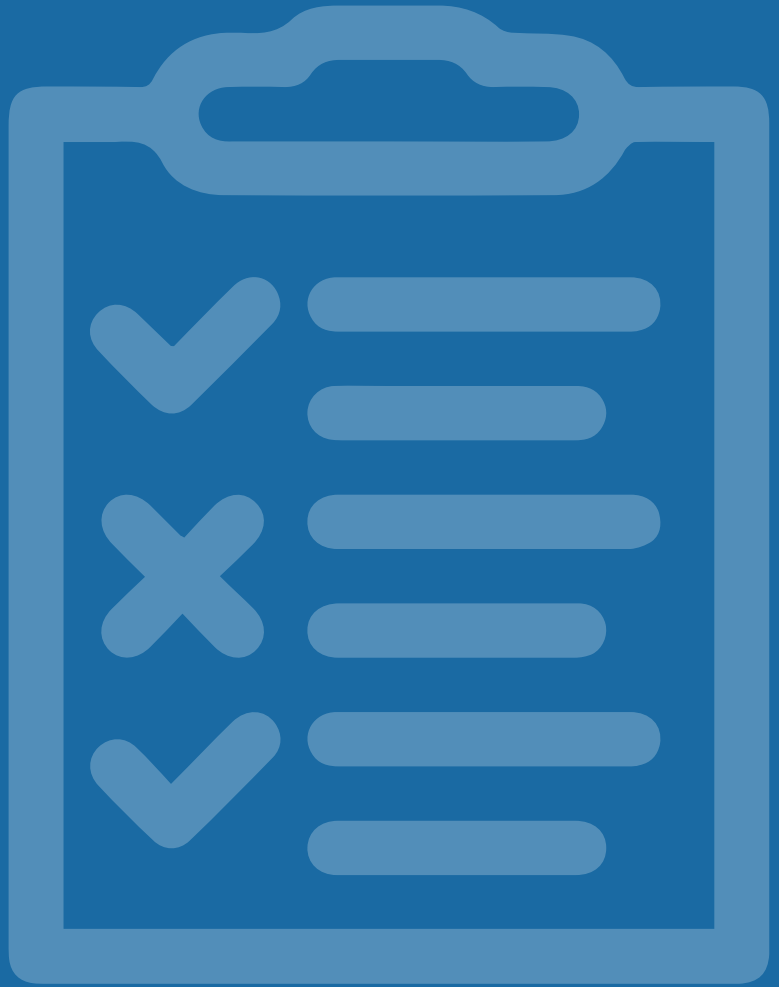
CMS GOALS



CMS Goals/Themes

- Person-Centered Care
- Quality of Life, Quality of Care
- Facility Assessment
- Alignment with HHS Priorities
- Comprehensive Review and Modernization
- Implementation of Legislation

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Let's Break These Goals Down a Bit

- Person-Centered Care
  - Choice!
  - Focus on the resident as the locus of control and support the resident in making their own choices and having control over their daily lives
  - Discharge planning
  - Pre-dispute arbitration agreements to be settled in court
- Quality of Life, Quality of Care
  - Restraints, pain management, trauma-informed care, bowel incontinence, dialysis services
  - Quality Assurance and Performance Improvement (QAPI)

Facility Assessment and Competency-Based Approach

- *Not* one-size-fits-all
- Know your facility, your staff and your residents
- Focus on each resident achieving their highest practicable physical, mental and psychosocial well-being
- Account for and allow for diversity in populations and facilities

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Align with Current HHS Initiatives

- Reducing unnecessary hospital readmissions
- Reducing incidences of healthcare-acquired infections
- Improving behavioral healthcare
- Safeguarding NH residents from the use of unnecessary psychotropic medications

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Comprehensive Review & Modernization

- Consistent with current health & safety knowledge
- Updated & reorganized
  - Reference numbers in regulatory text: F203, F205, and F455 through F469
  - Regulation text: F221, F223-F225, F246, F247, F252, F309, F319, F320, F329, F333

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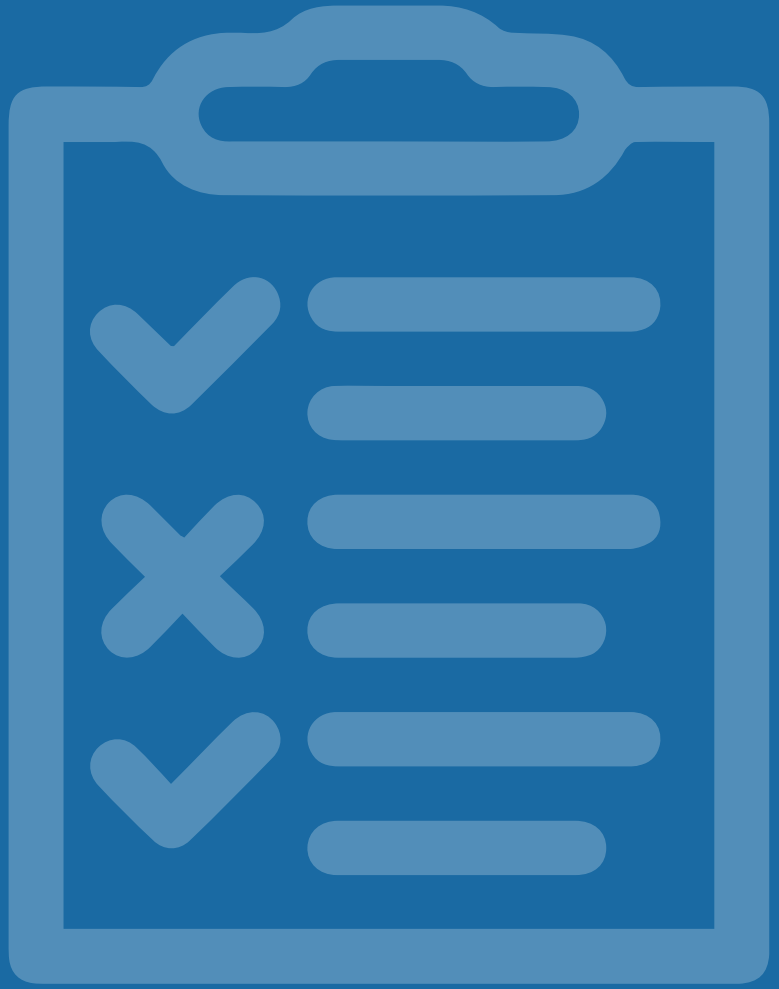
Implementation of Legislation

- Affordable Care Act (ACA)
  - March 23, 2010
  - Compliance programs required by October 23, 2013; regulations not ready on time so CMS dropped this requirement into Final Rule
  - Compliance & ethics program, QAPI, reporting suspicion of crimes to law enforcement, dementia & abuse training
- IMPACT Act of 2014
  - October 7, 2014
  - Discharge planning requirements for SNFs

TIMELINES



Implementation Timeline

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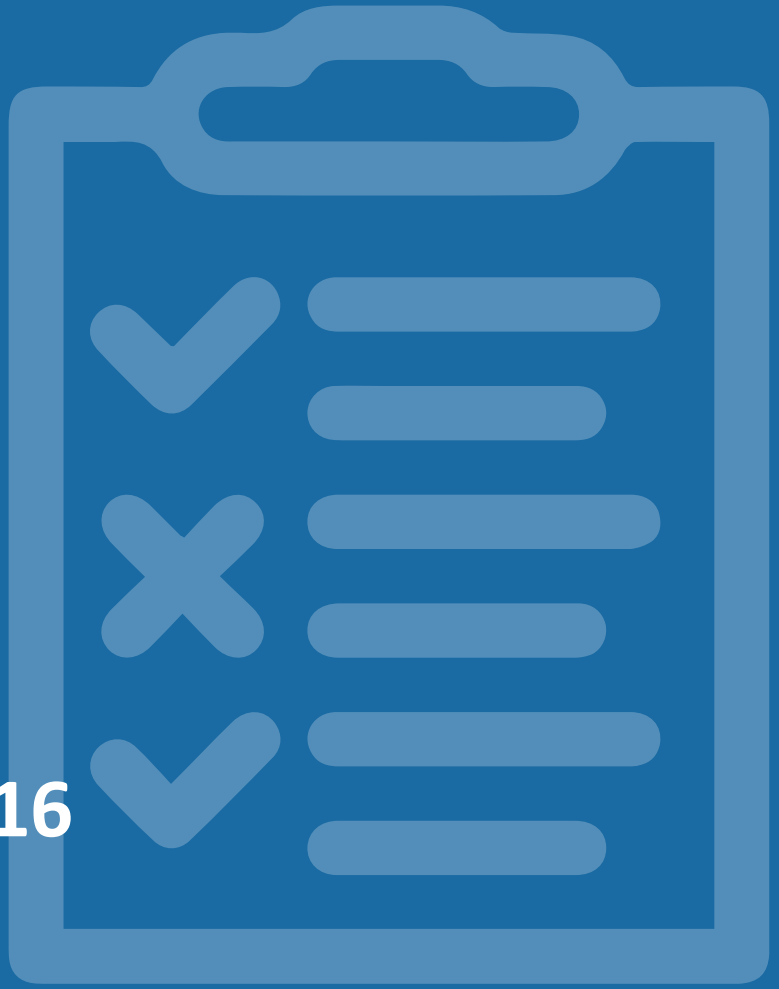
PHASE 1
NOVEMBER 28, 2016



Phase 1 Focus Areas

Phase	Primary Implementation
Phase 1 *(* this section is partially implemented in Phase 2 and/or 3)*	• Resident Rights and Facility Responsibilities* • Freedom from Abuse Neglect and Exploitation* • Admission, Transfer and Discharge* • Resident Assessment • Comprehensive, Person-Centered Care Planning* • Quality of Life • Quality of Care* • Physician Services • Nursing Services* • Pharmacy Services* • Laboratory, radiology and other diagnostic services • Dental Services* • Food and Nutrition* • Specialized Rehabilitation • Administration (Facility Assessment – Phase 2)* • Quality Assurance and Performance Improvement* - QAA Committee • Infection Control – Program* • Physical Environment*

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Resident Rights

- All pre-existing rights retained in addition to new rights
- Reorganizes/updates language
- Advances in electronic communication – cellphones, email, video
- Terminology changes – Resident Representative
- Same sex spouse rights
- Addresses roommate choice
- Fully informed in a language he/she can understand – total health status
- Self-determination through support of resident choice
- Grievances, identify Grievance Officer
- Facility responsibilities regarding resident rights 

    - Promote & protect

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Abuse, Neglect & Exploitation

- Right to be free from neglect & exploitation (additional new language)
- Clarification of abuse, neglect, exploitation, mistreatment
- Coordination with QAPI program
- Staff training, including feeding assistants

Abuse is the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. Instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology. **Willful**, as used in this definition of abuse, means **the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm**.

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Transitions of Care

- Admission, Discharge, Transfer
- Provision of (minimum) information to the receiving entity upon discharge or transfer
  - Demographics, representative information, advance directives
  - HX of present illness, reason for transfer with PCP contact information
  - Past medical/surgical HX with procedures
  - Active diagnoses/current problem list & status
  - Lab tests/results of pertinent lab & diagnostics
  - Functional status
  - Psychosocial assessments including cognition
  - Behavioral health issues
  - Medications, allergies, immunizations
  - Smoking status
  - Vital signs
  - Unique identifiers for implanted devices
  - Comprehensive care plan goals, health concerns, preferences, interventions, efforts to meet resident needs

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Comprehensive Resident Assessment & Care Planning

- Use of RAI/MDS process
- Assessment to include:
  - Needs
  - Strengths
  - Goals
  - Life history
  - Preferences

- IDT to include physician, RN, nursing assistant caring for resident, member of food & nutrition services, social services and resident/resident representative
- Resident-centered care plans; resident right to see & sign care plan after changes
- Discharge plan to be included in care plan along with goals for admission, desired outcomes, preferences and potential for future discharge to the community
- Clarified coordination of PASRR implemented in Phase 1

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Discharge Planning & DC Summary

- Post-discharge plan of care
  - Focus on resident's discharge goals
  - Prepare & encourage residents to be active partners in post-discharge care; IDT also involved in this plan
  - Effective transition from SNF to post-SNF
  - Reduce factors leading to preventable readmissions
- If discharge from facility not feasible, document why & note who made that decision
- Discharge summary to include medication reconciliation of all pre-discharge medications with the post-discharge medications, including OTC
- Facilities must provide prior written notice to resident, resident representative and LTC Ombudsman of all transfers and discharges (involuntary/voluntary; planned/unplanned)

Quality of Life & Care

- ADL abilities clarified
- Minimum requirements for Activity Director
  - Must have completed a training course approved by the state
  - Eligible for certification as activities professional or therapeutic specialist
  - 2 years experience in social or recreational program within past 5 years, 1 of which was FT in an activity program
- Unnecessary medications, med errors & immunizations moved to pharmacy services
- Personnel must provide basic life support – including CPR – subject to the resident's advance directives…no more No-CPR facilities
- Now called assisted nutrition & hydration
  - Enteral/parenteral tubes & fluids

Physician & Nursing Services

- Physician visit prior to transfer from LTC removed
- Physician can delegate dietary orders
    - Qualified dietitian or other qualified nutritional professional in accordance with state law
- Sufficient and competent nursing staff based on facility assessment (tied to Facility Assessment in Phase 2)
    - Capacity
    - Census
    - Acuity
    - Range of diagnoses
    - Care plan content

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Miscellaneous Phase 1 Focus Areas

- Specialized rehab services – respiratory services added
- Qualified dietary staff – also sufficient and competent
- Education requirements for Dietitian & Food Service Manger – 5 year implementation for current employees; 1 year for new hires
- Reasonable efforts to address religious, ethnic & cultural needs of resident (i.e. menus reflect, eating at non-traditional times, etc.)
- Food brought in by family & visitors; use & storage of food
- FT Social Worker for 120+ beds/qualifications
- Incorporation of recent regs re: hospice, PBJ, facility closure

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More Misc. Phase 1 Focus Areas

- Annual review of flu & pneumococcal vaccination programs
- Administrator's accountability to the governing body
- Governing body responsible and accountable for QAPI
- QAPI Committee members
- Updated P&Ps re: infection control & prevention policies including handwashing, storage & processing of linens, immunizations, employees with communicable disease/infection
- New requirements for reconstruction as well as regular inspection of bedframes, bedrails & mattresses
- Visitation policies

PHASE 2
NOVEMBER 28, 2017

Phase 2 Focus Areas

Phase 2	• Behavioral Health Services* • Quality Assurance and Performance Improvement* - QAPI Plan • Infection Control – Facility Assessment and Antibiotic Stewardship ** • Compliance and Ethics* • Physical Environment- smoking policies *

*This section is partially implemented in other phases

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Phase 2 - Specific Focus Areas

- Baseline care plan within 48 hours implemented here; also summary of baseline care plan provided to resident/representative
- Drug regimen review & reporting
    - Must include review of medical chart
    - Forwarding, review & action by physician, DON & Medical Director
- Behavioral health services
    - Highest practicable well-being, specialized rehabilitation & medical social services
    - Resident with dementia has treatment & services to meet his/her needs
    - Non-pharmacological interventions
    - Sufficient, competent staff

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Phase 2 - Specific Focus Areas

- New requirements for facility replacement of lost dentures
- Only thing left from Phase 1 – Resident Rights: providing contact info for Aging & Disability Resource Center and Medicaid Fraud Control Unit
- Transfer & discharge documentation requirements implemented here
- Smoking policies
- Antibiotic Stewardship
    - Monitoring of antibiotic use

Additional Phase 2 – Specific Focus Areas

- PRN usage of psychotropic medications
  - Limitation of PRN orders for psychotropic drugs – 14 days…cannot be continued unless/until the physician evaluates the resident for appropriateness and documents rationale for continuation
  - Verbiage changed from antipsychotic to psychotropic medications
- Compliance & Ethics program
  - C&E Officer
  - Annual review of C&E program
  - Responding to violations
  - Provisions for NH chains/corporations
- Annual (at a minimum) facility assessment implemented in this phase
- Provision of initial QAPI plan provided to Survey Team at annual survey

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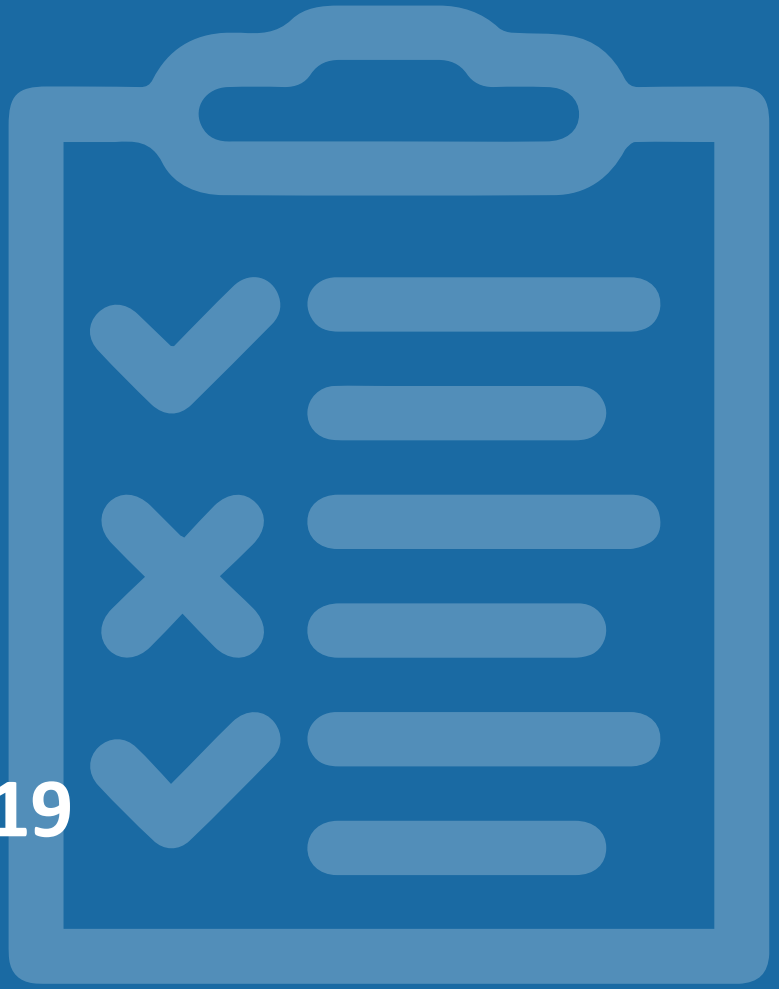
PHASE 3
NOVEMBER 28, 2019



Phase 3 Focus Areas

Phase 3	• Quality Assurance and Performance Improvement* - Implementation of QAPI • Infection Control – Infection Control Preventionist * • Compliance and Ethics* • Physical Environment-call lights at resident bedside * • Training *

*This section is partially implemented in other phases

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Phase 3 – Specific Focus Areas

- QAPI must be involved in review of allegations/incidences of abuse, neglect & exploitation
- Trauma-informed (includes PTSD) care implemented in this phase
- Infection Control Preventionist w/specialized training
    - Must be part of QAPI Committee in this phase
- Resident call next to bed
- Training requirements for all staff, contractors & volunteers

TIPS ON WORKING WITH ROPS

Working with RoPs

- Start now if you haven't already
- Review the Final Rule
- Use the Chunk approach
- Use the February 10, 2017 Appendix PP to get started
- Watch for Interpretive Guidance for Appendix PP to be posted
- Attend education sessions to increase understanding
- Start training your staff
- Use consultants, state & national LTC associations & vendors for assistance in achieving compliance

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Resources

- https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R167SOMA.pdf
- https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-19.pdf

  Revisions to SOM Appendix PP: CMS has revised regulation text into the SOM Appendix PP to correct identified technical errors and correct the numerical order of tags. The revised version was released on February 10, 2017. The regulation text is effective November 28, 2016; the Interpretive Guidance has not been updated. Interpretive Guidance will be revised at a later date.

- https://www.federalregister.gov/documents/2016/10/04/2016-23503/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities
- http://surveyortraining.cms.hhs.gov/pubs/ClassInformation.aspx?cid=0CMS_P1INNHR_PROVIDER (Phase 1 training - available until July 2017)

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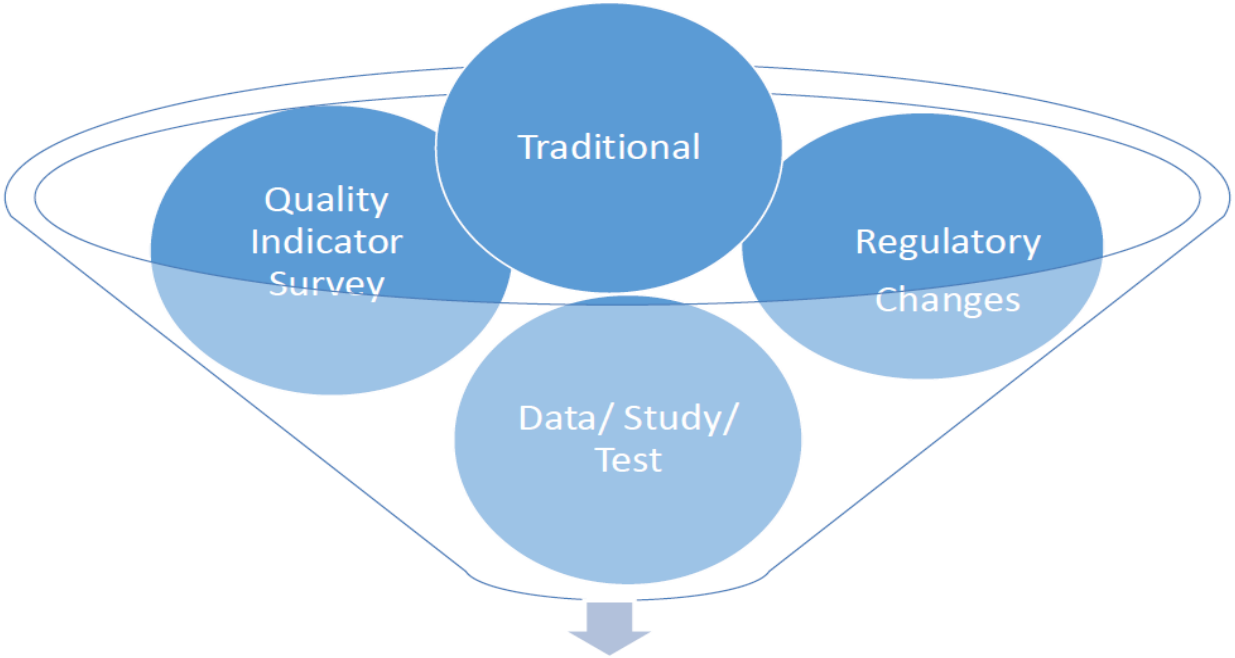
November 2017 (Sneak Peak)



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QUESTIONS & ANSWERS

Thank you for attending!

The webinar recording/slides can be found at:

simpleltc.com/rop

For more info on SimpleLTC software, please visit:

simpleltc.com/products

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Mary Madison is a registered nurse with over 43 years of experience in the healthcare field, with 40 years in the long-term care industry. Mary has held positions of Director of Nursing in a 330-bed SNF, DON in two 60-bed SNFs, Reviewer with Telligen (Iowa QIO), Director of Continuing Education, Manager of Clinical Software Support, Clinical Software Implementer and Clinical Educator. Mary has conducted numerous MDS training and other educational sessions across the country in the past two decades.

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