



# **Changes to the 2016 Federal Nursing Facility Regulations: What's Proposed, What's Final, and What to Do About It**

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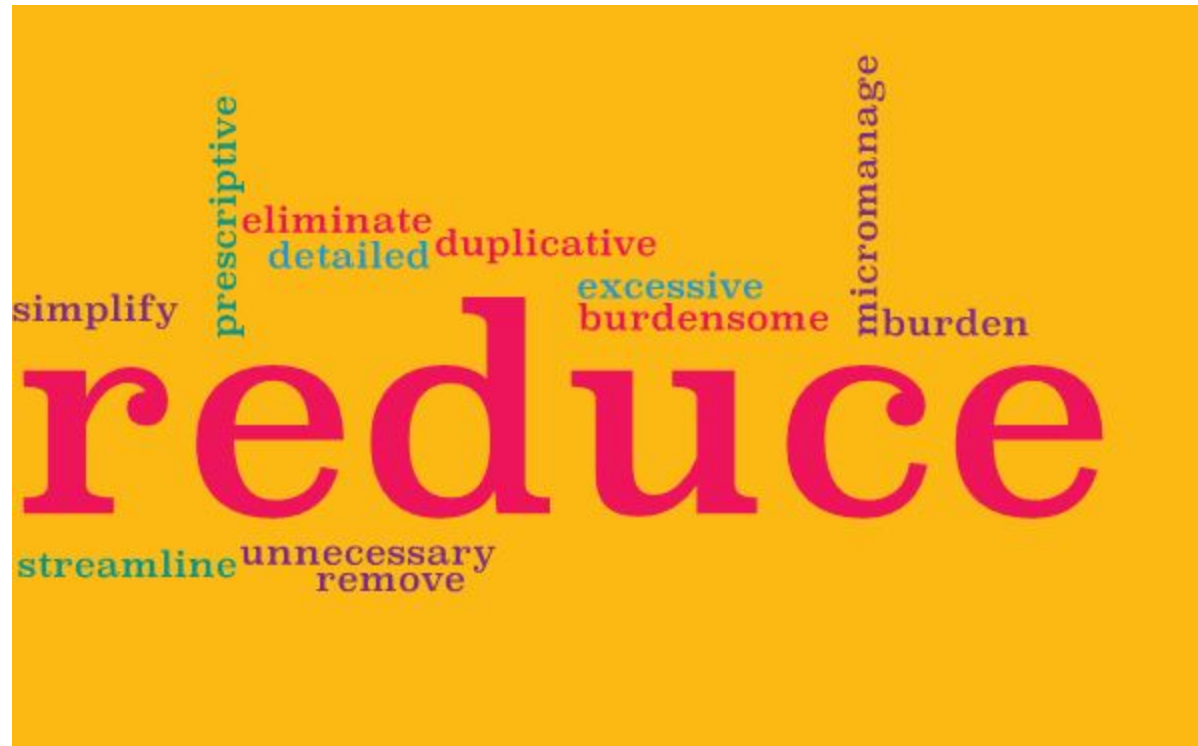
Eric Carlson, Justice in Aging

Robyn Grant, Consumer Voice

Lori Smetanka, Consumer Voice

# Current Federal Nursing Home Regulations

- Issued October 4, 2016
- Important new protections
- Implementation in three phases



# Agenda

- Introduction
  - *Robyn Grant, Director of Public Policy & Advocacy, National Consumer Voice for Quality Long-Term Care*
- Grievances; Admissions/Transfer/Discharge; Nursing Services; Administration (Facility Assessment)
  - *Robyn Grant*
- Behavioral Health Services; QAPI; Compliance and Ethics; Training
  - *Eric Carlson, Directing Attorney, Justice in Aging*
- Pharmacy Services; Infection Control; Physical Environment; Survey, Certification, and Enforcement Procedures
  - *Toby Edelman, Senior Policy Attorney, Center for Medicare Advocacy*
- Arbitration Final Rule
  - *Lori Smetanka, Executive Director, National Consumer Voice for Quality Long-Term Care*
- Q&A
- Advocacy & Closing
  - *Robyn Grant*

# WHAT'S PROPOSED

# GRIEVANCES

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# Grievances

Distinguishes between “general feedback” and “grievances”

§ 483.10(j)(1)

- General feedback: stems from general issues that can typically be resolved by staff present at the time a concern is voiced
- Grievances: more serious and generally require investigation into allegations regarding the quality of care

Right to voice grievances to facility, other agencies/entities would apply only to what the facility defines as grievances

# Grievances

## Eliminates position of Grievance Official § 483.10(j)(4)(ii)

- Facility would identify “an individual” to oversee the grievance process

## Eliminates all the duties of the Grievance Official

- Duties include:
  - Receiving and tracking grievances
  - Leading any necessary investigation
  - Maintaining confidentiality
  - Issuing written grievance decisions
  - Coordinating with state and federal agencies when necessary



# Grievances

- Eliminates majority of information to be included in written grievance decisions § 483.10(j)(4)(v)
- Would only have to include “pertinent information” which would include but not be limited to, a summary of the findings and any corrective actions
- Would not include:
  - Date grievance received
  - Summary statement of grievance
  - Steps taken to investigate grievance
  - Statement about whether grievance was confirmed or not
  - Date of written decision

# Grievances

- Reduces time frame for keeping evidence of grievance results from 3 years to 18 months § 483.10(j)(4)vii)

# ADMISSION, TRANSFER & DISCHARGE RIGHTS

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# Transfers/Discharges

- Limits notices to the ombudsman to facility-initiated, involuntary transfers and discharges § 483.15(c)(3)(i)
  - Would not include emergency transfers to an acute care facility when return is expected

# NURSING SERVICES

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# Nursing Services

- Reduces amount of time facilities must keep posted daily nurse staffing data from 18 to 15 months § 483.35(g)(4)

# ADMINISTRATION

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## Facility Assessment

# Facility Assessment

- Reduces the frequency of reviewing and updating the assessment to at least every two years instead of at least yearly § 483. 70(j)(e)



# Facility Assessment

- Eliminates a facility-based and community-based risk assessment using an all-hazards approach

§ 483. 70(j)(e)(3)

*Note: indicated in Preamble but not in proposed regulation*

# BEHAVIORAL HEALTH SERVICES

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# CMS Proposes to Retain But Shorten Section

- Behavioral Health (Section 483.40)
  - Deleting language relating to highest practicable well-being, assessments, and resident acuity, claiming that this language is duplicative.
  - Deleting language relating to rehabilitative services, claiming that this language is duplicative to the section specifically focused on rehabilitative services.

# QUALITY ASSURANCE & PERFORMANCE IMPROVEMENT (QAPI)

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# Eliminating Specifics

- QAPI (Section 483.75)
  - Must address full range of services at facility, but eliminate specific references to:
    - Care and management practices.
    - Clinical care, quality of life, and resident choice.
    - Evidence of quality that reflects processes that have been shown to be beneficial to residents.
  - Must address feedback and monitoring, but eliminate specific references to:
    - Input from staff and residents on frequent problems.
    - Systems to collect information from all departments.
    - Adverse event monitoring.

# Eliminating Specifics (cont.)

- QAPI (Section 483.75) (cont.)
  - Must address performance improvement through analysis and action, but eliminate specific references to:
    - How to use a systematic approach.
    - How to develop corrective actions.
    - How to monitor effectiveness of performance improvement activities.

# COMPLIANCE & ETHICS

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# Retaining Program, But Eliminating Certain Specific Requirements

- Compliance and Ethics (section 483.85)
  - Change annual review of compliance program to “periodic assessment.”
  - Eliminate requirement for compliance and ethics program contact person for receiving complaints. Facilities can develop their own systems for receiving complaints, which must include ability to submit anonymous complaints.
  - For entities with 5 or more facilities, eliminate requirement of compliance officer and designated compliance liaison. Instead, entity has more discretion, with each facility being required to assign a specific person to oversee compliance.
  - Requirement that high-level personnel oversee compliance, but eliminate “such as” reference to CEO and directors.



# Training on Compliance and Ethics

- Training (Section 483.95)
  - Eliminate requirement that entities with 5 or more facilities conduct annual training on their compliance and ethics programs.
    - The regulations retain the general requirement that facilities communicate the program's standards, policies and procedures.

# HHS Inspector General Has Guidance

- CMS refers facilities to HHS OIG Guidance on compliance programs, at 65 Federal Register 14,289 (2000), and 73 Federal Register 56,832 (2008).

# Basic Requirements of Compliance and Ethics Programs

- Policies designed to reduce criminal and civil violations.
- Persons assigned to oversee compliance.
- Adequate resources.
- No delegation of authority to persons likely to commit violations.
- Steps to communicate program to staff, contract providers, and volunteers.

# Basic Requirements of Compliance and Ethics Programs (cont.)

- Reasonable steps to achieve compliance with program, including monitoring and auditing systems, and enabling persons to make reports without fear of retribution.
- Appropriate disciplinary procedures, including discipline for failure to report.
- System to accept anonymous reports.
- Modifying program as necessary to respond to violations.

# PHARMACY SERVICES

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# Pharmacy Services, § 483.45, pp. 34743-34744

- Proposed change:
  - Removes current limitation that allows PRN (as needed) orders for antipsychotic drugs for 14 days and then requires attending physician or prescribing practitioner to evaluate the resident (CMS guidance says: in person examination.)
  - Makes the rule consistent with rule for other psychotropic medications (i.e., prescriber may document in resident's record and order PRN for more than 14 days).

# Pharmacy Services

- CMS rationale: “feedback from provider community concerning the burden,” p. 34743.
  - Facilities argue negative effect on resident care, especially in small facilities, rural areas.
  - Facilities argue there would be interruptions in resident care.
- But CMS cites Human Rights Watch report “‘They Want Docile’ – How Nursing Homes in the United States Overmedicate People with Dementia” (2018).

# Pharmacy Services

- CMS conclusion:
  - Current requirements could result in interruptions in care.
  - Same rules for PRN orders for psychotropics and antipsychotics “will simplify the survey process and reduce improper deficiency citations” and “remove potential obstacles for mental health professionals to provide quality care for residents,” p. 34744.
- CMS does not anticipate cost savings from the change, p. 34759.



# Pharmacy Services

- CMS solicits comments on whether proposed changes “provide sufficient protection for residents,” p. 34744.
- CMS requests feedback on whether it should retain current policy, impact of current policy, alternative policies, whether 14-day limit is reasonable, whether resident should be re-evaluated before PRN antipsychotic is re-prescribed, etc., p. 34744.

# Pharmacy Services: Concerns

- Antipsychotic drugs are special problem in nursing homes – overprescribed and misprescribed (often, as substitute for adequate staffing), especially for people with dementia (as reported for decades, including HHS Inspector General’s 2011 report; CMS Partnership).
- FDA’s Black Box warnings say these drugs are dangerous for and may kill older people with dementia.
- Final 2016 rule allowed 14 days for PRN antipsychotic drugs (proposed rules had said 48 hours).
- Further loosening rules for antipsychotic drugs is bad policy.

# INFECTION CONTROL

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# Infection Control, § 483.80, pp. 34746-34747

- Proposed change
  - Removes current requirement that infection preventionist (IP), whose job duty is overseeing facility's infection prevention and control program (IPCP), be present "part-time" in facility.
  - Substitutes requirement for IP to spend "sufficient time."

# Infection Control

- CMS rationale:
  - providers expressed concern about burden;
  - most infection control deficiencies cited as D (no harm)
    - average of 15% of facilities cited with infection control deficiency 2000-2007.
- CMS does not anticipate savings from change, which it calls “clarification,” p. 34760.

# Infection Control: Concerns

- CMS reports in preamble, “Infection is the leading cause of morbidity and mortality among the 1.7 million residents.”
  - 1.6-3.8 million infections each year in nursing facilities.
  - Almost 388,000 residents die each year from infections.
  - Infections’ estimated cost \$673 million-\$2 billion each year.
  - (2016 rule also said infections result in 150,000 hospitalizations of residents per year. 81 Fed. Reg. 68688, 68808 (Oct. 4, 2016).)

# Infection Control

- CMS explicitly solicits “specific” comments on how to determine if IP has sufficient time to devote to ICPC, p. 34747.

# PHYSICAL ENVIRONMENT

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# Physical Environment, 483.90, pp. 34748-34749

## Life Safety Code

- Final rules (81 Fed. Reg. 26871, May 4, 2016) adopted 2012 edition of LSC.
- To meet the Fire Safety Equivalency Systems (FSES) in 2012 LSC, facilities would have to improve construction type to provide at least 2 hours of fire rated protection – requiring “burdensome” construction for facilities (\$4.75 million for each of 50 facilities).
- Proposes to allow these 50 facilities to continue using 2001 FSES (CMS estimates savings of \$240 million, p. 34760).

# Physical Environment, § 483.90(e)(1)(i)

## Resident rooms

- 2016 final rules
  - required newly constructed, re-constructed, or facilities first certified after Nov. 28, 2016 to accommodate no more than 2 residents per room ( § 483.90(e)(1)(i)).
  - required newly constructed or facilities first certified after Nov. 28, 2016 to equip each resident room with its own bathroom (including commode and sink) ( § 483.90(f)).

# Physical Environment (resident rooms)

- “[I]ndustry stakeholders have continued to share concerns regarding the burden associated with these requirements, specifically noting that the requirements discourage building, remodeling, upgrading, and the purchase of facilities,” p. 34749.

# Physical Environment

- Proposes to revise requirements for number of residents per room ( § 483.90(e)(1)(5)) and bathrooms ( § 483.90(f)) to apply “only to newly constructed facilities and newly certified facilities that have never previously been a long-term care facility, ”p. 34749.
  - § 483.90(e)(1)(i) would continue to allow up to four residents per room.
- CMS estimates savings in first year of \$328,000,000, less in subsequent years, pp. 34760-34761.

# SURVEY, CERTIFICATION & ENFORCEMENT

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## Survey, Certification, Enforcement, pp. 34749-34751

- In contrast to CMS's approach with RoPs (relaxing or eliminating requirements), CMS adds new more prescriptive language to survey and certification requirements.

# Dispute Resolution, § 488.331

- Proposes to add to informal dispute resolution (IDR) ( § 488.331(b)(1)) language from independent informal dispute resolution (IDDR) the requirement that IDR be completed within 60 days of facility's request for IDR, if facility's request is timely.
- Proposes that facilities be provided with written record of IIDR decision; written statement if CMS disagrees ( § 488.431(a)(2)).
- Proposes to add language from State Operations Manual that survey results not be uploaded to Certification and Survey Provider Enhanced Reports (CASPER) before resolution of IDR or IIDR ( § 488.331(b)(2)).

# IIDR Qualifications

- Proposes to add from SOM the qualifications for approved IIDR reviewer – requiring specific understanding of Medicare and Medicaid ( § 488.431(4)(i)).
- CMS does not estimate savings from change, p. 34761.



## Civil Money Penalties, § 488.436, p. 34751

- Proposes to create “constructive waiver” of right to appeal (that is, facility would no longer have to submit written waiver of appeal rights) and still receive 35% reduction in amount of CMP.
- CMS writes “the constructive waiver process would meet the needs of most facilities facing CMPs.” p. 34751.
- CMS estimates total annual savings to facilities of \$1,108,226; annual savings to CMS of \$125,886, p. 34751.

WHAT'S FINAL

# ARBITRATION AGREEMENTS

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# Background

- October 2016 Final Rules – Banned pre-dispute, binding arbitration agreements
- October – November 2016 – NH Industry goes to court seeking, and receiving, an injunction enjoining enforcement of this section
- December 2016 – CMS directs State Survey Directors not to enforce the arbitration provisions of the rule
- June 2017 – CMS issues new proposed rules that would allow pre-dispute, binding arbitration, including that they could be a condition of admission

# Final Rules published July 18, 2019

- More than 1000 comments
  - “overwhelming majority of commenters” recommended CMS keep the requirements in the 2016 prohibiting the use of these forced arbitration agreements
- 483.70(n)
- Arbitration Rule becomes effective – September 16, 2019

# Pre-Dispute Arbitration Agreements Allowed

*However....*

- Cannot be required as a Condition of Admission
- Cannot be a requirement to continue Receiving Care in the facility
- Facility must explicitly inform residents and representatives of their right NOT to sign the agreement

# Pre-dispute Arbitration Agreements must:

- Provide for selection of a neutral arbitrator agreed upon by both parties
- Provide for the selection of a venue that is convenient to both parties
- Explicitly grant the right to rescind the agreement within 30 calendar days
- Explicitly state that neither the resident or representative is required to sign as a condition of admission or requirement for continuing to receive care

# Pre-dispute Arbitration Agreements may not:

- Contain language that prohibits or discourages the resident or anyone else from communicating with federal, state, or local officials, including:
  - Surveyors
  - Federal or State Health Department Employees
  - Long-Term Care Ombudsman Program Representatives



# Facility must ensure:

- Agreement is explained in a form, manner, and language the resident and representative understand
- Resident or representative acknowledges that s/he understands the agreement
- Right to rescind within 30 days must be explained when facility explains the rest of the agreement

# Retained by the facility

When a dispute is resolved through arbitration, the facility must retain

- (1) The signed agreement for binding arbitration; and
  - (2) The arbitrator's final decision
- For Five (5) years
  - Be available for inspection upon request by surveyors

# Which agreements are covered?

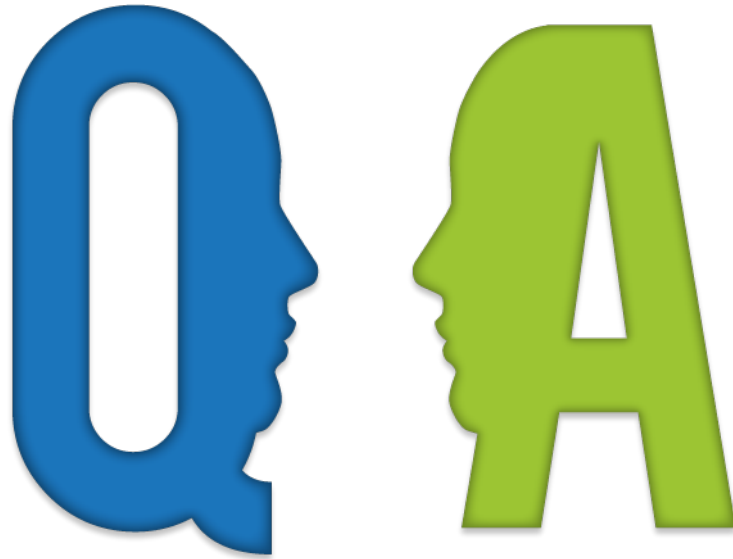
- This rule applies prospectively
- Current, valid agreements are still valid

*“We do believe it would be good policy and we would encourage LTC facilities to offer current residents who have signed arbitration agreements the opportunity to rescind those agreements and proceed with a new agreement that conforms to these regulations.”  
(CMS at 84 FR 34729)*

# Advocacy Steps:

- **EDUCATE** – residents, families, facilities
- **ENCOURAGE** – residents and representatives who have signed to obtain legal advice
- **EVALUATE** – these agreements and admissions packets that contain them for compliance

# Question and Answer



**WHAT TO DO ABOUT IT**

Advocacy: Proposed Nursing Home Regulations

**COMMENT!**

**COMMENT!!**

**COMMENT!!!**

**Due: September 16, 2019**

# Advocacy: Proposed Nursing Home Regulations

**We will help you!**

**Sample comments**

**BUT**

**Even better:**

**Your own comments**

**Personalized sample comments**



# The 3 E's: Final arbitration rule

**Educate Consumers:** Look for materials and training

**Encourage:** Residents and representatives who have signed to obtain legal advice

**Evaluate:** These agreements and admissions packets that contain them for compliance

# Contact Information

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*Thank  
You!*