

**Center for Medicare and Medicaid Services (CMS)
REQUIREMENTS OF PARTICIPATION Final Rule for Nursing Homes
September 2016**

LeadingAge Provider Summary

Background: The new Requirements of Participation for Nursing Homes represent the greatest change in practice and care delivery since the revised rules of 1991. We at LeadingAge, both in the National Office and with each of the State Associations, wish to provide you with as much information as we can about these rule changes. Our goal is to outline the significant changes, let you know the timelines required for compliance, and where possible – offer resources. There will be announcements for webinars, both from the National Office and many of the State Associations, as well as links to other materials on the LeadingAge website and through your State Associations.

Since we are still awaiting the Guidance to Surveyors, much of the information is still at a high level. The guidance documents will be valuable in better understanding how CMS will look to survey for compliance in these various areas. We hope to have the opportunity to comment on draft guidance and will share these documents once we have received them from CMS.

One or more staff members from LeadingAge State Associations or LeadingAge National prepared each section. You may notice some slight differences in language style or format. This was truly a “national” effort by all to get this resource to you as soon as we could.

The summaries are identified by section number and title for your convenience. Each section has: a summary and key points, a timeline for completion, how the rule differs from existing language, what providers need to do, and resources, if any.

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Basis and Scope (§ 483.1)

Effective Date: November 28, 2016.

Summary:

In addition to the specific statutory requirements contained in sections 1819 (Medicare) and 1919 (Medicaid) of the Social Security Act (the Act), the Secretary of the Department of Health and Human Services may establish additional requirements for the health, safety, and well-being of skilled nursing facility/nursing facility (SNF/NF) residents. The Final Rule retains existing statutory and regulatory authority of the Requirements of Participation for long-term care facilities, adds new requirements, eliminates existing duplicative or unnecessary requirements, and reorganizes certain requirements at 42 CFR Part 483. CMS has updated this section by amending the statutory authority in accordance with changes made under the Affordable Care Act (ACA). Citations are added for sections 1128(b) and (c) and section 1150(b) of the Act, to include the compliance and ethics program, quality assurance and performance improvement (QAPI), reporting of suspicion of crime requirements, and dementia and abuse prevention training for nursing assistants.

What does this mean for providers?

Basis and scope are included in Phase 1 with implementation effective by November 28, 2016. Providers should begin preparing for compliance with the respective new and revised requirements.

Next steps

Providers will be expected to revise facility policy and procedures to reflect the new and revised requirements.

Definitions (§483.5)

Effective Date: November 28, 2016 (Phase 1).

CMS has added and/or revised definitions including “adverse event”, “documentation”, “resident representative”, “abuse”, “sexual abuse”, “neglect”, “exploitation”, “misappropriation of resident property”, and “person centered care”. The definitions for “facility”, “distinct part”, and “major modification” are retained.

Summary

- **Abuse** is “...the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish.” It includes deprivation by an individual of goods or services necessary to attain or maintain physical,

mental, and psychosocial well-being. Also, verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through use of technology.

- **Willful** means the individual must have acted deliberately, not that he/she must have intended to inflict injury or harm.
- **Adverse event** is an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof.
- **Common area** is expanded to recognize the inclusion of living rooms or other similar areas where residents gather.
- **Exploitation** means taking advantage of a resident for personal gain through the use of manipulation, intimidation, threats, or coercion.
- **Misappropriation of resident property** is the deliberate misplacement, exploitation, or wrongful, temporary, or permanent use of a resident's belongings or money without the resident's consent.
- **Mistreatment** is inappropriate treatment or exploitation of a resident.
- **Neglect** is the failure of the facility, its employees or service providers to provide goods and services to a resident necessary to avoid physical harm, pain, mental anguish, or emotional distress.
- **Nurse aide** is amended to include those individuals who furnish services who provide these services through an agency or under contract.
- **Person-centered care** means to focus on the resident as the locus of control and support the resident in making their own choices; having control over their daily lives.
- **Resident representative** is an individual chosen by the resident to act on his/her behalf to support decision-making; access medical, social or other personal information; manage financial matters, receive notifications; a person authorized by State or Federal law to act on behalf of the resident in decision-making access medical, social or other personal information; manage financial matters, receive notifications; legal representative; court-appointed guardian or conservator.
- **Sexual abuse** is non-consensual sexual contact of any type with a resident.
- **Licensed health professional** adds respiratory therapist and certified respiratory therapy technician.

What does this mean for providers?

Definitions are included in Phase 1 with implementation effective by November 28, 2016. Providers should begin preparing for compliance with the respective new and revised definitions.

Next steps

Providers will be expected to revise facility policy and procedures to reflect and apply the new and revised definitions.

Resident Rights (§483.10)

Effective Date: November 28, 2016 (Phase 1), with the exception of §483.10(g)(4)(ii)-(v) (relating to a resident’s receipt of certain notices from the facility), which will be effective November 28, 2017 (Phase 2).

Summary:

Revised §483.10 does the following: (i) retains all of the requirements from current §483.10, but renumbers, reorders, and revises the wording of many of those requirements; (ii) incorporates various resident rights provisions currently located in §483.15, and revises the wording of many those provisions; and (iii) includes the “Facility Responsibilities” that CMS had proposed to include in a new §483.11, but with revisions to some of those proposed rules.

CMS has combined proposed §483.10 and §483.11 to create a comprehensive section that includes in a single location both statements of resident rights and the attendant facility responsibilities to support those rights. Person-centered care is an overarching principle of this section.

For a cross-walk showing how current §483.10 and certain aspects of current §483.15 are incorporated into new §483.10, see Table 1 of the Final Rule. What follows is a summary of key points in new §483.10(a)-(k):

§483.10(a) Residents Rights

- Introductory language expands on existing requirements that reinforce a resident’s right to dignity, self-determination and person-centered care, and includes a statement that the facility must protect and promote the rights of the resident. CMS explains that the “protect and promote” language is meant to ensure clarity that it is a facility’s responsibility to recognize/effectuate resident rights.
- Relocates language from current rule §483.12(c) regarding equal access but adds the underlined language: “The facility must provide equal access to quality care regardless of diagnosis, severity, condition or payment source.” The preamble explains that the provision is not intended to require that every facility have every possible capability and unlimited capacity, but neither is it intended to facilitate selective admissions or transfers.

§483.10(b) Exercise of Rights

- Adds new language that a resident has a right to be supported by the facility in the exercise of his or her rights.

- Adds new language detailing the right of a resident not adjudicated incompetent to designate a representative, the right of the representative to exercise the resident's rights, and the facility's obligation to treat the representative's decisions as those of the resident.
- Adds new language to confirm the same-sex spouse of a resident must be afforded treatment equal to an opposite-sex spouse if the marriage was valid where it occurred.
- Adds new language requiring a facility to report concerns if it has reason to believe a resident representative is not acting in the resident's best interests.
- Adds new language addressing the role of a court-appointed resident representative in cases where a resident is adjudged incompetent, including requirements to ensure that a resident continues to have a role in care planning even when adjudged incompetent: (i) where a court has granted only limited powers to a guardian/other representative, the resident retains rights; (ii) representative must consider the resident's wishes and preferences, and (iii) resident must be provided opportunities to participate in care planning, to the extent practicable.
- Note: These provisions frequently refer to the relevance of applicable state law to the issues addressed, so providers will need to review the new provisions in that light.

§483.10(c) Planning and Implementing Care

- Adds new, detailed statements of a resident's right to participate in the development and implementation of his or her person-centered plan of care, including requirements that affect both the initial planning process and changes to the plan of care. Among other requirements, the planning process must facilitate inclusion of the resident/representative, assess both strengths and needs, and incorporate his/her personal and cultural preferences.
- Adds new provisions (broadly consistent with current rules and interpretive guidelines) specifying the right of residents to receive advance information about his/her care, type of professional delivering care, and risks and benefits of treatments and options.
- Broadens current §483.10(b)(4) to state that a resident not only has a right to refuse treatment and refuse experimental research, but also the right to request treatment and/or discontinue treatment.
- Revises current §483.10(n) (self-administration of drugs) by changing the term "drugs" to "medications" and stating that the interdisciplinary team must determine that self-administration is "clinically appropriate," rather than "safe" as stated in the current regulation.

§483.10(d) Choice of Attending Physician

- Notably, CMS has withdrawn proposed §483.10(c)(2), which would have required that physicians meet facility credentialing requirements.

- Consistent with current regulations, this section states that a resident has a right to choose his or her attending physician, but then adds new provisions that:
 - the physician must be licensed to practice and must meet applicable regulatory requirements, and
 - in the event the facility determines that a physician is not meeting those requirements and seeks alternative physician participation, the facility must discuss this with the resident and honor the resident’s preference among options/selection of a new physician.
- Broadens current §483.10(b)(9) (contact information for resident’s physician) so that it applies both to the physician and other primary care professionals responsible for the resident’s care; also revises the language from “the facility must inform” to “the facility must ensure that each resident remains informed” of this information.

§483.10(e) Respect and Dignity

- Adds new language stating the resident has the right so share a room with his or her roommate of choice when practicable, when both residents live in the same facility and both consent to the arrangement.
- Revises the current right to receive written notice before a change of room or roommate, by adding that the notice must include the reason for the change.
- Revises the current right to refuse to transfer to another room in certain circumstances by adding that the resident may refuse if the transfer is purely for the convenience of staff.

§483.10(f) Self-Determination

- Amends §483.15(b)(1) as follows (underlined language is new): The resident has the right to (1) choose activities, schedules (including sleeping and waking times), health care and providers of health care services consistent with his or her interests, assessments, plan of care and other applicable provisions of this part.
- Amends §483.15(b)(3) to add that a resident has a right to participate in community activities.
- Visitation:
 - Adds new general language affirming the resident’s right to receive visitors of his/her choosing, and to deny visitation, in a manner that does not impose on the rights of another resident.
 - Amends current §483.10(j)(1) by adding the resident representative to the list of visitors who are entitled to immediate access to the resident, without condition.
 - Amends current §483.10(j)(1)(viii), relating to “others who are visiting with the resident’s consent,” by requiring any imposed limitations relate to clinical and safety restrictions.

- Adds a new requirement for facilities to have written policies and procedures regarding visitation, including any restrictions and the rationale.
- Adds new language requiring facilities to provide certain visitation-related information to residents.
- Adds new language requiring facilities not to discriminate, and to ensure full and equal rights of all visitors.
- Resident and family groups:
 - Adds a requirement for the facility to take reasonable steps, with the approval of the group, to make residents and family members aware of upcoming meetings in a timely manner.
 - Adds a requirement that the staff member designated to assist and respond must be approved by the resident or family group and the facility.
 - Revises current language relating to a facility's response: (i) requires that a facility must consider (currently "listen to") the views of a resident or family group, (ii) that it must act upon grievances and recommendations promptly (not defined), and (iii) the facility must be able to demonstrate its response and rationale.
 - Regarding family groups: (i) Adds language that a resident has a right to participate in family groups; (ii) reframes the language to say the resident has a right to have family groups (including, under the new language, other resident representatives besides family) meet in the facility, rather than stating that a resident's family itself has that right.
- Financial affairs/resident funds
 - Adds a requirement that, if a resident chooses to deposit personal funds, the facility must act as a fiduciary of those funds; this is consistent with the current interpretative guidelines, but it is meaningful to have it added to the regulation itself.
 - Adds new language to clarify the different thresholds (\$100 v. \$50) that require resident funds to be deposited in an interest bearing account.
 - Current regulation requires a facility to convey resident funds and a final accounting within 30 days of a resident's death; the new regulation extends these requirements to discharge and eviction (i.e. involuntary discharge) scenarios.
 - In the list of items and services for which a facility may not charge during a Medicare- or Medicaid-covered stay: (i) amends "dietary services" to "food and nutrition services"; amends "bathing" to "bathing assistance"; and adds "hospice services elected by the resident and paid for under the Medicare Hospice Benefit or paid for by Medicaid under a state plan."
 - Current regulation identifies items and services a facility may charge to resident funds, so long as certain conditions are met. The new rule affects this requirement as follows: (i) adds introductory language stating that the facility may not charge if

the item/service is “required to achieve the goals stated in the resident’s care plan”; (ii) adds references to modern electronic devices; (iii) adds “cost to participate in” with reference to social events; and (iv) states the facility may not charge for special food and meals ordered by a practitioner, consistent with §483.60.

- If a resident requests a non-covered item or service, the new regulation adds a requirement that a facility must inform the resident about applicable charges both orally and in writing.

§483.10(g) Information and Communication

- Resident Access to Records
 - Updates language to state that a resident has right to access – and facility must provide – personal records in addition to medical records.
 - Requires the facility to provide records in the form and format requested by the resident, if readily producible, or if not in hard copy or other agreed upon form.
 - Consistent with recent guidance from the Office of Civil Rights regarding access to protected health information, the new rule specifies that a facility may impose only a reasonable cost-based fee in relation to records requests.
- With the exception of information described in §483.10(g)(2) (personal and medical records)(facilities can charge residents for translated summaries of these records) and 483.10(g)(11) (survey results and related materials), a facility must ensure that information is provided in a form and manner the resident can access and understand, including in an alternative format or in a language the resident can understand.
- New §483.10(g)(4) specifies various notices which a resident has a right to receive from the facility both orally (meaning spoken) and in writing (including Braille) in a format and language he or she understands. The categories are generally consistent with current requirements, but there are some updates and additions.
- Postings:
 - Current §483.10(b)(7)(iii) requires facilities to post contact information for all pertinent state client advocacy groups. New §483.10(g)(5) does three things:
 - Amends (b)(7)(iii) to require that email addresses be included in that posting;
 - Adds a new requirement that facilities post a written statement that a resident may file complaints with the state survey agency, in addition to including that information in a written notice of rights provided to the resident; and
 - States that facility postings must provide information in a form and manner accessible and understandable to residents and resident representatives.
 - The new rule expands the current requirement relating to posting survey results:
 - In its preamble, CMS states that it has finalized new §483.10(g)(11)(i) to make clear that a facility must post the results of the most recent survey in a

readily accessible place, without the requirement for a request by a resident (or family, etc.) to examine them.

- §483.10(g)(11) adds a new requirement that facilities have three years of “reports with respect to any surveys, certifications, and complaint investigations” available for review upon request, and that facilities post a notice about their availability in areas that are prominent and accessible to the public.
- Communications
 - The current rule provides a resident has a right to reasonable access to use of a phone; the new rule updates this right to include TTY and TDD services, as well as use of a cell phone at the resident’s own expense.
 - New §483.10(g)(7) adds a new general requirement that a facility must protect and facilitate a resident’s right to communicate with individuals and entities within and external to the facility, including reasonable access to the internet, to the extent available to the facility. §483.10(g)(9) creates additional new language on this topic, stating that the resident has the right to have reasonable access to and privacy in their use of electronic communications such as email and video communications and for internet research – provided the access is available to the facility, at the resident’s expense if the facility incurs costs, and the use complies with state and federal law (e.g. does not involve access to illegal on-line content, etc.)
- Notification of Changes: Under current §483.10(b)(11) a facility must notify the resident and, if known, family/legal representative, and consult with the resident’s physician, under certain listed circumstances.
 - Under new §483.10(g)(14)(i) the list of circumstances is the same, except that, with respect to a “need to alter treatment significantly,” the new rule makes clear that this includes a need to change a current treatment, in addition to discontinuing a current treatment or commencing a new treatment, as stated in the current rule.
 - When providing information to a physician under this section, the new rule requires that facilities ensure that all pertinent information specified in new §483.15(c)(2) (which requires that certain information be provided to a receiving provider for a transfer including all special instructions or precautions for ongoing care and the contact information of the practitioner responsible for the care of the resident) is available and provided upon request to the physician.
 - The new section inserts references to resident representative in various places, and requires that facilities keep an up-to-date email address on file for the resident representative.

- The current rule requires facilities to provide information about Medicaid-covered and non-Medicaid covered services (i) to residents “entitled to Medicaid” and (ii) at the time of admission to the nursing facility or when the resident becomes eligible for Medicaid. New §483.10(g)(17) makes two changes here where clarification will be needed from CMS: (i) changes “entitled to Medicaid” to “eligible for Medicaid” and (ii) changes at the time of admission or when eligible to at the time of admission and when eligible.
- Current §483.10(b)(6) requires that the facility must inform each resident before, or at the time of admission, and periodically during the resident’s stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility’s per diem rate. The new rule adds five sub-requirements:
 - Notice as soon as reasonably possible of changes to Medicare and/or Medicaid coverage
 - 60 day advance written notice of changes in charges for non-Medicare/non-Medicaid-covered services
 - If a resident dies or is hospitalized or is transferred and does not return to the facility, the facility must refund to the resident, resident representative, or estate, as applicable, any deposit or charges already paid, less the facility’s per diem rate, for the days the resident actually resided or reserved or retained a bed in the facility, regardless of any minimum stay or discharge notice requirements
 - Payment of any and all refunds due within 30 days of discharge.
 - The terms of an admission contract by or on behalf of an individual seeking admission to the facility must not conflict with the requirements of these regulations.

§483.10(h) Privacy and Confidentiality

- Expands current language granting ombudsman representatives the right to examine a resident’s clinical records; the new rule states “medical, social and administrative records”; CMS explains this is a necessary change to conform to the separate, recently-finalized federal rule governing the ombudsman program.
 - Notably, the new rule drops language about “with resident permission,” and CMS clarification should be sought.
- For more information about privacy of records, see new §483.70(i).

§483.10(i) Safe Environment

- The rule adds new language that a resident “has a right to a safe, clean, comfortable and homelike environment, including but not limited to receiving treatments and supports for daily living safely.”
- It expands current §483.15(h)(1) by stating that the facility’s obligation to provide a safe, clean and homelike environment includes:

- ensuring that the resident can receive care and services safely and that the physical layout of the facility maximizes resident independence and does not pose a safety risk; and
- the facility shall exercise reasonable care for the protection of the resident's property from loss or theft.

§483.10(j) Grievances

- The new rule includes a lengthy and detailed set of requirements relating to grievances. Highlights of the new key requirements include:
 - Establishment of a facility grievance policy
 - Resident notification requirements regarding grievances
 - Identifying a Grievance Official responsible for overseeing policies (does not have to be the person's only job)
 - Specifications for written grievance decisions, and
 - Maintaining 3 years of evidence demonstrating the results of all grievances

§483.10(k) Contact with External Entities

- States that a facility may not prohibit or in any way discourage a resident from communicating with federal, state or local officials regarding any matter.

What does this mean for providers?

Phase 1 requirements will be effective November 28, 2016, meaning providers should begin preparing now in order to be in compliance. While many of the new sections cover existing resident rights without making significant changes, CMS has revised and updated the language in many instances, so careful reading of familiar provisions is important. At the same time, CMS has expanded selected existing rights in substantive ways, and has added new rights and provider responsibilities.

What are next steps/ what do nursing home providers need to do to comply?

- On many issues covered in this section, CMS indicates that it will provide additional detail in its interpretive guidance. Providers should be sure to obtain and study that guidance when CMS releases it, and any related announcements from state survey agencies.
- Identify necessary changes to written notices and posters currently in use (bill of rights pamphlets, standard notifications covered by these new regulations, etc.)
- Examine and update, if needed, a facility's policies, procedures and protocols relating to engagement with resident representatives, as defined in the new rule. Read the new federal regulations in conjunction with applicable state law, clarifying the latter if needed.

- Review the summary above of §483.10(c) together with the summary of §483.21 and identify process changes necessary to comply with new, person-centered care planning requirements.
- Develop procedures relating to confirmation of licensure for a resident's attending physician; ensure policies and procedures align with new requirements relating to a facility's determination that alternative physician involvement is needed.
- Develop systems for accommodating the roommate-of-choice requirement, and for notifying residents of room or roommate changes.
- Prepare written policies and procedures relating to visitation, as now required by 483.10(f).
- Determine a process for reaching and documenting agreement with resident/family groups about what staff will serve as liaison.
- Work with billing/financial personnel to identify changes necessary to comply with the requirements relating to financial issues, resident funds, and covered- and non-covered charges set forth in 483.10(f) and 483.10(g).
- Assess your readiness to meet the general requirement in §483.10(g) to provide a broader range of information in a form and manner a resident can access and understand, including in an alternative format or in a language the resident can understand.
- Identify tools/resources that can be used to assess your physical environment as it relates to safety risks but also maximization of resident independence.
- Evaluate current policies/procedures for protecting resident property from loss and theft; focus must be on prevention.
- Prepare a written policy and procedure relating to grievances, being sure to include all of the required elements specified in 483.10(j).

Freedom from Abuse, Neglect and Exploitation (§ 483.12)

Effective Date: November 28, 2016 (Phase 1), with two exceptions:

- §483.12(b)(4) requiring a facility to develop and implement written policies and procedures that establish coordination with the QAPI program required under §483.75 will be implemented in Phase 3 (November 28, 2019).
- §483.12(b)(5) requiring a facility to develop and implement written policies and procedures that ensure reporting of crimes in accordance with section 1150B of the Social Security Act (the Elder Justice Act requirement) will be implemented in Phase 2 (November 28, 2017).

Summary:

CMS re-designates current section §483.13 “Resident Behavior and Facility Practices” as §483.12 and retitles it as “Freedom from Abuse, Neglect and Exploitation,” to more accurately reflect the section’s contents and intent.

What follows is a summary of §483.12, noting changes from the current rule when applicable:

- The new rule adds “exploitation” (see definition below) to the list of actions/occurrences from which a facility must protect its residents and incorporates the concept into the various elements of §483.12 (employment prohibitions, prevention, training, reporting, investigating, etc.)
- Consistent with the current rule, the new rule addresses the inappropriate use of restraints. CMS also addresses restraints in §483.25 “Quality of Care and Quality of Life”. It is unclear where CMS will position its interpretive guidelines on this topic.
- The current rule prohibits facilities from employing certain individuals (list below). The new rule expands this by stating that facilities may not employ or otherwise engage such individuals – meaning that it includes individuals who provide services under a different arrangement, such as a volunteer or a contractor. In the preamble to the new rule CMS states that facilities must exercise reasonable care in selecting volunteers and contractors and promises to provide additional, sub-regulatory guidance on this issue.
- The new rule expands the list of individuals whom a facility may not employ or otherwise engage:
 - The current rule prohibits facilities from employing individuals who have been found guilty of abuse, neglect, or mistreatment by a court of law. The new rule adds exploitation of residents and misappropriation of resident property to that list.
 - The current rule prohibits facilities from employing individuals who have had a finding entered into the state nurse aide registry concerning abuse, neglect, or mistreatment of residents or misappropriation of their property. The new rule adds exploitation of residents to that list.
 - The new rule adds a category that the current rule does not include, stating that a facility may not employ or otherwise engage a person who has a disciplinary action in effect against his or her professional license by a state licensure body as a result of a finding of abuse, neglect, exploitation, mistreatment of residents or misappropriation of resident property. CMS notes that this prohibition applies to

disciplinary actions against a professional license that are currently in effect, which leaves facilities some flexibility to exercise discretion with regard to previous disciplinary actions. As to the scope of inquiry that facilities will be required to make, CMS states in the preamble that it will expect a facility to check the state in which the facility is located and potentially bordering states or other states the individual is known to have been licensed in, based on his/her resume or other employment information available to the facility. Further guidance is expected on this topic.

- The new rule retains and does not change the existing requirement that a facility must report to the state nurse aide registry or licensing authorities any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff.
- The new rule states that facilities must develop and implement written policies and procedures that prohibit and prevent abuse, neglect, and exploitation of residents and misappropriation of resident property, and establish policies and procedures to investigate any such allegations. This is consistent with current interpretive guidelines, but the regulation itself now requires written policies. Note, again, the addition of exploitation.
- A facility's written policies and procedures must include the new training requirements for abuse, neglect and exploitation set out in §483.95.
- The new rule adds the requirement that facility's policies and procedures must coordinate with the QAPI program required under §483.95, to be implemented in Phase 3.
- New §483.12(b)(5) requires facilities to establish policies and procedures to ensure reporting of crimes in accordance with section 1150B of the Social Security Act (the "Elder Justice Act" reporting requirements). The regulation is consistent with the Act and previous survey and certification guidance, to be implemented in Phase 2.
- In response to public comments, CMS is aligning the reporting requirements for reporting a reasonable suspicion of a crime in §483.12(b) and the requirements for reporting allegations of abuse, neglect, and exploitation in §483.12(c). New §483.12(c) will require that facilities: "ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, are reported immediately, but not later than 2 hours after the allegation is made, if the events that cause the allegation involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the

allegation do not involve abuse and do not result in serious bodily injury, to the administrator of the facility and to other officials (including to the State Survey Agency and adult protective services where state law provides for jurisdiction in long-term care facilities) in accordance with State law through established procedures.”

- The new rule adds adult protective services to the list of officials who must be notified in accordance with state law, where state law provides for jurisdiction in long-term care facilities.
- Under the current rule, a facility must prevent further potential abuse from occurring while it investigates an alleged violation of the rule. The new rule is broader and makes clear that a facility must prevent any further violation from occurring during its investigation – whether it be abuse, neglect, exploitation, or mistreatment.

What does this mean for providers?

Phase 1 requirements will be effective November 28, 2016, meaning providers should begin preparing now in order to be in compliance. Providers should be sure to watch for CMS’ release of interpretive guidance about this section. That guidance will be especially important to understanding the new concept of exploitation, for example.

What are next steps / what do nursing home providers need to do to comply?

1. Revise policy and procedures to reflect the new requirements, including all new and revised definitions, including the new concept of exploitation.
2. Revise policies and procedures for applicant screening and employee discipline to reflect the revised employment prohibitions; extend the same to individuals whom a facility does not employ but otherwise engages – such as a volunteer or contractor.
3. Compare existing staff training to the requirements in new §483.95, and align as needed.
4. As you begin to develop your QAPI program and written plan, note the Phase 3 requirement to ensure that a method for monitoring of incidents (trends, patterns etc.) indicating abuse, neglect, misappropriation and exploitation are reviewed and discussed within the QAPI program.
5. Reporting: (1) Determine if adult protective services (APS) has jurisdiction in long-term care facilities in your state; if so revise reporting protocols to include APS; (2) Work with your state survey agency on implementation of new 483.12(c) regarding timing of reports.

Admission, Transfer and Discharge Rights (§483.15)

(In the proposed rule titled Transitions of Care)

Effective Date: November 28, 2016 with the following exception:

(c)(2) Transfer/Discharge Documentation—Implemented in Phase 2, November 28, 2017.

Summary:

- §483.12 “Admission, Transfer and Discharge Rights” is now §483.15 “Admission, Transfer and Discharge Rights”. While the section title remains the same, the intent of the revisions to the section is to reflect all instances where care of a resident is transitioned between provider/care settings and community settings. This section also cross-references §483.5 “Definition of Transfer and Discharge”, §483.21 “Comprehensive Person Centered Care Planning” and §483.10 “Resident Rights”.
- Incorporates the new definition of resident representative – an individual chosen by the resident to act on their behalf; person authorized by State or Federal law.
- Updates terminology for admissions, transfers and discharges including resident rights changes. This section reflects all instances of transitioning a resident between care settings.
- Clarifies for the resident what constitutes a composite distinct part of an organization (e.g. Dementia Unit, Medicare Unit, Behavioral Health Unit, etc.)
- Clarifies resident rights around transferring from a composite distinct part to another location in the organization, medically necessary or voluntarily agree to the move.
- Facility must establish and implement an admissions policy, which is not the same as an admissions agreement. A facility must have a policy, it must be compliant with the requirements for participation, and that the facility must follow it. This increases provider responsibility and outlines areas that will need to be added to the admission agreement. It clarifies definitions and communicates facility policies to resident / representatives related to:
 - distinct language related to rights around admission and transfer from a composite distinct unit,
 - disclosure in the admission agreement of its physical configuration, including the various locations that comprise the composite distinct part, and
 - specification of the policies that apply to room changes between different locations.

- Residents or potential residents – facility cannot request or require residents or potential residents to waive their rights to Medicare/Medicaid benefits
- Facility must not request or require a third party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in facility.
- Facility may ask representative to sign the admission agreement if they have legal access to resident resources, without incurring personal financial responsibility, to provide payment from the resident resources.
- Facility must establish, maintain, and implement identical policies for transfer, discharge, and the provision of services for all individuals regardless of payment.
- Facility may charge any amount for services furnished to non-Medicaid residents unless otherwise limited by state law.
- Equal access to quality care – must provide same access to care regardless of pay source – specific language related to provider responsibilities for establishment and implementation of policies and practices regarding transfer and discharge and the provision of services regardless of pay source
- Right to not waive rights related Medicare, Medicaid, arbitration, and loss of property. Binding arbitration agreements cannot be used until after a dispute arises between parties. Prohibits facility use of pre-dispute arbitration agreements.
- Clarifies when a resident can be discharged and how it must be handled.
- Clarifies physician documentation related to basis for transfer, the residents' needs that cannot be met at the facility, the facility attempts to meet the residents' needs and the services available at the receiving facility to meet the resident's needs.
- Includes communication expectations during transitions of care, admission, transfer, and discharge – including the exchange of pertinent clinical and non-clinical information.
- Clarifies bed hold and facility requirements.

- Need for policy on permitting residents to return following leave of absence (LOA) per updated requirements. Must have written policy on permitting residents to return to facility after they are hospitalized or placed on therapeutic leave. The policy must include specific provisions outlined in the regulation.
- Facility closure language revisions and policy changes.
- Transfer and Discharge - new language and facility requirements.
 - Reasons for transfer or discharge have been further clarified. Updates to language to be in alignment with new standards of practice. Includes further clarification between the terms safety and health.
 - Transfer or discharge must be documented and include:
 - Contact information of the practitioner responsible for the care
 - Resident representative information
 - Advance directive information
 - All special instruction or precautions for ongoing care
 - Comprehensive care plan goals
 - History of present illness
 - Document if there is danger that failure to transfer or discharge would pose
 - Reason for transfer
 - Needs that cannot be met and facilities attempt to meet the residents needs and the available services at the receiving facility to meet those needs
 - Past medical/surgical history
 - Exchange with receiving provider or facility
 - Appeal rights
 - Further clarification for physician documentation related to transfer or discharge
 - Additional clarification on what information is provided to the receiving provider
 - Involuntary transfer and notice of transfer – Update language and clarification related to this type of transfer and required notices (e.g. timing, content, appeal rights, intellectual disability and mental illness)
 - Orientation of resident for transfer or discharge – revisions to language, which requires orientation of resident for transfer or discharge to ensure safe

and orderly, transfer or discharge.

- Bed hold – Bed hold language changes as well as the need to provide state reserve bed payment policy.
- Return to a composite distinct part – provides clarifications to readmission language and provider responsibilities.

How is it different from prior regulations?

The section has been combined and moved from §483.12 to section §483.15. The following table reflects a comparison of the significant differences from the prior requirements to the Final Rule. Changes in language, new subsections added are indicated in **bold**.

Subsection	Prior Requirements	Final Rule
Section	§483.12 Admission, Transfer and Discharge Rights	§483.15 Admission, Transfer and Discharge Rights
Admissions Policy	<ul style="list-style-type: none"> ▪ No wording for an Admissions Policy (§483.12d (1)(i) Admissions Policy) ▪ (1) The facility must— ▪ (i) not require residents or potential residents to waive their rights to Medicare or Medicaid and ▪ Not require oral or written assurance that residents or potential residents are not eligible for, or will not apply for, Medicare or Medicaid benefits ▪ §483.12d(2) The facility must not require a third party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in the facility. However, the 	<ul style="list-style-type: none"> ▪ §483.15 (a)(1) ▪ New- “the facility must establish and implement and admission policy” ▪ New - (2) the facility must— <ul style="list-style-type: none"> (i) Not request or require residents or potential residents to waive their rights as set forth in this subpart and in applicable state, federal or local licensing or certification laws, including but not limited to their rights to Medicare or Medicaid; (ii) Not request or require oral or written assurance that residents or potential residents are not eligible for, or will not apply for, Medicare or Medicaid benefits. (iii) Not request or require residents or potential residents to waive potential facility liability for losses of personal property ▪ (3) The facility must not request or require a third party guarantee of payment to the facility as a condition of admission or expedited admission, or

Subsection	Prior Requirements	Final Rule
<p data-bbox="185 1037 380 1100">Equal Access to Quality Care</p> <p data-bbox="185 1608 350 1671">Transfer and Discharge</p>	<p data-bbox="457 252 854 529">facility may require an individual who has legal access to a residents income or resources available to pay for facility care, to sign a contract, without incurring personal financial liability, to provide facility payment from the residents income or resources</p> <p data-bbox="412 1180 815 1243">§483.12 (c) Equal Access to Quality Care</p> <p data-bbox="412 1251 860 1642">(1) A facility must establish and maintain identical policies and practices regarding transfer and discharge, and the provision of services under the State plan for all individuals regardless of source of payment (2) The facility may charge any amount for services furnished to non-Medicaid residents consistent with the notice requirement 483.10(b)(5)(i) and (b)(6) describing the charges; and</p> <p data-bbox="412 1822 824 1885">§483.12a(2) Transfer and Discharge Requirements</p>	<p data-bbox="935 252 1419 529">continued stay in the facility. However, the facility may request and require an individual who has legal access to a residents income or resources available to pay for facility care, to sign a contract, without incurring personal financial liability, to provide facility payment from the residents income or resources</p> <p data-bbox="886 680 1403 852">NEW - (6) A nursing facility must disclose and provide to a resident or potential resident prior to time of admission, notice of special characteristics or service limitations of the facility.</p> <p data-bbox="886 894 1429 1209">New (7) A nursing facility that is a composite distinct part as defined in §483.5 must disclose in its admission agreement its physical configuration, including the various locations that comprise the composite distinct part, and must specify the policies that apply to room changes between its different locations under paragraph (b)(10) of this section.</p> <ul data-bbox="886 1360 1425 1856" style="list-style-type: none"> ▪ §483.15 (b) Equal access quality care ▪ (1) A facility must establish, maintain and implement identical policies and practices regarding transfer and discharge, as defined in §483.5 and the provision of services for all individuals regardless of source of payment, consistent with §483.10(a)(2); ▪ (2) The facility may charge any amount for services furnished to non-Medicaid residents unless otherwise limited by state law and consistent with the notice requirement in §483.10(g)(3) and (g)(4)(i) describing the charges; and

Subsection	Prior Requirements	Final Rule
	<p>(iii) The safety of individuals in the facility is endangered;</p> <p>(v) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a nursing facility, the nursing facility may charge a resident only allowable charges under Medicaid;</p>	<p>§483.15 (c) Transfer and discharge (numbering in the section is new)</p> <p>(C) The safety of individuals in the facility is endangered due to the clinical or behavioral status of the resident;</p> <p>(E) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. Non-payment applies if the resident does not submit the necessary paperwork for third party payment or after the third party, including Medicare or Medicaid, denies the claim and the resident refuses to pay for his or her stay. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid;</p> <p>New (F) (ii) (ii) The facility may not transfer or discharge the resident while the appeal is pending, pursuant to §431.230 of this chapter, when a resident exercises his or her right to appeal a transfer or discharge notice from the facility pursuant to §431.220(a)(3) of this chapter, unless the failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility. The facility must document the danger that failure to transfer or discharge would pose.</p>
<p>Documentation (transfer and discharge)</p>	<ul style="list-style-type: none"> ▪ §483.12(a)(3) Documentation. When the facility transfers or discharges a resident under any of the Circumstances specified in paragraphs (a)(2)(i) through (v) of this section, the resident’s clinical record must be documented. The documentation must be made by – <ul style="list-style-type: none"> (i) The resident's physician when transfer or discharge is necessary under paragraph 	<ul style="list-style-type: none"> ▪ §483.15 (2) Documentation. When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (c)(1)(i)(A) through (F) of this section, the facility must ensure that the transfer or discharge is documented in the resident’s medical record and appropriate information is communicated to the receiving health care institution or provider. (i) Documentation in the resident’s medical record must include:

Subsection	Prior Requirements	Final Rule
	<p>(a)(2)(i) or paragraph (a)(2)(ii) of this section; and</p> <p>(ii) A physician when transfer or discharge is necessary under paragraph (a)(2)(iv) of this section.</p>	<p>(A) The basis for the transfer per paragraph (c)(1)(i) of this section.</p> <p>(B) In the case of paragraph (c)(1)(i)(A) of this section, the specific resident need(s) that cannot be met, facility attempts to meet the resident needs, and the service available at the receiving facility to meet the need(s).</p> <p>(ii) The documentation required by paragraph (c)(2)(i) of this section must be made by—</p> <p>(A) The resident's physician when transfer or discharge is necessary under paragraph (c)(1)(A) or (B) of this section; and</p> <p>(B) A physician when transfer or discharge is necessary under paragraph (b)(1)(i)(C) or (D) of this section.</p> <p>(iii) Information provided to the receiving provider must include a minimum of the following:</p> <p>(A) Contact information of the practitioner responsible for the care of the resident</p> <p>(B) Resident representative information including contact information.</p> <p>(C) Advance Directive information.</p> <p>(D) All special instructions or precautions for ongoing care, as appropriate.</p> <p>(E) Comprehensive care plan goals,</p> <p>(F) All other necessary information, including a copy of the residents discharge summary, consistent with §483.21(c)(2), as applicable, and any other documentation, as applicable, to ensure a safe and effective transition of care.</p>
<p>Notice before transfer</p>	<p>§483.12(a)(4) Notice Before Transfer Before a facility transfers or discharges a resident, the facility must—</p> <p>(i) Notify the resident and, if known a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand.</p> <p>(ii) Record the reasons in the clinical record; and</p>	<p>§483.15 (2) Before a facility transfers or discharges a resident, the facility must—</p> <p>(i) Notify the resident and the resident's representative(s) of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. The facility must send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman.</p> <p>(ii) Record the reasons for the transfer or discharge in the resident's medical record in accordance with paragraph (c)(2) of this</p>

Subsection	Prior Requirements	Final Rule
	<p>(iii) Include in the notice the items described in paragraph (a)(6) of this section.</p>	<p>section; and (iii) Include in the notice the items described in paragraph (b)(5) of this section.</p>
<p>Contents of the Notice</p>	<p>§483.12(a)(6) Contents of the Notice</p> <ul style="list-style-type: none"> ▪ (iv) A statement that the resident has the right to appeal the action to the State: (v) The name, address and telephone number of the State Long-Term Care Ombudsman; (vi) For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals, established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and (vii) For nursing facility residents who are mentally ill, the Mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals established under the Protection and Advocacy for Mentally Ill Individuals Act. 	<p>§483.15 (5)(iv)</p> <p>A statement of the resident’s appeal rights, including the name, address (mailing and email), and telephone number of the entity which receives such requests; and information on how to obtain an appeal form and assistance in completing the form and submitting the appeal hearing request;</p> <p>(v) The name, address (mailing and email) and telephone number of the Office of the State Long-Term Care Ombudsman;</p> <p>(vi) For nursing facility residents with intellectual and developmental disabilities or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with developmental disabilities established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (Pub. L. 106-402, codified at 42 U.S.C. 15001 et seq.); and</p> <p>(vii) For nursing facility residents with a mental disorder or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with a mental disorder established under the Protection and Advocacy for Mentally Ill Individuals Act.</p>
<p>Changes to the Notice</p>		<p>§483.15 (6) Changes to the Notice New - (6) Changes to the notice. If the information in the notice changes prior to effecting the transfer or discharge, the facility must update the recipients of the notice as soon as practicable once the</p>

Subsection	Prior Requirements	Final Rule
		updated information becomes available.
Orientation for transfer or discharge.	§483.12(a)(7) A facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.	§483.15 (7) A facility must provide and document sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility. This orientation must be provided in a form and manner that the resident can understand.
Notice in advance of facility closure.	§483.12(a)(8) Notice in advance of facility closure. In the case of facility closure, the individual who is the administrator of the facility must provide written notification prior to the impending closure to the Secretary, the State Long-Term Care Ombudsman, residents of the facility, and the legal representatives of the residents or other responsible parties, as well as the plan for the transfer and adequate relocation of the residents, as required at §483.75(r).	§483.15 (8) Notice in advance of facility closure. In the case of facility closure, the individual who is the administrator of the facility must provide written notification prior to the impending closure to the State Survey Agency , the Office of the State Long-Term Care Ombudsman, residents of the facility, and the resident representatives , as well as the plan for the transfer and adequate relocation of the residents, as required at §483.70(I) .
Room changes in a composite distinct part	§483.12(a)(9) Room changes in a facility that is a composite distinct part (as defined in §483.5(c) must be limited to moves within the particular building in which the resident resides, unless the resident voluntarily agrees to move to another of the composite distinct part's locations.	§483.15 (9) Room changes in a facility that is a composite distinct part (as defined in §483.5) are subject to the requirements of §483.10(e)(7) and must be limited to moves within the particular building in which the resident resides, unless the resident voluntarily agrees to move to another of the composite distinct part's locations.
Bed Hold	§483.12(b) Notice of Bed Hold Policy and Readmissions (1) Notice before transfer. Before a nursing facility transfers a resident to a hospital or allows a resident to go on therapeutic leave, the nursing facility must provide written information to the resident and a family member or legal representative that specifies— (i) The duration of the bed-hold policy under the State plan, if any, during which the resident is permitted to return and resume residence in the	§483.15 (d) Notice of bed-hold policy and return — (1) Notice before transfer. Before a nursing facility transfers a resident to a hospital or the resident goes on therapeutic leave, the nursing facility must provide written information to the resident or resident representative that specifies— (i) The duration of the state bed-hold policy , if any, during which the resident is permitted to return and resume residence in the nursing facility; (ii) The reserve bed payment policy in the

Subsection	Prior Requirements	Final Rule
	<p>nursing facility; and</p> <p>(ii) The nursing facility policies regarding bed hold periods, which must be consistent with paragraph (b)(3) of this section, permitting a resident to return</p>	<p>state plan, under §447.40 of this chapter, if any;</p> <p>(iii) The nursing facility's policies regarding bed-hold periods, which must be consistent with paragraph (c)(3) of this section, permitting a resident to return; and</p> <p>(iv) The information specified in paragraph (c)(3) of this section.</p>
<p>Bed-hold notice upon transfer.</p>	<p>§483.12(b)(2)</p> <p>At the time of transfer of a resident for hospitalization or therapeutic leave, a nursing facility must provide to the resident and a family member or legal representative written notice which specifies the duration of the bed-hold policy described in paragraph (b)(1) of this section.</p>	<p>§483.15 (d)</p> <p>At the time of transfer of a resident for hospitalization or therapeutic leave, a nursing facility must provide to the resident and the resident representative written notice which specifies the duration of the bed-hold policy described in paragraph (c)(1) of this section.</p>
<p>Permitting residents to return to facility.</p>	<p>§483.12(b)(3)</p> <p>A nursing facility must establish and follow a written policy under which a resident whose hospitalization or therapeutic leave exceeds the bed hold period under the State plan, is readmitted to the facility immediately upon the first availability of a bed in a semi-private room if the resident</p> <p>(i) Requires the services provided by the facility; and</p> <p>(ii) Is eligible for Medicaid nursing facility services.</p>	<p>§483.15 (d)</p> <p>A facility must establish and follow a written policy on permitting residents to return to the facility after they are hospitalized or placed on therapeutic leave. The policy must provide for the following.</p> <p>(i) A resident, whose hospitalization or therapeutic leave exceeds the bed-hold period under the State plan, returns to the facility to their previous room if available or immediately upon the first availability of a bed in a semi-private room if the resident</p> <p>(A) Requires the services provided by the facility; and</p> <p>(B) Is eligible for Medicare skilled nursing facility services or Medicaid nursing facility services.</p> <p>(ii) If the facility that determines that a resident who was transferred with an expectation of returning to the facility cannot return to the facility, the facility must comply with the requirements of paragraph (c) as they apply to discharges.</p>
<p>Readmission to a composite distinct part.</p>	<p>§483.5(c)</p>	<p>Relocated to §483.15 (d)</p> <p>Readmission to a composite distinct part. When the facility to which a resident returns is a</p>

Subsection	Prior Requirements	Final Rule
		composite distinct part (as defined in §483.5), the resident must be permitted to return to an available bed in the particular location of the composite distinct part in which he or she resided previously. If a bed is not available in that location at the time of return, the resident must be given the option to return to that location upon the first availability of a bed there.

Key actions stated (resource allocation) Phase I

Staff, financial and resource allocation will vary between providers based upon organization readiness and access to resources. The below areas reflect overall considerations in preparing for the changes.

- Leadership and key staff allocation of hours to review, develop, implement and monitor:
 - Pre-admission, admission, transfer and discharge processes, policies and procedures
 - Contractual agreements and forms (admission agreements, partner agreements as it relates to admissions, transfers and discharges)
 - Care transition and discharge protocols, communication standardization, sending and receiving facility expectations, monitoring of resident transfer and potential readmission, key data points for monitoring to ensure effective care transitions
 - Acute care and physician communication processes
- Development of staff training and competency plan - Training and education allocation of hours (Updates as indicated above as well as respective roles and responsibilities).
 - Staff
 - Leadership
 - Interdisciplinary team
 - Direct care staff
 - Preparation for Phase II – Determine staff allocation of hours as well as resources
 - Documentation requirements, safe care transitions and discharge process, corresponding policies and procedures, required training

and monitoring outcomes protocols.

What does this mean to providers?

The Final Rule includes specific regulations related to how an organization conducts, communicates and implements its admission, transfer and discharge processes. This Rule has embraced the intent of the National Quality Strategy as it relates to safe care transitions, allowing residents to have a voice as well as ensuring proper communication across the health care continuum.

Providers will be expected to understand the specific changes in this section, the specific revisions to current policies, and their organization’s roles and responsibilities related to admission, transfer and discharge processes. Staff across all levels of an organization has a key role in the safe transition of care within their respective organization and throughout the health care continuum. It is important to note that this section will be implemented in two phases per the implementation timeframes in the Final Rule:

Phase I – Language changes, clarifications, policy and procedure needs and facility responsibilities

Phase II - Transfer / Discharge documentation requirements

What are next steps / what do they need to do to comply?

1. Conduct a detailed review of §483.15 requirements with leadership team. Conduct a comparative analysis – current policies, procedures, and processes to Final Rule requirements. Develop a detailed action plan to include:
 - a. Review all current policies and procedures related to admission, discharge, and transfer. Revise based upon the Final Rule updates and changes:
 1. Preadmission
 1. Composite distinct part
 2. Facility must coordinate assessments with the PASARR (preadmission screening and resident review) program under Medicaid in subpart C of this part to the maximum extent practicable to avoid duplicative testing and effort.
 3. Facility must incorporate recommendations from PASARR level II determination and the PASARR evaluation report into a resident’s assessment, care planning, and transitions of care.

2. Admission Policy - An admissions policy means that a facility must have such a policy, that the policy must be compliant with the requirements for participation, and that the facility must follow its policy. This increases provider responsibility and outlines areas that will need to be added to the Admission Agreement, also clarifies definitions and communicate facility policies to resident / representatives.
 3. Transfers – Reflect new requirements and language changes
 1. Internal
 2. Composite distinct part
 3. External
 4. Involuntary
 5. Notice of transfer
 4. Bed hold - Reflect new requirements and language changes
 5. Return from LOA - written policy on permitting residents to return to facility after they are hospitalized or placed on therapeutic leave: the policy must include specific provisions outlined in the regulation.
 6. Discharge - Reflect new requirements and language changes and safe care transition best practice
 1. Composite distinct part
 2. Death
 3. Community
 4. Another health care organization
 5. Acute care
 7. Communication expectations during transitions of care – including the exchange of pertinent clinical and non-clinical information.
 8. Documentation requirements - Reflect new requirements and language changes.
- b. Review and revise admission contractual documents to reflect the Final Rule updates.
 - c. Review discharge planning and care transition standards of practice. Determine differences between current organizations policies and practices compared to best practices. Prioritize opportunities for improvement based upon timelines for implementation.
 - d. Review electronic health record defined assessments and tools to align with required changes.

2. Meet with the Medical Director to address policy, process, communication and documentation changes respective to resident specific information on admission, discharge, and transfer. Additionally identify the areas for training for all primary care physicians and extenders associated with the organization.
3. Develop a communication plan related to admission, discharge, and transfer with all affected constituents including but not limited to: residents, resident representatives, physicians/extenders, pharmacy and other clinical consultants, partners (ACO, BPCI, and network), payers, and organization staff.
 - a. Include communication expectations during transitions of care – including the exchange of pertinent clinical and non-clinical information.
4. Develop a detailed training and competency plan to include leadership, interdisciplinary team members and all other staff related to admission, discharge, and transfer policies, procedures, roles/responsibilities, documentation and communication requirements.
5. Track, trend and analyze admission, discharge, and transfer outcomes to determine adherence to updated protocols. Include applicable data within the QAPI process. Develop Performance Improvement Plans as indicated.

Resident Assessment (§483.20)

Effective date: This section will be implemented in Phase 1 on November 28, 2016.

Summary:

Key points

Reflects MDS 3.0 person-centered planning philosophy through:

- adding “strengths, goals, life history and preferences” to the assessment,
- changing “discharge potential” to “discharge planning”,
- clarifying requirements for coordinating assessments with PASARR,
- providing exceptions for PASARR screenings, and
- modernizing some terminology.

How it is different from prior regulations?

Removes language on care plans and discharge planning from this section and moves them to §483.21.

- Clarifies that the assessment is not just for understanding the resident’s needs but also to understand their strengths, goals, life history and preferences.
- Changes the wording of “discharge potential” to read “discharge planning”.
- Requires that the assessment process include direct observation and communication with the resident and communication with all direct care staff on all shifts.
- Clarifies that NFs need to incorporate the recommendations from the PASARR level II determination and evaluation report into the resident’s assessment, care planning, and transitions of care.
- Clarifies that PASARR coordination must include referral of all residents with newly evident or possible serious mental disorder, intellectual disability or related condition for a level II review upon significant change in assessment status. The status change could be either a decline or improvement in the resident’s condition.
- The rule also makes a few technical corrections regarding the PASARR. These changes include:
 - Exceptions to preadmission screening are delineated. These exceptions include not requiring determinations in the case of readmissions to a NF for someone who was transferred to a hospital from a NF. The exceptions also allow states to determine if they will apply PASARR to individuals admitted to the NF directly from a hospital after receiving inpatient care at the hospital, who requires NF services for the condition for which the individual received care in the hospital, and whose physician certifies the individual is likely to need less than 30 days of care in the NF.
 - Requires a NF to notify the appropriate state agency promptly after a significant change in condition of a resident who has a mental disorder or intellectual disability for review.

Key actions stated:

- Update any policies regarding resident assessments that discuss determination of residents’ needs to the newly revised language of understanding their strengths, goals, life history and preferences. CMS acknowledges that life history may be difficult to obtain for some residents but requires facilities to use their best attempt. They do not

specify what, if any, documentation of efforts may be required but facilities may want to begin explaining their efforts in this area.

- Update any policies regarding the resident assessment as it pertains to discharge potential to the new terminology of discharge planning. CMS is clear that facilities are encouraged to determine a resident's preferences and expectations in this area as opposed to using facility judgement. Again, CMS does not specify what, if any, documentation will be required in this regard but facilities may want to consider how they will explain their efforts in this area.
- NFs will want to be sure to document that the assessment process includes direct observation and communication with the resident as well as communication with direct care staff on all shifts.
- Update policies if not already coordinating assessments with PASARR consistent with the clarified requirements.
- Develop a process if one is not already in place to incorporate PASARR level II information into the resident's assessment, care planning, and transitions of care.
- Develop or update policy and educate staff on any exceptions to the PASARR process that are adopted by your state.
- Develop a policy and educate staff of the requirement to notify the appropriate state agency of significant change in condition of residents who are subject to PASARR level II review.

What does this mean to providers?

- Ensure that your facility follows the seemingly minor changes to the resident assessment, including the new terminology and the inclusion of the resident and all shifts of direct care staff in the process.
- Fewer PASARR assessments for residents who need to go to the hospital and come back, but more responsibility to coordinate with the state agency and provide them with updates if these residents' conditions change.

What are next steps / what do they need to do to comply?

CMS states that there is potential for additional changes to the MDS in the future to implement the revised language in this section.

Comprehensive Resident-Centered Care Plans (§ 483.21)

NEW SECTION - (Phase 1 effective 11/28/16)

Summary:

- Baseline Care Plan: Requires facilities to develop a baseline care plan for each resident, within 48 hours of their admission, which includes the instructions needed to provide effective and person-centered care that meets professional standards of quality care.
 - Includes initial goals, physician orders, medications, dietary orders, therapy orders, social services, and PASARR recommendations
 - Requires facilities to provide resident/representative with summary of baseline CP in a form and manner the resident can easily understand. Summary to include initial goals, medications, treatments, and diet.
- PASARR: Adds a requirement to include as part of a resident's care plan any specialized services or specialized rehabilitation services the nursing facility will provide as a result of PASARR recommendations. If a facility disagrees with the findings of the PASARR, it must indicate its rationale in the resident's medical record.
- Interdisciplinary Team (IDT):
 - Adds a nurse aide, a member of the food and nutrition services staff, to the required members of the interdisciplinary team that develops the comprehensive care plan. Participation is not required to be in-person at the care plan meeting. Can obtain information/participate via written or electronic conversation.
 - Includes participation of resident and/or representative for development of care plan, as well as any additional updates to the care plan, to the extent possible. May not be practical for residents with impaired decision-making or declared incompetent by a court. (Representative = individual of resident's choice, may include family, and individuals with legal standing.
 - Includes a provision for culturally competent and trauma-informed care (more details to be released before implementation deadline).
 - Requires facilities to provide a written explanation in a resident's medical record if the participation of the resident and their resident representative is determined to not be practicable for the development of the resident's care plan.
 - Requires notification of resident of his/her right to request meetings, request revisions to CP, and to be informed in advance of changes to CP. Resident has a right to see CP and sign CP after significant changes are made.

- Requires access to CP by any person involved in implementation of the CP
- Encourage facilities to allow resident/representative access to CP on a routine basis
- Discharge Planning:
 - The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113-185) amended Title XVIII of the Social Security Act by, among other things, adding Section 1899B to the Social Security Act. Section 1899B(i) requires that certain providers, including long term care facilities, take into account, quality, resource use, and other measures to inform and assist with the discharge planning process, while also accounting for the treatment preferences and goals of care of residents. This section implements the discharge planning requirements mandated by the IMPACT Act by revising, or adding where appropriate, discharge planning requirements for LTC facilities.
 - Requires facilities to document in a resident's care plan the resident's goals for admission, assess the resident's potential for future discharge, and include discharge planning in the comprehensive care plan, as appropriate.
 - Requires that the resident's discharge summary include a reconciliation of all discharge medications with the resident's pre-admission medications (both prescribed and over-the-counter).
 - Adds to the post discharge plan of care a summary of what arrangements have been made for the resident's follow up care and any post-discharge medical and non-medical services, and where the resident will reside.
 - Facilities to establish, maintain, and implement identical policies and practices related to admission, transfer, and discharge regardless of source of payment.
 - Requires facilities to present resident/representative with data from IMPACT quality measures to assist in making an informed decision in selection of post-acute provider. Facility must be able to show evidence that data was presented.
- How it is different from prior regulations:
 - Currently the requirements for care plans and discharge planning are under §483.20. The new requirements will be under a new section §483.21 Comprehensive Person-Centered Care Planning

- Defines components of baseline care plan within 48 hours
- Adds requirement to include NA and DT to IDT
- Adds requirement to provide copy of baseline CP to res/rep.
- Adds requirement for resident signature on CP
- Expands resident rights §483.10 to add notification requirements related to care planning and discharge planning
- Adds requirement for medication reconciliation at time of discharge
- Adds requirement to provide QM data for other post-acute care providers prior to discharge

Key actions stated:

Should not require additional staff without need for in-person participation in care planning process, however, will require reorganization of current staff duties and communication systems related to care planning.

Will require training session for staff to review new requirements and discuss reorganization for some facilities that do not currently have nurse aides or dietary staff involved in the care planning process.

What does this mean to providers?

- a. Providers will need to document participation in care planning in a different way to reflect inclusion of the nursing assistant and food/nutrition services staff. Development of policy/procedure related to method of participation.
- b. Development of informational material for resident/representative for rights related to participation in the care planning process, determining who will represent them.
- c. Development/revision of forms for interim/baseline care plan to ensure inclusion of required information and to reflect participation by resident/representative.
- d. Development/revision of forms for baseline CP for copy to resident, discharge summary/instructions for resident to be compliant with required information.
- e. Development of process to complete and document medication reconciliation at the time of discharge.

Quality of Care and Quality of Life (§ 483.25)

Effective Date: Phase 1 effective November 28, 2016

Summary:

- **Overarching Principles:** Clarifies that quality of care and quality of life are overarching principles in the delivery of care to residents of nursing homes and should be applied to every service provided.
- **Activities of Daily Living (ADLs):** Clarifies the requirements regarding a resident's ability to perform ADLs and prevention of decline unless unavoidable, as well as redefining scope of ADL definition.
- **Facility must ensure appropriate personnel to provide basic life support/CPR.**
- **Activities program to include consideration of care plan and resident preferences, as well as potential for independence and ability to interact with the community.**
- **Updating current practices:** Modifies existing requirements for nasogastric tubes to reflect current clinical practice, and to include enteral fluids in the requirements for assisted nutrition and hydration.
- **Special Need Issues:** Adds a new requirement that facilities must ensure residents receive necessary and appropriate pain management.
 - Restraints used must be least restrictive for least amount of time with ongoing evaluation of need for use.
 - Bed rails have expanded language related to use, alternatives, safety requirements, and resident/representative informed consent.
 - Skin care updated to include language about professional standards and foot care to prevent complications related to medical conditions.
 - Mobility/range of motion: language related to services to prevent decline
 - Tube feeding/diet: updated definition to include G-Tube, PEG tube, J-tube. Modifies language to allow resident right to choose therapeutic diet or not.
 - Trauma survivors: provision to address special needs of trauma survivors.

- Re-designation of Requirements: Relocates the provisions regarding unnecessary drugs, antipsychotic drugs, medication errors, and influenza and pneumococcal immunizations to §483.45 “Pharmacy Services”.

How it is different from prior regulations?

- §483.25 “Quality of Care” renamed to “Quality of Care and Quality of Life”
- §483.25 (a)(3) newly added section – CPR
- §483.25(d)(1) Restraints (currently located under “Resident Behavior and Facility Practices”) to be moved under “Quality of Care and Quality of Life”
- §483.25(d)(8) – assisted nutrition and hydration; §483.25((a)(3) – cardiopulmonary resuscitation; and §483.25 (d)(13) – pain management have already been incorporated into the current survey process through CMS Survey & Certification Memoranda.

Key actions stated:

- No additional staff required.
- Many of the additions are related to adding language that addresses processes most facilities have in place: staff competent in CPR, addressing pain management, reduction of alarm use and bedrail use (required to use alternatives first), and so on. This would require staff training to inform of new rules, but no mandated training.

What does this mean to providers?

Facilities will need to review policies and procedures related to the use of alarms/bedrails to ensure it is compliant with new guidance. Education of staff related to alternatives and individualized care planning.

With regard to mobility, pain, nutritional services – facilities will need to review processed to ensure compliance and address any refusals by the resident to ensure residents do not decline even if resident is refusing intervention.

What are next steps / what do they need to do to comply?

- Update policies and procedures related to pain, restraints, bedrails, ADL assistance, mobility/ROM, CPR.
- Educate staff on new requirements and documentation of alternatives and all efforts to maintain function.
- Educate staff on expanded definition of ADLs to include communication and increased focus on mobility maintenance.

Physician Services (§483.30)

Effective Date: Entire section will be implemented in Phase 1 (November 28, 2016)

- I. CMS has relocated the requirements regarding physician services to a new section (§483.30) from their current location at §483.40. CMS has finalized its proposal to require that, in addition to a physician's recommendation that an individual be admitted to a facility, a physician, physician's assistant, nurse practitioner or clinical nurse specialist must provide orders for the resident's intermediate care needs. Nursing facilities will need to evaluate and, if necessary, modify their policies and procedure to reflect this change. In addition, CMS has finalized providing the **attending** physician with the flexibility to delegate a qualified dietitian or other clinically qualified nutrition professional the task of writing dietary orders and to delegate to a qualified therapist the task of writing therapy orders, to the extent permitted under state law. CMS modified the language to clarify that only the attending physician has the authority to delegate in this manner. Nursing facilities must review individual state scope of practice laws and regulations to determine how this may affect them.

- II. CMS did **not** finalize its proposal to require an in-person evaluation of a resident by a physician, a physician assistant, nurse practitioner, or clinical nurse specialist before a non-emergent transfer to a hospital. LeadingAge had provided CMS with detailed comments on the many challenges associated with this proposal. The majority of commenters had significant concerns about the burden this requirement would have placed on facilities, especially small facilities and those in rural areas. Among the concerns cited were cost, impact on recruitment of physicians, NPs, PAs and CNSs, delayed access to care and interference with residents' rights. Some commenters stated that the proposal failed to recognize the role for registered nurses in coordination with practitioners. While CMS noted that their intent was to encourage facilities to identify opportunities to treat residents in their facilities, and thereby, reduce the risks associated with hospitalization, they also stated that they are waiting for results from the second phase of "The Initiative to Reduce Avoidable Hospitalizations among Nursing Facility Residents." This will provide time to evaluate some of the alternatives to the proposed requirement.

Nursing Services (§483.35)

Effective Date: This section will be implemented in Phase 1 (effective November 28, 2016), except that the facility assessment required by §483.70(e) determining the sufficient number and competencies for staff will be implemented in Phase 2 (effective November 28, 2017).

Summary:

Key points

- The regulations add a competency-based staffing approach that requires the facility to evaluate its resident population and its resources, and base its staffing plans and assignments on these assessments. This evaluation must include:
 - the number and acuity levels of the residents;
 - the range of diagnoses and resident needs;
 - the content of individual care plans; and
 - the training, experience, and skill sets of individual staff members.
- The facility will have to take into account its assessment of all residents as well as the skill sets of individual staff when making staffing decisions.
- Facility determinations of what is sufficient staff as well as the necessary competencies and skill sets must take into account the number, acuity and diagnoses of the facility's resident population.
- The facility evaluation must be consistent with the evaluation required by §483.70(e) of the regulations.

How it is different from prior regulations?

- The new regulation adds the requirement that facilities ensure that licensed nurses have the specific competencies and skill sets necessary to care for residents' needs, as identified through resident assessments and care plans.
- Consistent with CMS's clarification that nurse aides are included in the term "other nursing personnel," the requirements relating to hiring and utilizing nurse aides previously located in §483.75 of the regulations are now included in §483.35. Specifically:
 - Non-permanent caregivers must meet the same competency, knowledge and skill requirements as permanent personnel. These caregivers may have less familiarity with a facility's residents and processes, which needs to be considered when using, orienting, and assigning non-permanent staff.

- Meeting the minimum requirements for hiring a nurse aide does not automatically mean meeting the staff competency requirement that would be specific to the needs of each individual resident.
- All of the existing provisions of §483.35 relating to dietary services have been moved to the new Food and Nutrition Services section (§483.60).

Key actions stated:

- This will require facilities to identify, document, and maintain any training, certification, and similar records in an existing personnel file or training record for direct care personnel.
- This specifically includes nursing services and food and nutrition services workers, but may apply to any direct care provider.

What does this mean to providers?

- The facility must ensure that licensed nurses and nurse aides have the knowledge and skills needed to care for residents' needs, as identified through resident assessments, and as described in each resident's individual plan of care.
 - Caring for a resident's needs includes assessing, evaluating, planning and implementing resident care plans and responding to each resident's needs.
 - These requirements apply equally to employees or contract staff utilized by the facility.
- CMS intends to focus on ensuring that not only are there a sufficient number of staff in a facility, but also that staff have the necessary abilities, knowledge and competencies to be effective and efficient in carrying out the work necessary to meet the needs of each resident receiving care in the facility.
- CMS considered, but has decided to NOT mandate that facilities:
 - have a 24/7 RN presence (8 hours per day remains the minimum requirement); or
 - meet any specific nurse staffing ratios at this time.

What are next steps?

- CMS anticipates that any initial competency requirements will be identified by the facility assessment with documentation of individual accomplishments managed by an administrative position as an addition to existing documentation.

Behavioral Health Services (§483.40)

Effective Date: See below for implementation dates by section

Summary:

- Each resident must receive, and the facility must provide necessary behavioral health care services
- The facility must ensure that they have sufficient staff who provide direct services to residents with “appropriate” competencies, which include (Implementation Phase 3, November 28, 2019):
 - Caring for residents with mental illness/psychological disorders, as well as with residents with a history of trauma and/or post-traumatic stress disorder; and
 - Implementing non-pharmacological interventions
- Based off the resident assessment, the facility must ensure that (Implementation Phase 1, November 28, 2016):
 - A resident who displays or is diagnosed with a mental/psychological disorder receive appropriate care.
 - A resident whose assessment did NOT reveal a mental/psychological disorder does not display decreased social interaction or increased withdrawn, angry or depressive behaviors unless the resident’s clinical conditions demonstrates that this is unavoidable.
 - If rehabilitative services are required in the resident’s comprehensive plan of care, the facility must:
 - Provide the required services, including specialized rehab services as required in §483.45; or
 - Obtain the required services from an outside resource from a Medicare and/or Medicaid provider of specialized rehabilitative services.
 - The facility must provide medically related social services to “attain or maintain the highest practicable mental and psychological well-being of each resident (Implementation Phase 1, November 28, 2016).

How it is different from prior regulations?

- §483.40 is a brand new section that focuses on the requirement to provide necessary behavioral health care and services in accordance with their comprehensive assessment and plan of care

Key actions stated:

- Requires facilities to determine their direct care staff needs based on the facility assessment and behavioral health of their residents.
- Facility must ensure that that staff attain and maintain appropriate competencies and skills set to provide behavioral health services
- Clarifies that facilities with 120 or more beds must employ a full-time social worker (as is true in current law), but also re-iterates that CMS has the statutory authority to require facilities with fewer beds to employ a full-time social worker should they choose to do so.

What does this mean to providers?

- Providers will need to maintain a strong level of oversight on their staffing needs as it relates to the facility assessment and the behavioral health of their residents
- This section is currently a bit open-ended in terms of clear definitions and expectations, though CMS has indicated that sub-regulatory guidance is forthcoming on this section.

What are next steps / what do they need to do to comply?

- Facilities will to determine their staffing needs based on the facility assessment and behavioral health of their residents.
- Facility must ensure that that staff attain and maintain appropriate competencies, as highlighted above

Pharmacy Services (§483.45)

Effective Date: Entire section will be implemented in Phase 1 (November 28, 2016) with the exception of medical chart review – Phase 2 (November 28, 2017) and psychotropic drugs – implemented in Phase 2 (November 28, 2017)

CMS finalized the relocation of the requirements regarding pharmacy services from §483.60 to §483.45.

With regard to drug regimen review (DRR), CMS had proposed that the pharmacist be required to review the resident's medical record concurrently with the DRR when:

- The resident is new to the facility
- A prior resident returns or is transferred from a hospital or other facility

- During each monthly DRR when the resident has been prescribed or is taking a psychotropic drug, an antibiotic, or any drug the QAA committee has requested be included in the pharmacist’s monthly drug review.

Based on comments received, CMS has finalized that the pharmacist should review the resident’s medical record **during every monthly DRR, not just under the specific circumstances noted in the proposal. This provision will take effect November 28, 2017.** CMS believes this will help identify irregularities sooner and help address polypharmacy.

In existing regulations, pharmacists are required to report any irregularities identified in the monthly DRR to the attending physician and director of nursing. However, the term “irregularities” is not defined. CMS proposed to define “irregularities” as including, but not limited to, the use of any drug that meets the criteria for an unnecessary drug. CMS also proposed adding the medical director to the individuals who should be notified of irregularities. Under the proposal, the pharmacist would be required to prepare a written report that is dated and contains the resident’s name, the relevant drug, and the irregularity identified. The attending physician would be required to document in the resident’s medical record that he or she has reviewed the report and what, if any, action has been taken to address it along with a rationale if no changes are being made. **CMS has finalized all of these proposed changes in the final rule. In addition, in response to comments expressing concern that there are no timeframes governing the monthly DRR process, and that there is no requirement regarding what pharmacists should do if they believe the identified irregularity requires urgent or emergency action to protect the resident, CMS has added a requirement that facilities establish policies and procedures to address the entire DRR process, including timeframes for various actions and the process for a pharmacist to follow when immediate action is needed. Facilities must review any existing policies and procedures and prepare to educate pharmacists who are conducting drug regimen reviews, as well as nursing and medical staff.**

CMS had proposed to revise existing requirements regarding “antipsychotic” drugs to refer to “psychotropic” drugs. In addition, CMS proposed to require that facilities ensure residents who have not used psychotropic drugs not be given these drugs unless medically necessary. Residents who receive psychotropic drugs would be required to receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue use of these psychotropic drugs. In response to commenters who argued that gradual dose reductions are not appropriate for many residents receiving psychotropic drugs, CMS stated its expectation that each resident would be evaluated by their attending physician to determine whether a gradual dose reduction and behavioral interventions are clinically contraindicated. If they are found to be clinically

contraindicated, CMS expects the attending physician to document this in the resident’s clinical record.

“Psychotropic drug” was proposed to mean any drug that affects brain activities associated with mental processes and behavior. These drugs would include anti-psychotics, anti-depressants, hypnotics, opioid analgesics and any other drug that results in effects similar to the drugs in this list.

CMS finalized some, but not all, of these proposed changes. The agency’s goal is to ensure that residents receive psychotropic drugs only when these drugs are appropriate. In the final rule, CMS has modified the definition by removing the phrase and *any other drug that results in effects similar to the drugs listed in paragraphs (c)(3)(i) through (v) of this section*. CMS also removed opioid analgesics from the definition because of concerns about negative affects for pain management, especially since opioid analgesics are often given PRN and there could be interruptions in the prescriptions due to limitations on PRN prescriptions. The agency stated that it will continue to assess the opioid epidemic in the U.S. and will consider whether to propose additional requirements in future rulemaking.

The final definition reads as follows:

483.45(c)(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories:

- (i) anti-psychotic;*
- (ii) anti-depressant;*
- (iii) anti-anxiety; and*
- (iv) hypnotic.*

CMS proposed that residents would not receive psychotropic drugs via a PRN order unless the medication was necessary to treat a diagnosed specific condition that was documented in the clinical record. In addition, CMS proposed that PRN (pro re nata or as needed) orders for psychotropic drugs be limited to 48 hours. Orders could not be continued beyond that time unless the primary care provider (for example, the resident’s physician) reviewed the need for the medications prior to renewal of the order, and documented the rationale for the order in the resident’s clinical record. **CMS agreed with commenters that the 48-hour time limit could result in unintended consequences that could be detrimental to residents’ health, and in some cases, could be burdensome for the facility. Therefore, CMS has finalized a 14-day limitation on PRN orders for psychotropic medications. There is an exception for psychotropic drugs that the attending physician believes are needed for a longer than 14-day period. For psychotropic drugs**

that the attending physician believes a PRN prescription for longer than 14 days is appropriate, the attending physician can extend the prescription beyond 14 days by documenting their rationale in the resident's clinical record. However, CMS does not believe this exception would be appropriate for anti-psychotic drugs. When an attending physician believes a resident requires an anti-psychotic drug on a PRN basis for more than 14 days, the attending physician will be required to write a new PRN prescription every 14 days after the resident has been evaluated. All the newly finalized requirements related to psychotropic drugs take effect November 28, 2017. CMS will develop detailed requirements in sub-regulatory guidance. Facilities will need to evaluate and revise their facility policies and prepare to educate their pharmacy providers, physicians and nursing departments.

Laboratory, Radiology, and Other Diagnostic Services (§483.50)

Effective date: November 28, 2016 (phase 1)

Summary:

New Section – Identifies who can order services and notification requirements of results.

- Requires a facility to provide or obtain laboratory and radiology and other diagnostic services when ordered by a physician, a physician assistant, nurse practitioner, or clinical nurse specialist, if the practitioners are acting in accordance with state law, including scope of practice laws and facility policy
- Notify the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist to be notified of laboratory, radiology or other diagnostic test results that fall outside of clinical reference ranges *in accordance with facility policies and practitioner orders for notification*
- The facility must assist, as needed, transportation to and from the source of service.
- The facility must file in the resident's clinical record reports that are dated and contain the name and address of the testing laboratory, radiology service or other diagnostic testing service
- The facility is responsible for the quality and timeliness of the services

What does this mean for providers?

- It is important that you have identified laboratory, radiology and other diagnostic testing centers for which you have developed standards for timeliness of service, reference ranges and quality oversight.

- You must have in your facility policy and procedures language that specifies which practitioners are allowed to order what services by your state law and scope of practice laws.
- You should have clarification in your policy and procedures to outline how specific abnormal results should be communicated by test and results (e.g.: abnormal vs. critical) and the time frame required for notifications.

Next steps

It is important for your clinical leadership team (Director of Nursing Services, Medical Director and others) to create policies that direct staff when and how to report specific test results by type and by range of abnormality. AMDA has guidelines available on line. Often times the contracted laboratory will also have guidance for how staff should handle results notifications. It is important that any such guidelines be reviewed for appropriateness and for compliance with state law.

Dental Services (§483.55)

Effective Date: Entire section will be implemented in Phase 1 (November 28, 2016) except for loss or damage of dentures and policy for referral – Phase 2 (November 28, 2017) and referral for dental services regarding loss or damaged dentures – Phase 2 (November 28, 2017)

CMS finalized limited changes to this section as follows:

- A facility may not charge a resident for the loss or damage to dentures when the loss or damage is the responsibility of the facility
- If the resident requests assistance in scheduling a dental appointment, the facility would be required to provide it. Facilities are already required to provide assistance when it is needed. This adds *if requested*.
- Adds a requirement to arrange for transportation to and from dental services
- Requires facilities to make a dental referral within 3 days from the time the loss or damage to dentures is identified unless the facility can document extenuating circumstances that resulted in a delay beyond 3 days. Compliance with this requirement will be required as of November 28, 2017.
- Adds a requirement that facilities assist residents to apply for reimbursement of dental service as in incurred medical expense under the state plan as appropriate.

CMS also finalized the following additions:

- Facilities will be required to have a policy identifying those instances when the loss or damage of dentures is the facility’s responsibility. Compliance with this addition is required by November 28, 2017.
- Facilities must document what they did to ensure that the resident could eat and drink adequately while awaiting dental services.

Facilities will need to evaluate their current policies and practices related to dental services, particularly as they related to loss of or damage to dentures and ensure that nursing, food service and social work departments receive required education related to these changes.

Food and Nutrition (§483.60)

Effective Date: See below in each section.

Was previously section 483.35 Dietary Services

Summary:

- Requires facilities to employ sufficient staff based on new requirement of a facility assessment. Effective November 28, 2017.
- Establishes education requirements for qualified dietician or other clinically qualified nutrition professional. Rule is effective November 28, 2016 for newly hired dietitians and allows a 5-year phase in for dietitians hired before November 28, 2016.
- Establishes education requirements for director of food and nutrition services when qualified dietician or other qualified nutrition professional is not employed full-time.
- A member of the food and nutrition services staff must participate on the interdisciplinary team as required in §483.21(b)(2)(ii).
- Requires facilities to have menus that reflect the cultural and ethnic needs of residents. Effective November 28, 2016.
- Attending physician may delegate to a registered or licensed dietician the task of prescribing a resident’s diet, including a therapeutic diet, to the extent allowed by State law. Effective November 28, 2016.
- Facilities are required to have a policy regarding use and storage of food brought to residents by family and other visitors to ensure safe and sanitary storage, handling and consumption. Effective November 28, 2016.

How it is different from prior regulations?

- The requirement to determine staffing needs and competencies based on an annual facility assessment is new and impact on cost is yet to be determined. Effective November 28, 2017.
- Defines the educational requirements to be considered a “qualified dietician” or other “clinically qualified nutrition professional. Sets time frames to meet educational requirements for persons hired prior to November 28, 2016 and after November 28, 2016.
- There currently isn't a regulation that requires ethnic food but the regulations do talk about finding residents preferences in food.

Key actions stated:

Facilities will have one year to complete a facility assessment, which will determine impact to food and nutrition services staffing. Participation by a member of the food and nutrition staff on the interdisciplinary team should not have a significant impact. Other actions will be to review policies on purchasing food products from local producers as well as food products grown in facility gardens. A new policy is required for the safe and sanitary storage, handling and consumption of food brought into the facility by families and visitors.

What does this mean to providers?

Nursing home providers need to review the new regulations to confirm which practices they already have in place and begin implementation of those regulations they do not have in place.

What are next steps?

Providers should review their practices to see how they differ from the new regulations and begin the process of implementing any changes.

Specialized Rehabilitative Services (§483.65)

Summary:

- Relocate existing provisions to §483.65
- The addition of respiratory therapy to the list of specialized rehabilitative services

How it is different from prior regulations?

- Current regulation at §483.45; new regulation at §483.65

- CMS added respiratory therapy to the list of specialized rehabilitative services.
- This service (respiratory therapy) requires facilities to provide or obtain these services when necessary and meet the needs of residents facing respiratory issues.
- When it is necessary for facilities to obtain these (respiratory therapy) services from an outside source, the services obtained must come from a provider of specialized rehabilitative services that is not excluded from participating in any federal or state health care programs pursuant to sections 1128 and 1156 of the Act.
- CMS urges facilities to utilize the facility assessment that was proposed at §483.70(e) as a tool for appropriately assessing the resources necessary for providing care to its residents. Facilities should use this assessment to make decisions about their direct care staff needs as well as their capabilities to provide services to the residents in their facility.
- CMS added in §483.65 a cross reference to the PASARR regulations at §483.120(c) which set out the mental health or intellectual disability services a nursing facility must provide to all residents who need these services.

Key actions stated

In response to comments pertaining to the availability of respiratory therapists to meet this need and related to the request for clear discussion of the qualifications necessary for individuals to furnish these services to help providers better understand how to meet these requirements, CMS stated: all specialized rehabilitative services are considered facility services and are included within the scope of facility services. Therefore, the facility must provide the necessary respiratory therapy services for all residents who need them, so that the needs of the resident are met and support the resident in attaining or maintaining their highest practicable physical, mental, and psychosocial well-being. Regulations at §483.70(f) discuss staff qualifications and specify that the facility must employ on a full-time, part-time or consultant basis those professionals necessary to carry out the provisions of the requirements for LTC facilities. This would include those services related to specialized rehabilitative services, including respiratory therapy. In addition, the regulations at §483.70(f) require that professional staff must be licensed, certified, or registered in accordance with applicable state laws.

Actions Needed by Providers:

- Complete CMS facility assessment tool to determine staff needs and facility capabilities.
- Obtain respiratory therapy services either internally or from an outside provider of specialized rehabilitative services (Full time, Part time, or on a consultant basis) and;

- Establish a process to ensure the provider is not excluded from participating in any federal or state health care programs pursuant to sections 1128 and 1156 of the Act.

What does this mean to providers?

Providers should review the scope of practice for licensed nurses and respiratory therapists to determine which respiratory needs can be met safely and within the scope of nursing. Providers should also obtain/secure respiratory therapy services, whether on a FT, PT, or contracted bases much the same as they currently do for PT, OT, and ST services

What are next steps / what do they need to do to comply?

Providers should assess internal and external (contractor) capabilities of providing respiratory therapy services within their community and take the necessary steps to secure such services as needed.

Outpatient Rehabilitative Services (§483.67)

Section Withdrawn

CMS proposed to add a new §483.67 “Outpatient Rehabilitative Services” requirement to address facilities that choose to provide outpatient rehabilitative therapy services to individuals that do not reside in the facility.

CMS indicated the intent of the proposed rule was to establish requirements for outpatient rehabilitative services provided to non-residents in the LTC facility to ensure that these services meet health and safety standards.

After further review of all of the comments received and reviewing the comprehensive regulations for outpatient therapy providers found in part 485, and the CMS guidance regarding off-premise treatment activities, CMS has decided against finalizing the proposed requirements for outpatient therapy rehabilitative services. CMS believes it is necessary to study the issue further and consider proposals for future rulemaking.

CMS has withdrawn this proposed section in its entirety.

Administration (§483.70)

Effective dates: Facility Assessment is November 28, 2017 (phase 2), Board responsibility for QAPI is November 28, 2018 (phase 3), and the rest are due November 28, 2016 (phase 1)

There are four provisions in the section that are noteworthy. First, there is a requirement that the LTC administrator report to and be accountable to the governing body. Second, there is a requirement that the governing body be responsible and accountable for QAPI. Third, there is a requirement for an annual facility assessment. Fourth, there is a prohibition of pre-dispute arbitration agreements. The latter two are obviously major issues, but for our members the first two are also important.

1. Administrator reports to be accountable to the Governing Body.
Current requirement is for governing body to appoint the administrator; this adds reports to and is accountable to. For NH's that are part of a larger organization with a CEO like our Life Plan Community members, this would likely be in conflict with their governance model where CEO reports to board and administrator reports to the CEO. In the comments, CMS says this rule does not say "directly" report so a board could designate the CEO to "interface" with the administrator, but the governing body still is ultimately responsible for operation and management of the facility and the administrator is accountable to the governing body.
To be in compliance, it is likely that a governing body that appoints a CEO to act in its place for purposes of this rule will have to have formal documentation by way of a motion or board adopted policy.
2. Governing body is responsible and accountable for QAPI.
This is in conjunction with §483.75 (f), which states that the governing body and/or the executive leadership team are responsible. Net effect seems to be that both are, it is not an either/or proposition. §483.75 (f) sets out the responsibilities.
Governing bodies will have to adopt policies and practices to document they are meeting this oversight requirement.
3. Annual Facility Assessment.
This is an extensive requirement that I suspect will cause great anguish for our members. The facility-wide assessment must document what resources are necessary to care for its residents competently during day-to-day operation and in emergencies. This is to be updated annually, but the comments state that is the minimum and facilities can do it more often if they chose. The assessment must also be updated whenever there is change or a facility plans any changes that require a substantial modification of any part of the assessment.
The assessment includes:
 - Resident population, number and facility capacity; care required considering the diseases, conditions, physical and cognitive difficulties, overall acuity; staff competencies necessary for the level and types of care needed; the physical environment, equipment, services necessary to care for residents;

any ethnic, cultural, religious factors that could potential affect care including activities, food/nutrition.

- The facilities resources, including; buildings/physical structures, vehicles; medical and non-medical equipment; services provided such as PT, pharmacy, specific rehab therapies.
- All personal, including managers, staff (employees and contracted), volunteers, and education/training and competencies related to care
- Contracts/agreements to 3rd parties to provide services/equipment during operations or emergencies.
- HIT resources for managing care and electronically sharing info with other organizations.

In the comments CMS acknowledges most facilities don't do this or at least document that they do it. CMS sees this as tool to thoroughly assess their residents and resources needed for care and having it in writing will a record for future planning. CMS will be issuing sub-regulatory guidance on how to comply. They also warn that if a facility simply writes up an assessment to justify what they have "it will be evident in the facility assessment as well as their performance on surveys". It seems to LeadingAge that the surveyors will be looking hard at these.

A few other items in comments:

- Facilities are encouraged to seek out and consider input from outside entities (ombudsmen, residents, families, advocates), but it is not required.
- CMS does not view this requirement and overly complex or extremely burdensome (which means they are complex and burdensome) there is no standard format; they expect variation in how conducted and documented, each facility should have flexibility to do this in a manner best for them.
- Example they used as reason to do an update is if a facility wanted to start to admit morbidly obese, they would need an update to show the care needs, training and resources needed.
- CMS will look to 5 Star predicted staffing based on RUG scores to see if they can be used in a rule or guidance to provide presumptive levels for assessments.
- Surveyors will get guidance on constitutes compliance.

4. No pre-dispute binding arbitration agreements

Arbitration agreements are prohibited in certified facilities upon effective date. Existing agreements are grandfathered. If a facility wants to use arbitration after a dispute arises, it must show agreements is in writing and fully explained to the resident and representative, resident acknowledges they understand, it is voluntary, neutral arbitrator agreed to by both parties, is at a site convenient for resident. Resident cannot be required to sign in

order to stay in the facility and there can't be any restrictions on communicating with federal, state or local officials, including surveyors and health department staff.

One last more minor provision, a practitioner other than a physician can authorize a transfer to the hospital in an emergency consistent with state law and facility policy.

Quality Assurance and Performance Improvement (§483.75)

This section will be implemented in Phase 3 with the following exceptions:

- (a)(2) Initial QAPI Plan must be provided to State Agency Surveyor at annual survey—Implemented in **Phase 2**
- (g)(1) QAA committee—All requirements of this section will be implemented in **Phase 1** with the exception of subparagraph (iv), the addition of the ICPO (Infection Control Prevention Officer) (IP – Infection Preventionist) – note this team varies throughout the Rule), which will be implemented in **Phase 3**
- (h) Disclosure of information—Implemented in **Phase 1**
- (i) Sanctions—Implemented in **Phase 1**

Summary:

Although this section will be phased in per the implementation timeframes established in the Final Rule, providers are expected to retain the substance of the existing QAA requirements and begin the journey towards quality assurance and performance improvement as outlined in the Affordable Care Act. This section has significant revisions and additions to the current §483.75(o) QAA requirements. The overall intent of this section is to ensure that QAPI is engaged and implemented across all levels of the facility. The QAPI program is intended to identify and prioritize problems and opportunities based on performance indicator data; resident and staff input that reflects organizational processes, functions, and services provided to residents; identifies corrective actions necessary to address gaps in systems, and these actions are evaluated for effectiveness; and clear expectations that the QAPI program is established around the premise of safety, quality, rights, choice, and respect.

Key points

- Retain the substance of the existing QAA requirements at §483.75(o)
- Facility must develop a QAPI Plan by November 27, 2017 and submit to the Survey Agency at the first annual recertification survey. After first annual recertification, Survey Agency can request a copy of the Plan at each annual recertification visit or at any other survey. It must implement, and maintain

an effective, comprehensive, data-driven QAPI program, reflected in its QAPI plan, that focuses on systems of care, outcomes, and services for residents and staff

- QAPI program is across all levels and all departments of an organization
- The QAPI program shall be designed to monitor and evaluate performance of ALL services and programs of an organization, including contractual services. Elements of the program must include the following areas:
 - Design and Scope
 - Governance and Leadership
 - Feedback, Data Systems and Monitoring
 - Performance improvement projects
 - Systematic analysis and systemic action
- Facility governing body will ensure that the QAPI program is defined, implemented and maintained – addressing identified priorities.
- Facility will maintain documentation and demonstrate evidence of the QAPI program including the QAPI plan. Facility will present documentation and evidence of an ongoing QAPI program upon request of a State Agency or CMS.
- Design and Scope of QAPI program - ongoing, comprehensive and address the full range of care and services provided by the facility. The QAPI program will address all systems of care and management practices including clinical care, quality of life, and resident choice; utilize available evidence to define and measure indicators of quality and organization goals; reflect processes of care and facility operations; reflect the complexities, unique care and services that the facility provides.
- Facility must maintain effective systems to obtain and use feedback and input from direct care/direct access workers, other staff, and residents, resident representatives and families to identify opportunities for improvement
- Facility must develop QAPI policies and procedures - related to how the facility will identify, collect and use data from all departments as well as how the information would be used to identify high risk, high volume or prone areas
- Facility must develop a system, including policies and procedures related to “adverse events” - identification, reporting, analysis, and prevention of adverse events and potential adverse events or near misses; process for obtaining information from residents, family and direct care/direct access staff; and how the facility addresses and investigates the adverse event or potential adverse event and provides feedback to those same individuals

- Systemic Analysis and Action – the facility will take actions aimed at performance improvement, measurement of success and track performance to ensure that the improvements are sustained. Facility will develop correlating policies and procedures describing how they would use a systematic approach to determine underlying causes
- Facility will conduct a facility assessment per the new requirements
- Facility will identify priority areas for performance improvement including, but not limited to:
 - Patient safety
 - Coordination of care
 - Autonomy and choice
 - High risk, high volume of problem prone areas based upon a facility assessment
 - Medical errors
 - Adverse resident events
- Facility will conduct performance improvement projects – the number and frequency must reflect the scope and complexity of the facility’s services and resources.
- Facility must ensure that the QAPI program is defined, implemented and sustained during transitions of leadership and staff – must be adequately resourced - staff time, equipment and technical training
- QAA Committee membership requirements are a minimum but it must include ICPO (IP) in Phase III.

How is it different from prior regulations?

The following table reflects a comparison of the significant differences from the prior requirements to the Final Rule. Changes in language, new subsections added are indicated in **bold**.

Subsection	Prior Requirements	Final Rule
Section	§483.75 Quality Assurance and Assessment	§483.75 Quality Assurance and Performance Improvement
Quality Assurance and Assessment	<ul style="list-style-type: none"> ▪ §483.75(o) facility has an ongoing quality assessment and assurance (QAA) committee that includes designated key members and that meets at least quarterly; and the committee identifies quality 	During Phase I – All providers must retain the substance of the existing QAA requirements at §483.75(o) and pursuant to the requirements of the Affordable Care Act, with implementation

Subsection	Prior Requirements	Final Rule
	<p>deficiencies and develops and implements plans of action to correct these quality deficiencies, including monitoring the effect of implemented changes and making needed revisions to the action plans.</p> <ul style="list-style-type: none"> ▪ Composition of the QAA Committee <ul style="list-style-type: none"> ○ Administrator ○ Medical Director ○ Staff with responsibility for direct resident care and services, such as nursing aides, therapists, staff nurses, social workers, activities staff members; and ○ Staff with responsibility for the physical plant, such as maintenance, housekeeping, and laundry staff. ▪ Frequency of Meetings <ul style="list-style-type: none"> ○ Meetings of the QAA committee must be held at least quarterly or more often as the facility deems necessary to fulfill committee functions and operate effectively. The Committee should maintain a record of the dates of all meetings and the names/titles of those attending each meeting. ▪ Committee’s monitoring systems and identification of concerns with the quality of facility systems <ul style="list-style-type: none"> ○ Facilities can collect and analyze data about their performance from various 	<p>to “Quality Assurance and Performance Improvement” in Phase II and III.</p>

Subsection	Prior Requirements	Final Rule
	<p>sources that may help them to identify quality deficiencies. These may include information from reports such as open and closed record audits, facility logs and tracking forms, incident reports, consultants' reports, and other reports as part of the QAA function. Quality deficiencies related to facility operations and practices are not only related to those that cause negative outcomes, but also may be directed toward enhancing quality of care and quality of life for residents. The committee responds to quality deficiencies and serves a preventative function by reviewing and improving systems.</p> <ul style="list-style-type: none"> ▪ Modification and corrective action of facility systems when needed, including monitoring the effect of action plans. <ul style="list-style-type: none"> ○ Identify root causes, which led to their confirmed quality deficiencies, must develop appropriate corrective plans of action. Action plans may include, but are not limited to, the development or revision of clinical protocols based on current standards of practice, revision of policies and procedures, 	

Subsection	Prior Requirements	Final Rule
	<p>training for staff concerning changes, plans to purchase or repair equipment and/or improve the physical plant, and standards for evaluating staff performance.</p> <ul style="list-style-type: none"> ○ Implementation of Action Plans and Correction of Identified Quality Deficiencies ○ The facility’s action plans to address quality deficiencies may be implemented in a variety of ways, including: staff training and deployment of changes to procedures; monitoring and feedback mechanisms; and processes to revise plans that are not achieving or sustaining desired outcomes. The committee may delegate the implementation of action plans to various facility staff and/or outside consultants. 	
<p>Quality Assurance and Performance Improvement</p>		<p>483.75(a) Quality assurance and performance improvement (QAPI) program. Each LTC facility, including a facility that is part of a multiunit chain, must develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life. The</p>

Subsection	Prior Requirements	Final Rule
		<p>facility must—</p> <p>§483.75(a)(1) Maintain documentation and demonstrate evidence of its ongoing QAPI program that meets the requirements of this section. This may include but is not limited to systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events; and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities;</p> <p>§483.75(a)(2) Present its QAPI plan to the State Survey Agency no later than 1 year after the promulgation of this regulation;</p> <p>§483.75(a)(3) Present its QAPI plan to a State Survey Agency or Federal surveyor at each annual recertification survey and upon request during any other survey and to CMS upon request; and</p> <p>§483.75(a)(4) Present documentation and evidence</p>

Subsection	Prior Requirements	Final Rule
		<p>of its ongoing QAPI program’s implementation and the facility’s compliance with requirements to a State Survey Agency, Federal surveyor or CMS upon request.</p> <p>§483.75(b) Program design and scope. A facility must design its QAPI program to be ongoing, comprehensive, and to address the full range of care and services provided by the facility. It must: (1) Address all systems of care and management practices; (2) Include clinical care, quality of life, and resident choice; (3) Utilize the best available evidence to define and measure indicators of quality and facility goals that reflect processes of care and facility operations that have been shown to be predictive of desired outcomes for residents of a SNF or NF. (4) Reflect the complexities, unique care, and services that the facility provides.</p> <p>§483.75(c) Program feedback, data systems and monitoring. A facility must establish and implement written policies and</p>

Subsection	Prior Requirements	Final Rule
		<p>procedures for feedback, data collections systems, and monitoring, including adverse event monitoring. The policies and procedures must include, at a minimum, the following:</p> <p>§483.75(c)(1) Facility maintenance of effective systems to obtain and use of feedback and input from direct care staff, other staff, residents, and resident representatives, including how such information will be used to identify problems that are high risk, high volume, or problem-prone, and opportunities for improvement.</p> <p>§483.75(c)(2) Facility maintenance of effective systems to identify, collect, and use data and information from all departments, including but not limited to the facility assessment required at §483.70(e) and including how such information will be used to develop and monitor performance indicators.</p> <p>§483.75(c)(3) Facility development, monitoring, and evaluation of</p>

Subsection	Prior Requirements	Final Rule
		<p>performance indicators, including the methodology and frequency for such development, monitoring, and evaluation.</p> <p>§483.75(c)(4) Facility adverse event monitoring, including the methods by which the facility will systematically identify, report, track, investigate, analyze and use data and information relating to adverse events in the facility, including how the facility will use the data to develop activities to prevent adverse events.</p> <p>§483.75(d) Program systematic analysis and systemic action.</p> <p>§483.75(d)(1) The facility must take actions aimed at performance improvement and, after implementing those actions, measure its success, and track performance to ensure that improvements are realized and sustained.</p> <p>§483.75(d)(2) The facility will develop and implement policies addressing: (i) How they will use a systematic</p>

Subsection	Prior Requirements	Final Rule
		<p>approach to determine underlying causes of problems impacting larger systems; (ii) How they will develop corrective actions that will be designed to effect change at the systems level to prevent quality of care, quality of life, or safety problems; and (iii) How the facility will monitor the effectiveness of its performance improvement activities to ensure that improvements are sustained.</p> <p>§483.75(e) Program activities.</p> <p>§483.75(e)(1) The facility must set priorities for its performance improvement activities that focus on high-risk, high-volume, or problem-prone areas; consider the incidence, prevalence, and severity of problems in those areas; and affect health outcomes, resident safety, resident autonomy, resident choice, and quality of care.</p> <p>(2) Performance improvement activities must track medical errors and adverse resident events, analyze their causes, and implement preventive</p>

Subsection	Prior Requirements	Final Rule
		<p>actions and mechanisms that include feedback and learning throughout the facility. (3) As a part of their performance improvement activities, the facility must conduct distinct performance improvement projects. The number and frequency of improvement projects conducted by the facility must reflect the scope and complexity of the facility's services and available resources, as reflected in the facility assessment required at §483.70(e).</p> <p>Improvement projects must include at least annually a project that focuses on high risk or problem-prone areas identified through the data collection and analysis described in paragraphs (c) and (d) of this section.</p> <p>§483.75(f) Governance and leadership. The governing body and/or executive leadership or organized group or individual who assumes full legal authority and responsibility for operation of the facility) is responsible and accountable for ensuring that--(1) An ongoing QAPI program is</p>

Subsection	Prior Requirements	Final Rule
		<p>defined, implemented, and maintained and addresses identified priorities. (2) The QAPI program is sustained during transitions in leadership and staffing; (3) The QAPI program is adequately resourced, including ensuring staff time, equipment, and technical training as needed; (4) The QAPI program identifies and prioritizes problems and opportunities that reflect organizational process, functions, and services provided to resident based on performance indicator data, and resident and staff input, and other information. (5) Corrective actions address gaps in systems, and are evaluated for effectiveness; and (6) Clear expectations are set around safety, quality, rights, choice, and respect.</p> <p>§483.75(g) Quality assessment and assurance.</p> <p>§483.75(g)(1) A facility must maintain a quality assessment and assurance committee consisting at a minimum of: (i) The director of nursing services; (ii) The Medical Director or his or her</p>

Subsection	Prior Requirements	Final Rule
		<p>designee; (iii) At least three other members of the facility's staff, at least one of who must be the administrator, owner, a board member or other individual in a leadership role; and (iv) The infection control and prevention officer.</p> <p>§483.75(g)(2) The quality assessment and assurance committee reports to the facility's governing body, or designated person(s) functioning as a governing body regarding its activities, including implementation of the QAPI program required under paragraphs (a) through (e) of this section.</p> <p>The committee must:</p> <p>(i) Meet at least quarterly and as needed to coordinate and evaluate activities under the QAPI program, such as identifying issues with respect to which quality assessment and assurance activities, including performance improvement projects required under the QAPI program, are necessary; and (ii) Develop and implement appropriate plans of action to correct identified</p>

Subsection	Prior Requirements	Final Rule
		<p>quality deficiencies; and (iii) Regularly review and analyze data, including data collected under the QAPI program and data resulting from drug regimen reviews, and act on available data to make improvements.</p> <p>§483.75(h) Disclosure of information. A State or the Secretary may not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section.</p> <p>§483.75(i) Sanctions. Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.</p>

Key actions stated (resource allocation) Phase I

Staff, financial and resource allocation will vary between providers based upon organization readiness and access to resources. The below areas reflect overall considerations in preparing for the changes.

- Determine leadership and key staff allocation of hours to review, develop, implement and monitor an ongoing QAPI Program:
 - Phase I
 - Review current QAA requirements with current policies, procedures and practices within the facility
 - Revise policies and procedures
 - Retrain as indicated

- Phase II Preparation – this will require significant hours and resource allocation
 - Completion of a facility assessment
 - Develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life including the core elements as described in the Final Rule
 - Design and Scope
 - Governance and Leadership
 - Feedback, Data Systems and Monitoring
 - Performance improvement projects
 - Systemic analysis and systemic action
 - Governing Board Preparation
 - Determination of data collection processes and targets including adverse and potential adverse events – tools, resources and analysis needed
 - QAPI Lead – training and technical resources
 - Development of staff training and competency plan - Training and education allocation of hours (Updates as indicated above as well as respective roles and responsibilities)
 - Governing Board
 - Leadership
 - Interdisciplinary team
 - Direct care staff
- Phase III Preparation
 - Inclusion of ICPO (IP) – training, expectations and role/responsibility

What does this mean to providers?

The Final Rule includes specific requirements related to the development, implementation, and maintenance of an effective, comprehensive, data-driven Quality Assurance and Performance Improvement program, based off of a prescriptive plan, which focuses on the indicators of care and quality of life. QAPI is the merger of two complementary approaches to quality management, Quality Assurance (QA) and Performance Improvement (PI). QAPI engages all levels of staff in skilled nursing facilities allowing full participation in the planning and improving systems and processes to achieve positive outcomes.

As a direct result of Section 6102(c) Affordable Care Act, §483.75 Quality Assurance and Performance Improvement outlines detailed elements that must

be included in the formal Plan and program components (Design and Scope; Governance and Leadership; Feedback, Data Systems and Monitoring; Performance Improvement Projects; and Systematic Analysis and Systemic Action).

Providers will be expected to understand the specific changes in this section, the specific revisions to current policies, and their organization's roles and responsibilities related to the development, implementation and maintenance of a successful QAPI program across all levels of the organization. All facility staff has a key role in the QAPI program and its success. While QAPI may not be new to many organizations, the new requirements are extensive – requiring program development, significant initial and ongoing training, data management plan, monitoring activities as well as a comprehensive communication plan engaging staff, residents and resident representatives.

It is important to note that this section will be implemented in three phases per the Implementation Timeframes in the Final Rule.

What are next steps / what do they need to do to comply?

- Conduct a detailed review of §483.75 requirements with leadership team. Conduct a comparative analysis – current policies, procedures, and processes to Final Rule requirements.
- Review all current policies and procedures related to QAA. Develop a formal QAPI Plan including the necessary requirements and elements.
 - a. Design and Scope
 - b. Governance and Leadership
 - c. Feedback, Data Systems and Monitoring
 - d. Performance improvement projects
 - e. Systematic Analysis and Systemic Action
- Leadership role and responsibility
 - a. Develop a steering committee – provide QAPI leadership
 - b. Engage Governing Body
 - c. Engage Medical Director
 - d. Review and modify vision, mission, values, and purpose statements to convey vision of QAPI
 - e. Provide QAPI resources – including training and equipment as needed
 - f. Include staff from all departments
 - g. Leverage technology to improve interdisciplinary communications

- h. Evaluate organization readiness and culture for QAPI as well as identify potential barriers
- Develop a deliberate approach to team work
 - a. Assess the “effectiveness” of teamwork in organization
 - b. Discuss how Performance Improvement Project (PIP) teams will work to address QAPI goals
 - c. Determine how direct care staff and residents and families can be involved in PIPs
 - d. Create a climate of open communication and respect
- Conduct facility assessment
- Conduct a QAPI Awareness Campaign – training and education for all staff. Discuss engagement of residents and representatives in the process.
- Identify and begin to measure improvement in indicators for which there is evidence for improvement of health outcomes.
 - Examples: Reduction of hospitalizations and readmissions, improved safety, and increased quality of care for patients
- Develop a system for measuring, analyzing, and tracking quality indicators, including adverse resident events and other performance indicators; determining what data to collect or monitor; Determine a plan for data collection (who, what, and how often); review, compare, and interpret data from various sources
- Establish benchmarks for comparisons against programs with high performance ratings
- Identify gaps and opportunities for improvement
- Identify areas of improvement, consolidate, and then prioritize. Develop charter PIPs.
- Document QAPI projects and progress, including reason for project and measurable progress. Per the plan implement changes or corrective actions that will result in improvement or reduce the chance of the event recurring
- Develop a formalized communication plan and celebrate success

Infection Control (§483.80)

Effective Date: Phase 1 except for:

- (a) As linked to Facility Assessment at §483.70(e)—Phase 2
- (a)(3) Antibiotic stewardship—Phase 2
- (b) Infection preventionist (IP)—Phase 3
- (c) IP participation on QAA committee—Phase 3.

Summary:

Shorter hospital lengths of stay are resulting in nursing homes admitting residents with greater medical acuity and higher nursing care needs. This reality introduces opportunity for additional risk of infections for frail elderly residents that are also susceptible to malnutrition, dehydration, multiple comorbidities, functional limitations and medications that have potential to diminish their immunity and mobility.

Over and above these predispositions, regulatory expectations (providing social activities/events and a home-like environment) may also increase the risk of transmission and exposure to communicable diseases and infections.

The revised regulatory description of the infection control program prioritizes the prevention of infection as well as control and clarifies that the program must help prevent the development and transmission of communicable diseases as well as infections. It also places higher competency and responsibility expectations on the program manager and requires an allocation of necessary resources to support an effective program.

Prior regulatory language required LTC facilities to establish and maintain infection control programs. Under those regulations, the facility program must:

- investigate, control, and prevent infections in the facility
- issue and maintain protocols to guide decisions about what procedures, such as isolation, should be applied to an individual resident
- maintain a record of incidents and corrective actions related to infections
- prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food if direct contact will transmit the disease
- must require staff to wash their hands after each direct resident contact
- handle, store, process, and transport linens so as to prevent the spread of infection

Key actions stated in revised regulation at § 483.80

The following revisions are intended to reduce healthcare associated infections and contribute to reduced healthcare costs.

- The program must follow accepted national standards
- Be based upon the facility assessment and include (at a minimum) a system for preventing, identifying, reporting, investigating, and controlling infections and

- communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement.
- Revision of the description of the infection control program and the addition requirement to periodically review and update the program.
 - Development of an antibiotic stewardship program that includes antibiotic use protocols and a system for monitoring antibiotic use.
 - Designation of specific Infection Preventionist (IP).
 - Written policies and procedures for an Infection Prevention and Control Program (IPCP).
 - Education or training related to the infection control program.

What are next steps / what do nursing home providers need to do to comply?

- Designate a healthcare professional as the IP (LTC facilities may designate more than one IP) who is responsible for the IPCP, works at least part-time at the facility, and must have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field and can be qualified by education, training, experience or certification.
 - The time needed for an IPCO to devote to the IPCP is based (in part) on the facility assessment. Review the budget and ensure that an IPCO has sufficient time and resources necessary to properly develop, implement, monitor and maintain the IPCP.
 - The IPCO must be a member of the facility's Quality Assessment and Assurance (QAA) committee to ensure that the IPCO is an active participant in the facility's QAPI plan.
 - The facility will not be required to have an infection control committee.
- Develop a written infection prevention and control program (IPCP) which includes an antibiotic stewardship program that:
 - follows accepted national standards,
 - is based upon the facility wide assessment conducted according to proposed § 483.70(e)
 - includes a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement
 - is reviewed annually and analyzed to ensure the effectiveness of the IPCP and update the program as necessary

- Develop written standards, policies, and procedures for the IPCP, including but not limited to:
 - a system of surveillance designed to identify possible communicable disease or infections before it can spread to other persons in the facility
 - reporting requirements for possible incidents of communicable disease or infections (when to report and to whom)
 - when and how isolation should be used for a resident, including but not limited to, (A) the type and duration of the isolation depending upon the infectious agent or organism involved, and (B) that the type and duration of the isolation should be the least restrictive possible for the resident under the circumstances
 - identification of circumstances in which isolation should generally be used for a resident
 - identification of circumstances under which the facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if the contact is likely to transmit the disease
 - hand hygiene procedures to be followed by all staff as indicated by accepted professional practice
 - education of staff, volunteers, visitors, and other individuals providing services under a contractual arrangement on the IPCP standards, policies and procedures
 - personnel must handle, store, process and transport linens so as to prevent the spread of infection
- Develop an antibiotic stewardship program that includes:
 - antibiotic use protocols
 - system for monitoring antibiotic use
 - systems for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility
- Develop tools for surveillance; learn, educate, promote and put into practice infection control and containment practice; and adopt a proactive approach to preventing spread.
- Develop immunization policies and procedures reflecting;
 - before offering the influenza and pneumococcal immunizations, each resident or the resident's representative receives education regarding the benefits and potential side effects of the immunizations
 - each resident is offered an influenza immunization October 1 through March 31 annually, unless the immunization is medically

contraindicated or the resident has already been immunized during this time period

- each resident is offered a pneumococcal immunization, unless the immunization is medically contraindicated or the resident has already been immunized
- the resident or the resident's representative has the opportunity to refuse the immunizations; and
- the resident's medical record includes documentation indicating, at a minimum, the following;
 - the resident or resident's representative was provided education regarding the benefits and potential side effects of influenza and pneumococcal immunizations; and
 - the resident either received the influenza and pneumococcal immunizations or did not due to medical contraindications or refusal

Compliance and Ethics Program (§483.85)

Effective date: Providers will have to have a formal compliance and ethics program in place by November 28, 2017 at the earliest.

** There is an inconsistency in the final rule on the implementation date of this section. The commentary section and implementation chart states that these requirements will be implemented in Phase 3 – by November 28, 2019. The text of the regulatory language states the date of implementation as November 28, 2017. We will seek clarity on this from CMS.

Summary:

The Final Rule was implemented without material changes from the proposed rule.

Organizations with 5 or more facilities have some additional requirements identified below.

What Does this Mean for Providers?

Providers will have to have a formal compliance and ethics program in place by either November 28, 2017 or November 28, 2019.

Requirements for all facilities:

- Each facility shall establish a written compliance and ethics program with

standards, policies, and procedures capable of reducing the prospect of criminal, civil, and administrative violations of the Act and promote quality of care.

- Assignment of specific high-level personnel with responsibility to oversee compliance such as, but not limited to, the CEO, members of the board, or directors of major divisions in the operating organization.
- Dedicate sufficient resources and authority to the individual responsible to oversee the compliance and ethics program.
- Providers must effectively communicate the standards, policies and procedures to their entire staff, individuals providing services under a contractual arrangement, and volunteers, consistent with their expected roles.
- Take steps to achieve compliance through audits and/or monitoring and have an anonymous reporting mechanism.
- Enforce the program through appropriate disciplinary mechanisms.
- After a violation is detected, the organization must ensure all reasonable steps are taken to respond appropriately to the violation to prevent future similar incidents.
- Conduct an annual review of the compliance program.

Additional requirements for organizations with 5 or more facilities:

- Conduct mandatory annual staff training.
- Designate a compliance office that reports to governing body that is not subordinate to general counsel, chief financial officer, or chief operating officer.
- Designate a compliance liaison at each facility.

Next Steps

CMS will issue additional guidance on this section before the implementation date.

Providers should start reviewing their existing compliance programs and compare them to the regulatory language.

For those providers with 5 or more facilities, they may need to restructure their program to appoint a compliance officer and/or change the job description, reporting duties, or titles of an existing compliance professional. The organizations should also begin to identify potential liaisons at each community.

There are two existing CMS resources that provide guidance on compliance programs for nursing facilities that delineate the elements of an effective compliance program. The seven elements of an effective compliance program identified in the guidance are:

- Implementing written policies, procedures, and standards of conduct;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication
- Enforcing standards through well publicized disciplinary guidance
- Conducting internal monitoring and auditing; and
- Responding promptly to detected offense and developing corrective action.

Here is a link to the 2000 OIG Compliance Program Guidance for Nursing Facilities:

<https://oig.hhs.gov/authorities/docs/cpgnf.pdf>

Here is a link to the 2008 OIG Supplemental Compliance Program Guidance for Nursing Facilities: https://oig.hhs.gov/fraud/docs/complianceguidance/nhg_fr.pdf

Physical Environment (§ 483.90)

Effective date: In Section II above the first four items will become effective November 28, 2016. Item five (smoking) becomes effective November 28, 2017. However, facilities should be actively evaluating their smoking policies in light of current CMS smoking guidance (assessment and supervision).

Summary:

- After the effective date of the regulations for a facility that receives approval of construction or reconstruction resident rooms are allowed to accommodate no more than two individuals. (Phase 1 effective November 28, 2016)
- Reconstruction is defined as the “reconfiguration of space such that the space is not permitted to be occupied, or the entire building or an entire occupancy within the building such as a wing of the building, is modified.” The modifications that would have to be made if the facility was not compliant would only have to be made to the reconstructed area and not the entire building. (Phase 1)
- All resident rooms constructed or reconstructed after the effective date would require a bathroom (toilet/sink) for each room. A shared bathroom between two rooms would not be permitted. The original proposal to require constructed/reconstructed rooms to have a shower as well has been eliminated. (Phase 1)
- Nursing Homes will be required to conduct regular inspections of all bedframes, mattresses, and bed rails to ensure that bed rails are compatible with the bed frame and mattress. (Phase 1)

- Nursing Homes must establish policies in accordance with Federal, State, and local laws and regulations regarding smoking areas, and smoking safety. (Phase 2 effective November 28, 2017)
- The Nursing Home must be equipped to allow residents to call for staff assistance through a communication system which relays the call directly to staff member or to a centralized staff work area from the resident's bedside, toilet and bathing facility. (Phase 3 effective November 28, 2019)

How it is different from prior regulations

- The current regulations permit as many as four residents to a room.
- In many older facilities a bathroom shared between two rooms is permitted.
- While a current call system is required facilities may not have a system that relays a call directly to the staff member.
- Nursing homes currently have in place policies and procedures with respect to smoking.

Key actions stated

- Review of current procedures for determining the safety of bed rails/mattresses should be undertaken immediately and incorporation of these checks into a “regular” (not yet defined by CMS) inspection for safety. This may already be part of the current procedures as part of safety rounds.

What does this mean to providers?

- Any new construction or reconstruction not approved prior to November 28, 2016 will be subject to the new requirements.
- CMS states that it believes that the new requirements on construction/reconstruction will impact on fewer than 150 facilities per year. There is no data to determine costs for adding a bathroom as a result of new construction and no data with respect to reconfiguration of rooms from 4 residents to 2 residents.

Training Requirements (§483.95)

Summary:

- Adds a new section to the rule that sets forth all the requirements of an effective training program that facilities must develop, implement, and maintain **for all new and existing staff, individuals providing services**

under a contractual arrangement, and volunteers, consistent with their expected roles. Training topics must include:

- Communication: Requires facilities to include effective communications as a mandatory training for direct care personnel.
- Resident Rights and Facility Responsibilities: Requires facilities to ensure that staff members are educated on the rights of the resident and the responsibilities of a facility to properly care for its residents as set forth in the regulations.
- Abuse, Neglect, and Exploitation: Requires facilities, at a minimum, to educate staff on activities that constitute abuse, neglect, exploitation, and misappropriation of resident property, and procedures for reporting these incidents.
- QAPI & Infection Control: Requires facilities to include mandatory training as a part of their QAPI and infection prevention and control programs that educate staff on the written standards, policies, and procedures for each program.
- Compliance and Ethics: Requires the operating organization for each facility to include training as a part of their compliance and ethics program. Requires annual training if the operating organization operates five or more facilities.
- In-Service Training for Nurse Aides: Requires dementia management and resident abuse prevention training to be a part of 12 hours per year in-service training for nurse aides.
- Behavioral Health Training: Requires facilities to provide behavioral health training to its entire staff, based on the facility assessment at §483.70(e).
- Feeding Assistants: A facility may not use any individual as a paid feeding assistant unless that individual has successfully completed a State-approved program for feeding assistants as specified in 483.16

How it is different from prior regulations?

- The facility is required to provide behavioral health training to its staff based on the facility assessment §483.70(e).
- Training in dementia management shall take place at least annually. This applies not only to nurse aides but to direct staff as well. CMS has defined direct staff as “individuals who, through interpersonal contact with residents or resident case management, provide care and services to allow residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being”.

- Under the new requirement all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, receive dementia management and abuse prevention training consistent with their expected roles.
- Added to the definitions around abuse is “exploitation” which CMS defines as “taking advantage of a resident for personal gain through the use of manipulation, intimidation, threats, or coercion.” This must be added to the current abuse training in facilities.
- No specific training mechanism is proposed. CMS states that facilities have flexibility in how to train.
- The required annual facility assessment is utilized to determine competencies and skill sets needed for employees.

Key actions stated

- The entire Training section §483.95 will be implemented in Phase 3 (November 28, 2019) with the exception of training on Abuse/Neglect/Exploitation, Dementia Management, and the Feeding Assistant requirement. These 3 components are required by the Phase 1 implementation date of November 28, 2016.
- Abuse training is currently required but facilities will have to educate staff as to understanding of the new term “exploitation”.
- Dementia management training will need to be expanded beyond nurse aides to other direct staff. CMS indicates that training currently part of the nurse aide training program or existing materials such as “Hand-in-Hand” can be utilized.
- Staff not currently the recipients of the required training will need to be brought up to compliance with the new requirement.

What does this mean to providers?

- CMS acknowledges that yet to be developed surveyor interpretive guidelines will provide additional clarity on how to meet the requirements.
- We suspect that the Facility Assessment (§483.70) will impact on training within the facility and whether if resident needs are not met it is an indication of problems with the assessment. The Assessment requirement is a Phase 2 requirement and is not implemented until November 28, 2017.
- The expectation as to who is trained and how much training they receive has been expanded. Therefore, coordination of training for contract staff and even volunteers presents additional challenges.

- Although required under current regulations, record keeping and documentation of paid feeding assistants may receive additional scrutiny.

What are next steps / what do they need to do to comply?

- As a CMS initiative dementia care is a major focus. The earlier dementia-focused surveys identified deficits in training and CMS has continued the selective use of the dementia-focused survey. Materials produced from those surveys have been made available by CMS in S&C 16-04. Facilities should become familiar with these documents and use them to assess their current needs.